

ADMA BIOLOGICS, INC.
Form 10-Q
November 10, 2015

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, 2015

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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting

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

company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting
company

(Do not check if a smaller reporting company)

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

The number of shares outstanding of the issuer’s common stock as of November 10, 2015 was 10,713,087.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

INDEX

<u>PART I FINANCIAL INFORMATION</u>	1
Item 1. <u>Financial Statements.</u>	1
<u>Condensed Consolidated Balance Sheets as of September 30, 2015 (Unaudited) and December 31, 2014</u>	1
<u>Condensed Consolidated Statements of Operations (Unaudited) for the Three and Nine Months Ended September 30, 2015 and 2014</u>	2
<u>Condensed Consolidated Statement of Changes in Stockholders' Equity (Unaudited) for the Nine Months Ended September 30, 2015</u>	3
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) for the Nine Months Ended September 30, 2015 and 2014</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>	15
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	31
Item 4. <u>Controls and Procedures.</u>	31
<u>PART II OTHER INFORMATION</u>	32
Item 1. <u>Legal Proceedings.</u>	32
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds.</u>	32
Item 3. <u>Defaults Upon Senior Securities.</u>	32
Item 4. <u>Mine Safety Disclosures.</u>	32
Item 5. <u>Other Information.</u>	32
Item 6. <u>Exhibits.</u>	32
<u>SIGNATURES</u>	34

PART I
FINANCIAL INFORMATION

Item 1. Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2015 (Unaudited)	December 31, 2014 (Note 2)
ASSETS		
Current Assets:		
Cash and Cash Equivalents	\$ 9,177,767	\$ 17,199,030
Short-Term Investments	11,764,361	4,652,675
Accounts Receivable	1,200,615	383,961
Inventories	2,830,814	1,708,763
Prepaid Expenses	266,784	143,586
Total Current Assets	25,240,341	24,088,015
Property and Equipment at Cost, Net	2,518,638	2,840,698
Other Assets:		
Deferred Financing Costs	37,888	67,640
Deposits	27,163	27,163
Total Other Assets	65,051	94,803
TOTAL ASSETS	\$ 27,824,030	\$ 27,023,516
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	\$ 2,184,686	\$ 1,779,197
Accrued Expenses	1,949,419	2,223,639
Accrued Interest	-	105,664
Current Portion of Deferred Revenue	149,326	75,556
Current Portion of Leasehold Improvement Loan	14,804	13,841
Total Current Liabilities	4,298,235	4,197,897
Notes Payable, Net of Debt Discount	14,115,986	14,568,285
Warrant Liability	-	476,760
End of Term Liability, Notes Payable	1,432,000	132,500
Deferred Revenue	2,887,082	1,504,815
Deferred Rent Liability	136,316	83,214
Leasehold Improvement Loan	40,169	51,395
TOTAL LIABILITIES	22,909,788	21,014,866

COMMITMENTS AND CONTINGENCIES

STOCKHOLDERS' EQUITY

Common Stock \$0.0001 par value 75,000,000 shares authorized, and 10,713,087 and 9,291,823 shares issued

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

and outstanding as of September 30, 2015 and December,
31

2014, respectively	1,072	929
Additional Paid-In Capital	87,750,184	75,457,458
Accumulated Deficit	(82,837,014)	(69,449,737)
TOTAL STOCKHOLDERS' EQUITY	4,914,242	6,008,650
TOTAL LIABILITIES AND STOCKHOLDERS'		
EQUITY	\$ 27,824,030	\$ 27,023,516

See Notes to Unaudited Condensed Consolidated Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
REVENUES:				
Product revenue	\$1,821,229	\$1,347,041	\$4,596,490	\$4,370,141
License revenue	31,184	18,889	68,962	56,667
Total Revenues	1,852,413	1,365,930	4,665,452	4,426,808
OPERATING EXPENSES:				
Cost of product revenue	1,112,782	867,681	2,808,726	2,785,526
Research and development	2,111,505	1,482,929	5,019,138	7,597,295
Plasma centers	1,214,158	1,018,382	3,359,130	2,641,700
General and administrative	2,078,166	1,035,220	4,861,598	3,711,875
TOTAL OPERATING EXPENSES	6,516,611	4,404,212	16,048,592	16,736,396
LOSS FROM OPERATIONS	(4,664,198)	(3,038,282)	(11,383,140)	(12,309,588)
OTHER INCOME (EXPENSE):				
Interest income	11,102	3,508	25,878	8,912
Interest expense	(449,328)	(335,299)	(1,378,778)	(904,934)
Change in fair value of stock warrants	-	(14,616)	67,860	(44,196)
Loss on extinguishment of debt	-	-	(719,097)	-
OTHER EXPENSE, NET	(438,226)	(346,407)	(2,004,137)	(940,218)
NET LOSS	\$(5,102,424)	\$(3,384,689)	\$(13,387,277)	\$(13,249,806)
NET LOSS PER COMMON SHARE,				
Basic and Diluted	\$(0.48)	\$(0.36)	\$(1.28)	\$(1.43)
WEIGHTED AVERAGE SHARES				
OUTSTANDING, Basic and Diluted	10,707,728	9,291,823	10,425,310	9,291,823

See Notes to Unaudited Condensed Consolidated Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN
STOCKHOLDERS' EQUITY
(Unaudited)

For the Nine Months Ended September 30, 2015

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance - January 1, 2015	9,291,823	\$ 929	\$ 75,457,458	\$ (69,449,737)	\$ 6,008,650
Stock-based compensation	-	-	1,221,662	-	1,221,662
Issuance of common stock, net	1,408,750	141	10,245,239	-	10,245,380
Stock issued in connection with stock options exercised	7,514	1	49,226	-	49,227
Restricted stock	5,000	1	(1)	-	-
Elimination of warrant liability	-	-	408,900	-	408,900
Warrants issued in connection with note payable	-	-	367,700	-	367,700
Net loss	-	-	-	(13,387,277)	(13,387,277)
Balance - September 30, 2015	10,713,087	\$ 1,072	\$ 87,750,184	\$ (82,837,014)	\$ 4,914,242

See Notes to Unaudited Condensed Consolidated Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (13,387,277)	\$ (13,249,806)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	352,629	151,062
Stock-based compensation	1,221,662	921,394
Warrant liability	(67,860)	44,196
Amortization of debt discount	222,409	95,001
Amortization of deferred financing costs	39,717	94,257
Payment-in-kind interest	124,536	119,234
Amortization of license revenue	(68,962)	(56,667)
Loss on extinguishment of debt	719,097	-
Changes in operating assets and liabilities:		
Accounts receivable	(816,654)	(562,171)
Inventories	(1,122,051)	216,502
Prepaid expenses	(123,198)	13,068
Other assets	-	(14,586)
Accounts payable	311,899	(265,754)
Accrued expenses	(218,580)	671,367
Accrued interest	(105,664)	37,069
Deferred revenue	1,525,000	-
Deferred rent liability	53,102	(16,643)
Net cash used in operating activities	(11,340,195)	(11,802,477)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of short-term investments	(7,111,686)	(3,384,446)
Purchase of property and equipment	(30,569)	(1,766,963)
Net cash used in investing activities	(7,142,255)	(5,151,409)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from Oxford note payable	16,000,000	-
Proceeds from issuance of common stock	10,257,380	-
Proceeds from stock options exercised	49,226	-
Proceeds from Hercules note payable, net of fees	-	4,850,000
Repayment of Hercules note payable	(15,300,781)	-
Prepayment penalty of early extinguishment of note payable	(229,512)	-
Debt issuance costs	(172,363)	(30,140)
Payment of Hercules end of term fee	(132,500)	-
Equity issuance costs	-	(54,543)
Payments of leasehold improvement loan	(10,263)	(9,383)
Net cash provided by financing activities	10,461,187	4,755,934

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

NET DECREASE IN CASH AND CASH EQUIVALENTS	(8,021,263)	(12,197,952)
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	17,199,030	26,149,477
CASH AND CASH EQUIVALENTS - END OF PERIOD	\$ 9,177,767	\$ 13,951,525
SUPPLEMENTAL INFORMATION:		
Cash paid for interest	\$ 1,007,581	\$ 561,705
Supplemental Disclosure of Noncash Financing Activities:		
Elimination of warrant liability	\$ 408,900	\$ -
Reclassification of equity issuance costs	\$ 12,000	\$ -
Accrued equity issuance costs	\$ 37,888	\$ 17,265
Non-cash deferred financing fees	\$ 55,702	\$ -
End of term liability in connection with note payable	\$ 1,432,000	\$ -
Warrants issued in connection with note payable	\$ 367,700	\$ 219,588

See Notes to Unaudited Condensed Consolidated Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2015 AND 2014

1. ORGANIZATION AND BUSINESS

ADMA Biologics, Inc. (“ADMA” or the “Company”) is a late stage biopharmaceutical company that develops, manufactures, and intends to commercialize specialty plasma-based biologics for the treatment and prevention of certain infectious diseases. The Company’s targeted patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disease or who may be immune-suppressed for medical reasons. ADMA also operates its wholly-owned subsidiary, ADMA BioCenters Georgia, Inc., (“ADMA BioCenters”), a source plasma collection business with U.S. Food and Drug Administration (“FDA”) approved facilities in Norcross, Georgia and Marietta, Georgia. The Norcross, Georgia center also has achieved German Health Authority (“GHA”) and the Korean Ministry of Food and Drug Safety (“MFDS”) certifications. ADMA BioCenters provides ADMA with a portion of its raw material plasma for the manufacture of RI-002, ADMA’s lead product candidate, which is intended for the treatment of Primary Immune Deficiency Disease, (“PIDD”). A Biologics License Application (“BLA”) for RI-002 was submitted to the FDA on July 31, 2015 and accepted for review on September 18, 2015. The Company’s Marietta, Georgia center received FDA approval to sell human source plasma within the U.S. on September 17, 2015.

The Company has experienced net losses and negative cash flows from operations since inception in 2004 and expects these conditions to continue for the foreseeable future. Since inception, the Company has needed to raise capital from the sales of its equity securities and debt financings to sustain operations.

In June 2015, ADMA entered into a Loan and Security Agreement (the “LSA”) with Oxford Finance LLC (“Oxford”), as collateral agent and lender, pursuant to which ADMA accessed an initial term loan in the aggregate principal amount of \$16.0 million, of which \$15.7 million was used to repay an existing loan balance of \$15.0 million, along with \$0.4 million of interest and \$0.3 million of prepayment premium and other fees, under its prior loan and security agreement, dated December 21, 2012, with Hercules Technology Growth Capital, Inc. (“Hercules”, and such loan agreement, the “Prior Loan Agreement”), as amended on February 24, 2014, (the “Prior Loan Amendment”). ADMA may elect to access an additional term loan under the LSA in the aggregate principal amount of \$5.0 million if it receives approval of its BLA for RI-002 from the FDA on or before January 31, 2017. Also, at ADMA’s discretion, if it receives BLA approval for RI-002 from the FDA within the initial 18-month interest only period, it may elect to extend its interest only period for an additional six months. In March 2015, ADMA completed an underwritten public offering of its common stock, raising gross proceeds of \$11.3 million. Also, in October 2013, ADMA completed an Initial Public Offering (“IPO”) of its common stock, raising gross proceeds of \$29.1 million.

As of September 30, 2015, the Company had working capital of \$20.9 million, consisting primarily of \$9.2 million of cash and cash equivalents, \$11.8 million of short-term investments, \$1.2 million of accounts receivable, \$2.8 million of inventories, and \$0.2 million of prepaid expenses, offset primarily by \$2.2 million of accounts payable, \$1.9 million of accrued expenses and \$0.2 million of deferred revenue. Based upon the Company’s projected revenue and expenditures for 2015 and 2016, including the ongoing implementation of the Company’s commercialization and expansion activities, management currently believes that its cash, cash equivalents, short-term investments and accounts receivable as of September 30, 2015 are sufficient to fund ADMA’s operations into the second half of 2016. Because the Company does not anticipate receiving FDA approval for RI-002 earlier than the second half of 2016, if at all, the Company would not expect to generate revenue from the commercialization of RI-002 earlier than such time, if 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 anticipated. Due to numerous risks and uncertainties associated with the research and development and potential future commercialization of its product candidate, the Company is unable to estimate with certainty the amounts of increased capital outlays and operating expenditures

associated with its development activities. The Company's current estimates may be subject to change as circumstances regarding its business requirements evolve. The Company may decide to raise capital through public or private equity offerings, debt financings, obtain a bank credit facility, or corporate collaboration and licensing arrangements. The Company does not have any existing commitments for future external funding. The sale of additional equity or debt securities, if convertible, could result in dilution to the Company's stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict the Company's operations or other financing alternatives. Additional equity or debt financing, grants, or corporate collaboration and potential licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, the Company may be required to delay, reduce the scope of or eliminate the Company's research and development programs, reduce the Company's planned clinical trials and delay or abandon potential commercialization efforts of the Company's lead or other product candidates. Thereafter, the Company's ability to continue as a going concern will be dependent on its ability to achieve profitability or raise additional capital, to fund its research and development and commercial programs and meet its obligations on a timely basis.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2015 AND 2014

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 the FDA and other governmental regulations and approval requirements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation and principles of consolidation

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

The condensed consolidated financial statements for the interim periods included herein are unaudited; however, they contain all adjustments (consisting of only normal recurring adjustments) which in the opinion of management are necessary to present fairly the condensed consolidated financial position of the Company as of September 30, 2015 and its results of operations for the three and nine months ended September 30, 2015 and 2014 and cash flows for the nine months ended September 30, 2015 and 2014. The results of operations for the interim periods are not necessarily indicative of results that may be expected for any other interim periods or for the full year. These interim financial statements should be read in conjunction with the audited annual consolidated financial statements and notes thereto included in the Company's Annual Report for the year ended December 31, 2014 on Form 10-K, filed with the U.S. Securities and Exchange Commission, (the "Commission") on March 9, 2015.

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2015 AND 2014

Inventories

Plasma inventories (both plasma intended for resale and plasma intended for internal use in the Company's research and development and future anticipated commercialization activities) are carried at the lower of cost or market value determined on the first-in, first-out method. Research and development plasma used in clinical trials was processed to a finished product and subsequently expensed to research and development. Inventory at September 30, 2015 and December 31, 2014 consists of high titer plasma and normal source plasma.

Debt

In April 2015, the Financial Accounting Standards Board issued Accounting Standards Update (“ASU”) 2015-03, Interest—Imputation of Interest, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. Debt disclosures will include the face amount of the debt liability and the effective interest rate. The update requires retrospective application and represents a change in accounting principle. The update is effective for fiscal years beginning after December 15, 2015. Early adoption is permitted for financial statements that have not been previously issued. The Company has early adopted ASU 2015-03 in its second quarter 2015 condensed consolidated financial statements and recast the prior period balances to conform to the current period presentation.

Revenue recognition

Depending on the agreement with the customer, revenues from the sale of human plasma collected at the Company's FDA licensed plasma collection centers are recognized at the time of transfer of title and risk of loss to the customer, which occurs at the time of shipment. Revenue is recognized at the time of delivery if the Company retains the risk of loss during shipment. The Company's revenues are substantially attributable to one customer. Revenue from license fees and research and development services rendered are recognized as revenue when the performance obligations under the terms of the license agreement have been completed. Revenues for the three months ended September 30, 2015 are comprised of product revenues from the sale of normal source human plasma collected from the Company's plasma collection center segment and license revenues attributable to the out-licensing of RI-002 to Biotest AG to market and sell in Europe and selected countries in North Africa and the Middle East. Biotest AG and Biotest Pharmaceuticals Corporation, or Biotest, a subsidiary of Biotest AG, has provided the Company with certain financial payment and services in accordance with the related license agreement and is obligated to pay the Company certain amounts in the future if certain milestones are achieved. During the third quarter 2015, the Company recorded deferred revenue of \$1.5 million for a milestone payment provided to the Company upon its filing of the BLA for RI-002 with the FDA, in accordance with the terms of the license agreement. Deferred revenue of \$1.7 million was recorded in 2013 as a result of certain research and development services provided in accordance with the same license agreement. Deferred revenue is recognized over the term of the license. Deferred revenue is amortized into income for a period of approximately 20 years, the term of the license agreement.

Use of estimates

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ

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

7

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2015 AND 2014

Loss per common share

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

Diluted net loss per share is calculated by dividing net loss attributable to common stockholders as adjusted for the effect of dilutive securities, if any, by the weighted average number of common stock and dilutive common stock outstanding during the period. Potential common stock includes the shares of common stock issuable upon the exercise of outstanding stock options and warrants (using the treasury stock method). Potential common stock in the diluted net loss per share computation is excluded to the extent that it would be anti-dilutive. No potentially dilutive securities are included in the computation of any diluted per share amounts as the Company reported a net loss for all periods presented. The aggregate number of potentially dilutive securities upon the exercise of outstanding warrants and stock options was 1.6 million and 1.2 million as of September 30, 2015 and 2014, respectively.

Stock-based compensation

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

During the three months ended September 30, 2015, the Company granted stock options to purchase 81,500 shares of common stock to employees and during the nine months ended September 30, 2015, the Company granted stock options to purchase 312,500 shares of common stock to its directors and employees. During the three and nine months ended September 30, 2015, options to purchase 7,514 shares of common stock were exercised by an employee, and options to purchase 8,875 shares of common stock, and options to purchase 9,710 shares of common stock, respectively, were forfeited. On June 19, 2014, at the Annual Meeting of stockholders, the stockholders approved the 2014 Plan, which was approved by the Board of Directors of ADMA (the "Board") on February 21, 2014. During the nine months ended September 30, 2014, the Company granted stock options to purchase an aggregate of 167,932 shares of the Company's common stock under the 2014 Plan to three executive officers and non-qualified stock options to purchase 9,000 shares of the Company's common stock were granted to each of the Company's six non-employee directors.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2015 AND 2014

3. DEBT

Loan and Security Agreement

On June 19, 2015, the Company entered into the LSA with Oxford for up to \$21.0 million and refinanced its existing loan with Hercules. The first tranche of \$16.0 million from the Oxford loan was primarily used to repay its existing facility with Hercules and the remaining \$5.0 million is available at ADMA's option upon RI-002's BLA being approved from the FDA on or before January 31, 2017. The LSA bears interest at a rate per annum equal to the greater of (i) 7.80% and (ii) the sum of (a) the three (3) 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 Company is obligated to begin to repay the principal over 36 months beginning February 1, 2017, unless accelerated as a result of certain events of default. At the Company's option, if it receives BLA approval for RI-002 within the initial 18-month interest only period, the interest only period may be extended for an additional six months. A final payment equal to 8.95% of the funded loan amount is due at the earlier of loan maturity or prepayment. In the event of the six-month interest only extension, the final payment will be 9.95% of the funded loan, which shall also be due at the earlier of loan maturity or prepayment. In addition, a facility fee of \$105,000 was paid at closing. In the event the Company elects to prepay the loan, the Company is obligated to pay a prepayment charge corresponding to a percentage of the principal amount of the loan, with such percentage being: 3.0% if prepayment occurs through the second anniversary of funding, 1.0% if prepayment occurs after the second anniversary of the funding date and prior to maturity date of the principal amount of the term loans prepaid. The loan matures no later than January 1, 2020. The loan is 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 representations, warranties and covenants contained in the LSA were made only for purposes of such agreement and as of a specific date or specific dates, were solely for the benefit of the parties to such agreement, and may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosures exchanged between the parties in connection with the execution of the LSA. Events of default under the agreement include, but are not limited to: (i) insolvency, liquidation, bankruptcy or similar events; (ii) failure to pay any debts due under the LSA or other loan documents on a timely basis; (iii) failure to observe any covenant or secured obligation under the LSA or other loan documents, which failure, in most cases, is not cured within 10 days of written notice by lender; (iv) occurrence of any default under any other agreement between the Company and the lender, which is not cured within 10 days; (v) occurrence of an event that could reasonably be expected to have a material adverse effect; (vi) material misrepresentations; (vii) occurrence of any default under any other agreement involving indebtedness or the occurrence of a default under any agreement that could reasonably be expected to have a material adverse effect; and (viii) certain money judgments are entered against the Company or a certain portion of its assets are attached or seized. Remedies for events of default include acceleration of amounts owing under the LSA and taking immediate possession of, and selling, any collateral securing the loan.

In connection with the LSA, the Company issued to Oxford a 7 year warrant, expiring on June 19, 2022, to purchase 74,309 shares of common stock at an exercise price of \$8.51 per share. The Company recorded \$367,700 as the fair value of the warrant to additional paid-in capital and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included: volatility of 57% on the Company's common stock based upon a pro rata percentage of the Company's common stock's volatility and similar public companies' volatilities for comparison, an expected dividend yield of 0.0%, a risk-free interest rate of 1.99% and a term of 7 years. As a result of prepaying

the Hercules loan prior to maturity, the Company incurred a loss on extinguishment of debt of \$0.7 million comprised of unamortized debt issuance costs, unamortized debt discount related to the warrants issued to Hercules, along with a prepayment penalty.

A summary of the Oxford loan balance as of September 30, 2015 is as follows:

Gross	
proceeds	\$16,000,000
Less: debt	
discount, net	
End of term	
fee	(1,337,061)
Warrants	(337,573)
Financing	
fees	(209,380)
Note payable	\$14,115,986

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2015 AND 2014

In connection with the Prior Loan Agreement, the Company issued to Hercules a warrant to purchase 31,750 shares of common stock with an exercise price of \$7.56, and in connection with the Prior Loan Amendment, the Company issued to Hercules a warrant to purchase an additional 58,000 shares of its common stock, comprised of a warrant to purchase 23,200 shares of common stock issued in February 2014 and a warrant to purchase 34,800 shares of common stock issued in December 2014, each warrant issued under the amended Loan Agreement having an exercise price of \$7.50. The warrants expire after 10 years and have piggyback registration rights with respect to the shares of common stock underlying the warrant. The fair value of the Prior Loan Amendment warrant was calculated using a lattice-based option model in order to account for features in the warrant that could cause the exercise price to reset (“down round protection”) as a result of the next issuance of the Company’s common stock (“the next round of equity financing”). The Company initially recorded the fair value of the warrant of \$219,588 as warrant liability and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included the expected date of the next round of equity financing, volatility of 59% for the Company’s common stock based upon similar public companies’ volatilities for comparison, an expected dividend yield of 0.0%, a risk-free interest rate of 2.53% and a term of 10 years. As of December 31, 2014, the Company recorded \$476,760 as the fair value of the warrant for the purchase of 58,000 shares of common stock. As a result of the increase in warrant liability, the Company recorded an expense of \$74,356 from the change in the fair value of warrant liability. During the first quarter ended March 31, 2015, the Company recorded \$408,900 as the fair value of the warrant for the purchase of 58,000 shares of common stock. As a result of the decrease in warrant liability, the Company recorded a change in the fair value of stock warrants of \$67,860 from the December 31, 2014 balance. The key assumptions used to value the warrants included the expected date of the next round of equity financing, volatility of 58% based upon a pro rata percentage of the Company’s common stock and similar public companies’ volatilities, an expected dividend yield of 0.0%, a risk-free rate of 1.99% and a term of 10 years. This warrant liability was adjusted from the date of the Prior Loan Agreement on February 24, 2014, to fair value each reporting period using a lattice-based option model and the debt discount will be amortized to interest expense over the term of the loan. The down round warrant protection feature resulting in the warrant liability’s quarterly “mark-to-market” valuation has terminated as of February 24, 2015, which was the end of the one-year period following the amended loan closing on February 24, 2014 and as a result the warrant liability of \$408,900 was reclassified to additional paid-in capital.

A summary of the recast Hercules loan balance as of December 31, 2014 is as follows:

Gross proceeds	\$ 15,000,000
Plus: payment in kind interest	176,245
	15,176,245
Less: debt discount, net Warrants	(403,979)
Financing fees	(161,951)
End of term fee	(42,030)
Note payable	\$ 14,568,285

4.

STOCKHOLDERS' EQUITY

On March 18, 2015, the Company announced the closing of an underwritten sale of 1,225,000 shares of its common stock, as well as 183,750 additional shares of its common stock pursuant to the full exercise of the over-allotment option granted to the underwriters, for gross proceeds of approximately \$11.3 million. Net proceeds from this offering were approximately \$10.2 million, net of underwriting discounts and offering expenses of approximately \$1.1 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-200638) that was declared effective by the SEC on December 23, 2014.

10

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2015 AND 2014

Equity incentive plan

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

	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
Expected term	6.25 years	6.25 years	6.25 years
Volatility	51-54%	51-57%	63%
Dividend yield	0.0	0.0	0.0
Risk-free interest rate	1.75-2.14%	1.49-2.14%	2.22%

Guidance for stock-based compensation requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has not experienced any material forfeitures of stock options and, as such, has not established a forfeiture rate since the stock options currently outstanding are primarily held by its senior management and directors. The Company will continue to evaluate the effects of such future potential forfeitures, as they may arise, to evaluate its estimated forfeiture rate.

The weighted average remaining contractual life of stock options outstanding and expected to vest at September 30, 2015 is 7.2 years. The weighted average remaining contractual life of stock options exercisable at September 30, 2015 is 6.4 years.

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

	Nine Months Ended September 30, 2015	Weighted Average Exercise Price
	Shares	
Outstanding at beginning of period	1,048,927	\$ 7.24
Exercised	(7,514)	\$ 6.25
Forfeited	(9,710)	\$ 9.16
Granted	312,500	\$ 10.17

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

Outstanding at end of period and expected to vest	1,344,203	\$	7.91
Options exercisable	812,059	\$	7.11

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2015 AND 2014

Stock-based compensation expense for the three and nine months ended September 30, 2015 and 2014 is as follows:

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Research and development	\$ 184,302	\$ 66,202	\$ 514,107	\$ 191,112
Plasma centers	12,457	8,920	35,813	26,468
General and administrative	251,173	251,938	671,742	703,814
Total stock-based compensation expense	\$ 447,932	\$ 327,060	\$ 1,221,662	\$ 921,394

As of September 30, 2015, the total compensation expense related to unvested options not yet recognized totaled \$2,556,609. The weighted average vesting period over which the total compensation expense will be recorded related to unvested options not yet recognized at September 30, 2015 was approximately 2.5 years.

5. **RELATED PARTY TRANSACTIONS**

The Company leases an office building and equipment from an entity owned by related parties on a month-to-month basis. Rent expense amounted to \$24,112 and \$72,336 for each of the three and nine months ended September 30, 2015 and 2014, respectively.

The Company maintains deposits and other accounts at a bank which is less than 5%-owned by related parties and where a stockholder and Company director is a member of the Board of Directors of the bank.

6. **COMMITMENTS AND CONTINGENCIES**

General Legal Matters

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

7. **SEGMENTS**

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

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2015 AND 2014

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

Three Months Ended September 30, 2015	Plasma Collection Centers	Research and Development	Corporate	Consolidated
Revenues	\$ 1,821,229	\$ -	\$ 31,184	\$ 1,852,413
Cost of product revenue	1,112,782	-	-	1,112,782
Gross profit	708,447	-	31,184	739,631
Loss from operations	(505,711)	(2,111,505)	(2,046,982)	(4,664,198)
Other expense	-	-	(438,226)	(438,226)
Net loss	(505,711)	(2,111,505)	(2,485,208)	(5,102,424)
Property and equipment, net	2,387,682	-	130,956	2,518,638
Depreciation and amortization expense	105,192	-	12,738	117,930

Three Months Ended September 30, 2014	Plasma Collection Centers	Research and Development	Corporate	Consolidated
Revenues	\$ 1,347,041	\$ -	\$ 18,889	\$ 1,365,930
Cost of product revenue	867,681	-	-	867,681
Gross profit	479,360	-	18,889	498,249
Loss from operations	(539,022)	(1,482,929)	(1,016,331)	(3,038,282)
Other expense	-	-	(346,407)	(346,407)
Net loss	(539,022)	(1,482,929)	(1,362,738)	(3,384,689)
Property and equipment, net	2,227,587	-	153,613	2,381,200
Depreciation and amortization expense	41,135	1,110	11,954	54,199

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
SEPTEMBER 30, 2015 AND 2014

Nine Months Ended September 30, 2015	Plasma Collection Centers	Research and Development	Corporate	Consolidated
Revenues	\$ 4,596,490	\$ -	\$ 68,962	\$ 4,665,452
Cost of product revenue	2,808,726	-	-	2,808,726
Gross profit	1,787,764	-	68,962	1,856,726
Loss from operations	(1,571,366)	(5,019,138)	(4,792,636)	(11,383,140)
Other income (expense)	-	-	(2,004,137)	(2,004,137)
Net loss	(1,571,366)	(5,019,138)	(6,796,773)	(13,387,277)
Property and equipment, net	2,387,682	-	130,956	2,518,638
Depreciation and amortization expense	315,209	-	37,420	352,629
Nine Months Ended September 30, 2014	Plasma Collection Centers	Research and Development	Corporate	Consolidated
Revenues	\$ 4,370,141	\$ -	\$ 56,667	\$ 4,426,808
Cost of product revenue	2,785,526	-	-	2,785,526
Gross profit	1,584,615	-	56,667	1,641,282
Loss from operations	(1,057,085)	(7,597,295)	(3,655,208)	(12,309,588)
Other income (expense)	262	-	(940,480)	(940,218)
Net loss	(1,056,823)	(7,597,295)	(4,595,688)	(13,249,806)
Property and equipment, net	2,227,587	-	153,613	2,381,200
Depreciation and amortization expense	113,292	2,729	35,041	151,062

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

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements as of, and for, the three and nine months ended September 30, 2015 and 2014 and our Annual Report for the year ended December 31, 2014 on Form 10-K, filed with the U.S. Securities and Exchange Commission, or the Commission, on March 9, 2015.

Forward-Looking Statements

This quarterly report for the quarterly period ended September 30, 2015 on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain the words "estimate," "project," "intend," "forecast," "target," "anticipate," "plan," "planning," "believe," "will," "will likely," "is likely," "should," "could," "would," "may" or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements include, but are not limited to, statements concerning our plans and timing to develop, market and commercialize RI-002 and the success of such efforts, the expected timing of and our ability to obtain and maintain regulatory approvals for our product candidates, the timeframe within which we may receive approval from the U.S. Food and Drug Administration, or FDA, if at all, of our Biologics License Application, or BLA for RI-002, our ability to generate revenue, if any, from the potential commercialization of RI-002, if approved by the FDA, the timing, progress and results of the clinical development, our plans to increase our supplies of plasma, regulatory processes, interpretations of final data, possible characteristics of RI-002, acceptability of RI-002 for any purpose by physicians patients or payers, concurrence by FDA with our conclusions and the satisfaction by us of its guidance, the likelihood and timing of FDA action with respect to any further filings by us, results of the clinical development, continuing demonstrations of safety, comparability of results of RI-002 to other comparably run Injectable Immune Globulin (human), or IGIV trials, improvements in clinical outcomes, potential of RI-002 to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease, or PID, as well as to offer clinicians with an option for their immune compromised patients, market data and incidence of infection, potential clinical trial initiations, potential investigational new product applications, our intellectual property position, biologics license applications, expansion plans, the achievement of clinical and regulatory milestones, our manufacturing capability and strategy, our plans relating to manufacturing, supply and other collaborative agreements, our estimates regarding expenses, capital requirements and needs for additional financing, and commercialization efforts relating to our product candidates and the runway and limitation of our available cash and our ability to identify alternative sources of cash. The forward-looking statements contained in this report represent our estimates and assumptions only as of the date of this report and we undertake no duty or obligation to update or revise publicly any forward-looking statements contained in this report as a result of new information, future events or changes in our expectations, except as required by applicable law or rules. Forward-looking statements are subject to many risks, uncertainties and other important factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" in our Annual Report for the year ended December 31, 2014 on Form 10-K as filed with the U.S. Securities and Exchange Commission, or the Commission on March 9, 2015, and in other filings with the Commission.

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

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

Overview

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

Our BLA for RI-002 was submitted to the FDA on July 31, 2015 and accepted for review on September 18, 2015. The FDA could approve our BLA within approximately one year of submission, and potential first commercial sales could occur as early as the second half of 2016. As part of our commercialization efforts, we plan to hire a small, specialty sales force to market RI-002 to hospitals, physician offices/clinics, and other specialty treatment organizations. We anticipate staffing additional personnel for patient support, medical affairs, quality assurance, regulatory affairs, scientific affairs, reimbursement, inventory and logistics, human resources and financial and operational management. We may also use a network of national distributors to fulfill orders for RI-002.

RI-002 demonstrated positive results in a Phase III study in patients with PIDD, meeting its primary endpoint, of no Serious Bacterial Infections, or SBI reported. These results, included in the submission, more than meet the requirement specified by the FDA guidance of ≤ 1 SBI per patient-year. RI-002 is intended for the treatment of PIDD. RI-002 is an IGIV, derived from human plasma, which contains immune globulins extracted from source plasma in a manufacturing process called fractionation and is enriched with high levels of naturally occurring polyclonal antibodies (e.g., streptococcus pneumonia, H. influenza type B, Cytomegalovirus or CMV, measles, tetanus, etc.) as well as high levels of antibodies targeted to Respiratory Syncytial Virus, or RSV. 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 immune-compromised, RSV can lead to a more serious infection and may even cause death.

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 IGIV 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. These secondary outcome results follow the prior announcement that the trial achieved its primary endpoint with zero reported acute SBIs in the course of the trial.

The RI-002 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 9 treatment centers in the United States. 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 IGIV. 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.

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 United States, 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 4-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. Serum samples were obtained from 13 patients. Samples showed that patients had a 4-fold or greater rise in RSV antibody titers from baseline. Serum samples were not obtained from two patients that received Palivizumab. The drug was well-tolerated in these 15 patients and there were no reports of serious adverse events attributable to RI-001. Data from our Phase II trial, compassionate use experience and testing of RI-002 in the cotton rat RSV animal model has been presented at various conferences during 2014 and 2015.

During the second quarter of 2015, we received a notice of allowance from the United States Patent Office, or USPTO, for our RI-002 patent filed under U.S. patent application 14/592,721 entitled 'Compositions and Methods for the Treatment of Immunodeficiency,' which extends through January 2035. During the third quarter our U.S. Patent 9,107,906 was issued by the USPTO. Our proprietary microneutralization assay allows us to effectively identify and isolate donor plasma with high-titer RSV antibodies, to standardize RI-002's potency and thereby potentially garner a premium price.

We also operate through our wholly-owned subsidiary an FDA-licensed, German Health Authority, or GHA and Korean Ministry of Food and Drug Safety, or MFDS certified source plasma collection facility, at ADMA BioCenters located in Norcross, Georgia, and an FDA-licensed facility in Marietta, Georgia, which provides us with a portion of our raw material plasma for the manufacture of RI-002. In June 2013, ADMA BioCenters, Norcross, Georgia received a two-year certification from the GHA and in April 2015 ADMA BioCenters received GHA recertification through the end of April 2018. GHA certification allows plasma collected at ADMA BioCenters, Norcross, Georgia to be imported into the European Union, or EU and to be purchased and processed by European Plasma Fractionators. In September 2014, ADMA BioCenters, Norcross, Georgia received MFDS approval to sell source plasma into South Korea. During the third quarter of 2014, we completed the expansion of our Norcross, Georgia ADMA BioCenters facility by securing additional rented space to grow our donor and collection screening areas to meet an increase in market demand for source plasma. In January 2014, we also entered into another lease for a second plasma collection center in Marietta, Georgia, which we completed construction of this new facility during the fourth quarter of 2014. In November 2014, we announced the opening of our second plasma collection center in Marietta, Georgia, which is currently collecting plasma from donors. On September 17, 2015, FDA approval was received for this second center to sell human source plasma within the U.S. A typical plasma collection center, such as ADMA BioCenters, can collect 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 that is not used for making RI-002 is sold to customers in the U.S. and where we are approved globally under supply agreements or in the open "spot" market.

Financial Operations Overview

Revenues

Revenues for the three months ended September 30, 2015 are comprised of product revenues from the sale of normal source human plasma collected from our plasma collection center segment and license revenues attributable to the out-licensing of RI-002, to Biotest AG to market and sell in Europe and selected countries in North Africa and the Middle East. In exchange for the out-licensing of RI-002, Biotest AG and Biotest Pharmaceuticals Corporation, or Biotest, a subsidiary of Biotest AG, has provided us with certain financial payment and services in accordance with the related license agreement and is obligated to pay us certain amounts in the future if certain milestones are achieved. Depending upon the agreement with the customer, revenue is recognized at the time of transfer of title and risk of loss or revenue is recognized at the time of delivery if we retain the risk of loss during shipment.

Our revenues are substantially attributable to one customer within our plasma collection center segment. Revenue from license fees and research and development services rendered are recognized as revenue when we have completed the performance obligations under the terms of the license agreement. Deferred revenue was recorded in the third quarter of 2015 as a result of a milestone payment we received attributed to our BLA filing for RI-002 with the FDA and in the second quarter of 2013 as a result of certain research and development services provided, both in accordance with a license agreement and are being recognized over the term of the license.

Research and Development Expenses

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

The process of conducting pre-clinical 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 uncertainty 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 for the three months ended September 30, 2015 increased compared to the three months ended September 30, 2014, due to regulatory and third-party consulting fees and other costs incurred from the filing of our BLA for RI-002 with the FDA. R&D expenses throughout the remainder of 2015 will primarily be comprised of regulatory consulting fees and wages and benefits for employees, including stock-based compensation directly related to R&D of RI-002. We expect our R&D expenses to be lower throughout 2015 as compared to 2014 as a result of our BLA filing and acceptance by the FDA for RI-002 during the third quarter of 2015 and the completion of our Phase III clinical study of RI-002 during the fourth quarter of 2014.

General and Administrative Expenses

General and administrative, or G&A expenses, consist of wages, stock-based compensation, benefits for senior management and staff unrelated to R&D, legal fees, accounting and auditing fees, commercialization and marketing activities, information technology, investor relations fees, rent, maintenance and utilities, insurance, travel and other expenses related to the general operations of the business. The increased G&A expenses for the three months ended September 30, 2015 are primarily attributable to consulting expenses associated with commercialization activities in preparation for product launch for RI-002 during the second half of 2016. We expect that our G&A expenses will continue to increase throughout 2015 as a result of pre-launch, commercial planning activities, market research costs and the hiring of additional staff as part of the commercial development of RI-002.

Other Income and Expense

Interest income consists of interest earned on our cash, cash equivalents and short-term investments. Interest expense consists of interest incurred on our notes payable, as well as the amortization and write-off of deferred financing costs and debt discounts.

Results of Operations

Three Months Ended September 30, 2015 Compared to Three Months Ended September 30, 2014

Summary table

The following table presents a summary of the changes in our results of operations for the three months ended September 30, 2015 compared to the three months ended September 30, 2014:

	Three Months Ended September 30,		Percentage Increase/ (Decrease)	
	2015	2014		
Revenues	\$ 1,852,413	\$ 1,365,930	36	%
Cost of product revenue	\$ 1,112,782	\$ 867,681	28	%
Research and development expenses	\$ 2,111,505	\$ 1,482,929	42	%
Plasma center operating expenses	\$ 1,214,158	\$ 1,018,382	19	%
General and administrative expenses	\$ 2,078,166	\$ 1,035,220	>100	%
Total operating expenses	\$ 6,516,611	\$ 4,404,212	48	%
Other expense, net	\$ (438,226)	\$ (346,407)	27	%
Net loss	\$ (5,102,424)	\$ (3,384,689)	51	%
Net loss in plasma collection segment	\$ (505,711)	\$ (539,022)	(6)	%
Net loss attributable to research and development segment	\$ (2,111,505)	\$ (1,482,929)	42	%

Revenues

We recorded total revenues of \$1,852,413 for the three months ended September 30, 2015 and \$1,365,930 for the three months ended September 30, 2014. Product revenue was \$1,821,229 for the three months ended September 30, 2015, which is attributable to our plasma collection centers segment and derived from the sale of human source plasma collected in our FDA-licensed, GHA and MFDS certified Norcross, Georgia-based plasma collection center and the sale of human source plasma collected at our second plasma collection center in Marietta, Georgia, which received approval from the FDA during the three months ended September 30, 2015, compared to product revenue of \$1,347,041 for the three months ended September 30, 2014. Product revenue for the quarter ended September 30, 2015 was primarily attributable to sales made pursuant to our plasma supply agreement with Biotest under which Biotest purchases normal source plasma from our wholly-owned subsidiary, ADMA BioCenters, to be used in their manufacturing. The increase in product revenue of \$474,188 was primarily attributable to revenue generated from the sale of normal source plasma collected at our second plasma center. License revenue was \$31,184 for the three months ended September 30, 2015 and \$18,889 for the three months ended September 30, 2014, which relates to a milestone payment received from Biotest upon the FDA's acceptance of our BLA filing for RI-002 and for services previously provided in accordance with our license agreement. We have not generated any revenue from our therapeutics research and development business.

Cost of Product Revenue

Cost of product revenue was \$1,112,782 for the three months ended September 30, 2015, and \$867,681 for the three months ended September 30, 2014. The increase in cost of product revenues of \$245,101 for the three months ended September 30, 2015 and 2014 was primarily related to the increase in product revenues from our second FDA approval plasma center for the three months ended September 30, 2015 and 2014.

Research and Development Expenses

R&D expenses, which are attributable to our R&D segment, were \$2,111,505 for the three months ended September 30, 2015, an increase of \$628,576 from \$1,482,929 for the three months ended September 30, 2014. The increase in R&D expenses during the three months ended September 30, 2015, compared to the three months ended September 30, 2014, was primarily attributable to regulatory consulting and third party costs supporting the filing of our BLA for RI-002.

Plasma Center Operating Expenses

Operating expenses for our plasma collection centers segment attributed solely to ADMA BioCenters were \$1,214,158 for the three months ended September 30, 2015, an increase of \$195,776 from \$1,018,382 for the three months ended September 30, 2014. These operating expenses consist of G&A overhead, comprised of: rent, maintenance, utilities, wages 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 expenses was primarily a result of ADMA BioCenters opening its second plasma collection facility during the fourth quarter of 2014, which was attributable to the higher costs in wages, rent, maintenance and plasma collection supplies during the third quarter of 2015 compared to the third quarter of 2014. During the three months ended September 30, 2015, our second plasma collection facility received FDA approval to sell plasma in the U.S. During the three months ended September 30, 2015, we sold a portion of the normal source plasma previously collected from our second plasma center. We expect that as plasma collection increases, our operating expenses will also increase accordingly.

General and Administrative Expenses

G&A expenses were \$2,078,166 for the three months ended September 30, 2015, an increase of \$1,042,946 from \$1,035,220 for the three months ended September 30, 2014. The increase in G&A expenses was attributable to consulting expenses associated to pre-launch, commercial planning activities, market research and analysis in preparation for product launch for RI-002 during the second half of 2016. We expect that our G&A expenses will increase throughout the remainder of 2015 as a result of pre-launch, commercial planning activities, market research costs and the hiring of additional staff as part of the commercial development of RI-002.

Total Operating Expenses

Total operating expenses were \$6,516,611 for the three months ended September 30, 2015, an increase of \$2,112,399 from \$4,404,212 for the three months ended September 30, 2014, for the reasons stated above.

Other Income (Expense); Interest Expense

Other expense, net was \$438,226 for the three months ended September 30, 2015, compared to \$346,407 for the three months ended September 30, 2014. The increase of \$91,819 is primarily attributable to higher interest expense as we accessed an additional \$5,000,000 during the fourth quarter of 2014 upon the milestone achievement of announcing positive Phase III data in accordance with the Prior Loan Agreement with our previous venture debt lender.

Net Loss

Net loss was \$5,102,424 for the three months ended September 30, 2015, an increase of \$1,717,735 from \$3,384,689 for the three months ended September 30, 2014 for the reasons stated above.

Nine Months Ended September 30, 2015 Compared to Nine Months Ended September 30, 2014

Summary table

The following table presents a summary of the changes in our results of operations for the nine months ended September 30, 2015 compared to the nine months ended September 30, 2014:

	Nine Months Ended		Percentage Increase/ (Decrease)	
	September 30, 2015	2014		
Revenues	\$ 4,665,452	\$ 4,426,808	5	%
Cost of product revenue	\$ 2,808,726	\$ 2,785,526	1	%
Research and development expenses	\$ 5,019,138	\$ 7,597,295	(34)	%
Plasma center operating expenses	\$ 3,359,130	\$ 2,641,700	27	%
General and administrative expenses	\$ 4,861,598	\$ 3,711,875	31	%
Total operating expenses	\$ 16,048,592	\$ 16,736,396	(4)	%
Other expense, net	\$ (2,004,137)	\$ (940,218)	>100	%
Net loss	\$ (13,387,277)	\$ (13,249,806)	1	%
Net loss in plasma collection segment	\$ (1,571,366)	\$ (1,056,823)	49	%
Net loss attributable to research and development segment	\$ (5,019,138)	\$ (7,597,295)	(34)	%

Revenues

We recorded total revenues of \$4,665,452 for the nine months ended September 30, 2015 and \$4,426,808 for the nine months ended September 30, 2014. Product revenue was \$4,596,490 for the nine months ended September 30, 2015, which is attributable to our plasma collection centers segment and derived from the sale of human source plasma collected in our FDA-licensed, GHA and MFDS-certified Norcross, Georgia-based plasma collection center and the sale of human source plasma collected at our second plasma collection center in Marietta, Georgia, which received approval from the FDA during the nine months ended September 30, 2015, compared to product revenue of \$4,370,141 for the nine months ended September 30, 2014. Product revenue for the nine months ended September 30, 2015 was primarily attributable to sales made pursuant to our plasma supply agreement with Biotest under which Biotest purchases normal source plasma from our wholly-owned subsidiary, ADMA BioCenters, to be used in their manufacturing. The increase in product revenue of \$226,349 was primarily attributable to revenue generated from the sale of normal source plasma collected at our second plasma center. License revenue was \$68,962 for the nine months ended September 30, 2015 and \$56,667 for the nine months ended September 30, 2014, which relates to a milestone payment received from Biotest upon the FDA's acceptance of our BLA filing for RI-002 and for services previously provided in accordance with our license agreement. We have not generated any revenue from our therapeutics research and development business.

Cost of Product Revenue

Cost of product revenue was \$2,808,726 for the nine months ended September 30, 2015, and \$2,785,526 for the nine months ended September 30, 2014. The increased cost of product revenues of \$23,200 for the nine months ended September 30, 2015 and 2014 was directly related to the increase in product revenues for the nine months ended September 30, 2015 and 2014.

Research and Development Expenses

R&D expenses, which are attributable to our R&D segment, were \$5,019,138 for the nine months ended September 30, 2015, a decrease of \$2,578,157 from \$7,597,295 for the nine months ended September 30, 2014. R&D expenses decreased during the nine months ended September 30, 2015, compared to the nine months ended September 30, 2014, primarily attributable the Phase III study being completed during the fourth quarter of 2014 and substantially all drug product supply being manufactured during the nine months ended September 30, 2014.

Plasma Center Operating Expenses

Operating expenses for our plasma collection centers segment attributed solely to ADMA BioCenters were \$3,359,130 for the nine months ended September 30, 2015, an increase of \$717,430 from \$2,641,700 for the nine months ended September 30, 2014. These operating expenses consist of G&A overhead, comprised of: rent, maintenance, utilities, wages 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 expenses was primarily a result of ADMA BioCenters opening its second plasma collection facility during the fourth quarter of 2014, which was attributable to higher costs in wages, rent, maintenance and plasma collection supplies for the nine months ended 2015, compared to the nine months ended 2014. During the nine months ended September 30, 2015, our second plasma collection facility received FDA approval to sell plasma in the U.S. During the three months ended September 30, 2015, we sold a portion of the normal source plasma previously collected from our second plasma center. We expect that as plasma collection increases, our operating expenses will also increase accordingly.

General and Administrative Expenses

G&A expenses were \$4,861,598 for the nine months ended September 30, 2015, an increase of \$1,149,723 from \$3,711,875 for the nine months ended September 30, 2014. G&A expenses primarily increased as a result of fees incurred for consulting services provided to us related to pre-launch, commercial planning activities, market research and analysis in preparation for product launch for RI-002 during the second half of 2016. We expect that our G&A expenses will increase throughout the remainder of 2015 as a result of pre-launch, commercial planning activities, market research costs and the hiring of additional staff as part of the commercial development of RI-002.

Total Operating Expenses

Total operating expenses were \$16,048,592 for the nine months ended September 30, 2015, a decrease of \$687,804 from \$16,736,396 for the nine months ended September 30, 2014, for the reasons stated above.

Other Income (Expense); Interest Expense

Other expense, net was \$2,004,137 for the nine months ended September 30, 2015, compared to \$940,218 for the nine months ended September 30, 2014. The increase of \$1,063,919 is primarily related to a loss on extinguishment of debt of \$719,097, related to the June 2015 refinancing of an existing loan with a new venture debt lender. The loss on extinguishment includes costs of writing off the previous unamortized debt discount, unamortized deferred financing costs and a prepayment premium. The increase also includes higher interest expense as we accessed an additional \$5,000,000 during the fourth quarter of 2014 upon the milestone achievement of announcing positive Phase III data in accordance with the Prior Loan Agreement with our previous venture debt lender.

Net Loss

Net loss was \$13,387,277 for the nine months ended September 30, 2015, an increase of \$137,471 from \$13,249,806 for the nine months ended September 30, 2014 for the reasons stated above.

Cash Flows

Net Cash Used in Operating Activities

Net cash used in operating activities was \$11,340,195 for the nine months ended September 30, 2015. The net loss for this period was higher than net cash used in operating activities by \$2,047,082, which was primarily attributable to an increase in deferred revenue of \$1,500,000 from a milestone payment received from Biotest resulting from the BLA filing of RI-002, increased inventories of \$1,122,051 related to allocating additional plasma to inventory in preparation for commercial manufacturing activities anticipated in 2016, increases in accounts receivable of \$816,654, related to sales of our normal source plasma, and decreases in accrued expenses of \$218,580 related to payments made to vendors and service providers, offset by stock-based compensation of \$1,221,662, a loss on extinguishment of debt of \$719,097 attributable to the refinancing of previous debt with a new venture debt lender and depreciation and amortization of \$614,755.

Net cash used in operating activities was \$11,802,477 for the nine months ended September 30, 2014. The net loss for this period was higher than net cash used in operating activities by \$1,447,329, which was primarily attributable to increases in accounts receivable of \$562,171, related to sales of our normal source plasma, accrued expenses of \$671,367 related to vendors and service providers, and a decrease in accounts payable of \$265,754, inventories of \$216,502 related to the sales of our normal source plasma and use in our clinical trial, offset by stock-based compensation of \$921,394 and depreciation and amortization of \$340,320.

Net Cash Used in Investing Activities

Net cash used in investing activities was \$7,142,255 for the nine months ended September 30, 2015, which was related to the increase in short-term investments of \$7,111,686 and \$30,569 in purchases of computers and equipment.

Net cash used in investing activities was \$5,151,409 for the nine months ended September 30, 2014, which was related to the increase in short-term investments of \$3,384,446 and purchases of equipment and leasehold improvements of \$1,766,963 for the expansion of our ADMA BioCenters operation in Norcross, Georgia, which was completed in the beginning of September 2014 and construction of our second ADMA BioCenters operation in Marietta, Georgia, which was completed in November 2014.

Net Cash Provided by Financing Activities

Net cash provided by financing activities totaled \$10,461,187 for the nine months ended September 30, 2015, which primarily consisted of \$16,000,000 received from the loan from Oxford during the second quarter of 2015, and \$10,306,606 received from the issuance of common stock during the first quarter of 2015, offset by the \$15,300,781 related to the repayment of a pre-existing loan with Hercules, prepayment premium to Hercules of \$229,512, debt issue costs to Oxford of \$172,363 and an end of term fee payment of \$132,500 to Hercules in addition to amortization of our leasehold improvement loan for our ADMA BioCenters wholly-owned subsidiary.

Net cash provided by financing activities totaled \$4,755,934 for the nine months ended September 30, 2014, which primarily consisted of \$4,850,000 of net proceeds received from the loan by Hercules during the first quarter of 2014, offset by debt issue costs of \$30,140, equity issuance costs of \$54,543, and payments on our leasehold improvement loan for our ADMA BioCenters wholly owned subsidiary.

Liquidity and Capital Resources

Overview

We have had limited revenue from operations and we have incurred cumulative losses of \$82.8 million since inception. We have funded our operations to date primarily from equity investments, loans from venture debt lenders and loans from our primary stockholders. We received net cash proceeds of approximately \$10.2 million from the sales of our common stock in March 2015, \$26.6 million in October 2013 from our Initial Public Offering, or IPO, a total of \$16.0 million from venture debt lenders in various financings since 2012; and \$15.3 million in the 2012 financing.

As of September 30, 2015, we had working capital of \$20.9 million, consisting primarily of \$9.2 million of cash and cash equivalents, \$11.8 million of short-term investments, \$1.2 million of accounts receivable, \$2.8 million of inventories, and \$0.2 million of prepaid expenses, offset primarily by \$2.2 million of accounts payable, \$1.9 million of accrued expenses and \$0.2 million of deferred revenue. Based upon our projected revenue and expenditures for 2015 and 2016, including the ongoing implementation of our commercialization and expansion activities, we currently believe that our cash, cash equivalents and short-term investments and accounts receivable as of September 30, 2015, are sufficient to fund our operations into the second half of 2016. Because we do not anticipate receiving FDA approval for RI-002 earlier than the second half of 2016, if at all, we would not expect to generate revenue from the commercialization of RI-002 earlier than such time, if at all. 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, debt financings, or obtain a bank credit facility, or corporate collaboration and licensing arrangements. We do not have any existing commitments for future external funding. The sale of additional equity or debt securities, if convertible, could result in dilution to our current stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations or other future financing alternatives. Additional equity or debt financing, grants, or corporate collaboration and potential licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned clinical trials and delay or abandon potential commercialization efforts of our lead product candidate. See also “Future Financing Needs” below.

Future Financing Needs

The net proceeds of \$10.2 million from our March 2015 underwritten offering of our common stock, the net proceeds of \$26.6 million from our 2013 IPO and the \$16.0 million borrowed under the Oxford LSA are being used and have been used to conduct clinical trials, manufacture drug product, collect and procure plasma, test plasma donors for RSV titers, filing of our BLA for RI-002, ongoing pre-launch, commercialization and marketing activities, the buildout and expansion of our first plasma center and the buildout of our second plasma center and the remainder for payment of existing accounts payable, general and administrative expenses as well as other business activities and general corporate purposes. We anticipate that, based upon our projected revenue and expenditures for 2015 and 2016, our current cash, cash equivalents, short-term investments and accounts receivable will be sufficient to fund our operations into the second half of 2016. If our assumptions underlying our estimated expenses and revenues prove to be incorrect, we may have to raise additional capital sooner than anticipated.

Our long-term liquidity will be dependent on our ability to raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis. Because of numerous risks and uncertainties associated with the research, development and future commercialization of our product candidate, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our anticipated clinical trials and development activities. If we are unable to successfully raise sufficient additional capital we will likely not have sufficient cash flow and liquidity to fund our business operations, forcing us to delay, discontinue or prevent product development and clinical trial activities or the approval of any of our potential products or curtail our activities and, ultimately, potentially cease operations. Even if we are able to raise additional capital, such financings may only be available on unattractive terms, or could result 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, the incurrence of indebtedness would result in increased fixed obligations and could result in covenants that would restrict our operations or other financing alternatives. Thereafter, our ability to continue as a going concern will be dependent on our ability to achieve profitability or raise additional capital, to fund our research and development and commercial programs and meet our obligations on a timely basis.

Financial markets in the United States, 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. The continued instability in the credit and financial market conditions may negatively impact our ability to access capital and credit markets and our ability to manage our cash balance. While we are unable to predict the continued duration and severity of the adverse conditions in the United States and other countries, any of the circumstances mentioned above could adversely affect our business, financial condition, operating results and cash flow or cash position.

Recent Accounting Pronouncements

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

In April 2015, the FASB issued Update (ASU) 2015-03, Interest—Imputation of Interest, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. Debt disclosures will include the face amount of the debt liability and the effective interest rate. The update requires retrospective application and represents a change in accounting principle. The update is effective for fiscal years beginning after December 15, 2015. Early adoption is permitted for financial statements that have not been previously issued. We have early adopted ASU 2015-03 in the second quarter 2015 consolidated financial statements and recast the prior period balances to conform to the current period presentation.

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

Critical Accounting Policies and Estimates

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for qualifying public companies. 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 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.

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

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

Stock-Based Compensation

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

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

For purposes of valuing stock options granted to our employees, non-employees and directors and officers through the three months ended September 30, 2015, we used the Black-Scholes option pricing model. We granted options to purchase an aggregate of 81,500 and 312,500 shares of common stock during the three and nine months ended September 30, 2015. 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. We have not experienced any material forfeitures of stock options and, as such, have not established a forfeiture rate since the stock options currently outstanding are primarily held by our senior management and directors. We will continue to evaluate the effects of such future potential forfeitures, as they may arise, to evaluate our estimated forfeiture rate.

Research and Development Costs

Our expenses include all R&D costs as incurred, of which such expenses include costs associated with planning and conducting clinical trials, regulatory consulting and filing fees and the disposition of plasma and equipment for which there is no alternative future use.

Our agreement with Biotest AG includes the in-license of certain rights to incomplete, in-process technology, the terms of which we expect to finalize during 2015. As such, we expect to account for the value of this license as a charge to operations once the terms of the in-license agreement are finalized.

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. Revenue is recognized at the time of delivery if we retain the risk of loss during shipment. Our revenues are substantially attributable to one customer. 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 AG have been completed. During the third quarter 2015, we recorded deferred revenue of \$1.5 million in accordance with a license agreement payment we received related to the filing of our BLA with the FDA. Deferred revenue of \$1.7 million was recorded in 2013 as a result of certain research and development services provided in accordance with a license agreement. Deferred revenue is recognized over the term of the license. Deferred revenue is amortized into income for a period of approximately 20 years, the term of the license agreement.

Accounting for Loan and Security Agreement

On June 19, 2015, we entered into the LSA with Oxford for up to \$21.0 million and refinanced our existing loan with Hercules. The first tranche of \$16.0 million from the Oxford loan was primarily used to repay our existing facility with Hercules and the remaining \$5.0 million is available at our option upon RI-002's BLA being approved from the FDA on or before January 31, 2017. The LSA bears interest at a rate per annum equal to the greater of (i) 7.80% and (ii) the sum of (a) the three (3) month U.S. LIBOR rate (as reported in The Wall Street Journal) on the date occurring on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 7.54% on the outstanding principal balance. We are obligated to begin to repay the principal over 36 months beginning February 1, 2017, unless accelerated as a result of certain events of default. At our option, if we receive BLA approval for RI-002 within the initial 18-month interest only period, the interest only period may be extended for an additional nine months. A final payment equal to 8.95% of the funded loan amount is due at the earlier of loan maturity or prepayment. In the event of the six-month interest only extension, the final payment will be 9.95% of the funded loan, which shall also be due at the earlier of loan maturity or prepayment. In addition, a facility fee of \$105,000 was paid at closing. In the event we elect to prepay the loan, we are obligated to pay a prepayment charge corresponding to a percentage of the principal amount of the loan, with such percentage being: 3.0% if prepayment occurs through the second anniversary of funding, 1.0% if prepayment occurs after the second anniversary of the funding date and prior to maturity date of the principal amount of the term loans prepaid. The loan matures no later than January 1, 2020. The loan is secured by our assets, except for our intellectual property (which is subject to a negative pledge).

In connection with the LSA, we issued to Oxford a 7 year warrant, expiring on June 19, 2022, to purchase 74,309 shares of common stock at an exercise price of \$8.51 per share. We recorded \$367,700 as the fair value of the warrant to additional paid-in capital and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included, volatility of 57% on our common stock based upon a pro rata percentage of our common stock's volatility and similar public companies' volatilities for comparison, an expected dividend yield of 0.0%, a risk-free interest rate of 1.99% and a term of 7 years. As a result of prepaying the Hercules loan prior to maturity, we incurred a loss on extinguishment of debt of \$0.7 million comprised of debt issuance costs, debt discount related to the warrants issued to Hercules along with a prepayment penalty.

In connection with the Prior Loan Agreement, we issued to Hercules a warrant to purchase 31,750 shares of common stock with an exercise price of \$7.56, and in connection with the Prior Loan Amendment, we issued to Hercules a warrant to purchase an additional 58,000 shares of our common stock, comprised of a warrant to purchase 23,200 shares of common stock issued in February 2014 and a warrant to purchase 34,800 shares of common stock issued in December 2014, each warrant issued under the prior Loan Amendment having an exercise price of \$7.50. The warrants expire after 10 years and have piggyback registration rights with respect to the shares of common stock underlying the warrant. The fair value of the Prior Loan Amendment warrant was calculated using a lattice-based option model in order to account for features in the warrant that could cause the exercise price to reset ("down round protection") as a result of the next issuance of our common stock ("the next round of equity financing"). We initially recorded the fair value of the warrant of \$219,588 as warrant liability and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included the expected date of the next round of equity financing, volatility of 59% for our common stock based upon similar public companies' volatilities for comparison, an expected dividend yield of 0.0%, a risk-free interest rate of 2.53% and a term of 10 years. As of December 31, 2014, we recorded \$476,760 as the fair value of the warrant for the purchase of 58,000 shares of common stock. As a result of the increase in warrant liability, we recorded an expense of \$74,356 from the change in the fair value of warrant liability. During the first quarter ended March 31, 2015, we recorded \$408,900 as the fair value of the warrant for the purchase of 58,000 shares of common stock. As a result of the decrease in warrant liability, we recorded a change in the fair value of stock warrants of \$67,860 from the December 31, 2014 balance. The key assumptions used to value

the warrants included the expected date of the next round of equity financing, volatility of 58% based upon a pro rata percentage of our common stock and similar public companies' volatilities, an expected dividend yield of 0.0%, a risk-free rate of 1.99% and a term of 10 years. This warrant liability was adjusted from the date of the Prior Loan Agreement on February 24, 2014, to fair value each reporting period using a lattice-based option model and the debt discount will be amortized to interest expense over the term of the loan. The down round warrant protection feature resulting in the warrant liability's quarterly "mark-to-market" valuation has terminated as of February 24, 2015, which was the end of the one-year period following the amended loan closing on February 24, 2014 and as a result the warrant liability of \$408,900 was reclassified to additional paid-in capital.

Off-Balance Sheet Arrangements

We have entered into leases for our ADMA BioCenters' facilities in Norcross, Georgia and Marietta, Georgia. The Norcross, Georgia lease expires on September 30, 2023, and the Marietta, Georgia lease expires on January 31, 2024. There is a total minimum rent due under these leases of \$3.0 million through the end of the lease terms.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

As of the end of the nine months ended September 30, 2015, our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures. Based on such evaluation of our disclosure controls and procedures, management, including our principal executive officer and principal financial officer, has concluded that our disclosure controls and procedures were effective as of September 30, 2015.

Changes in Internal Control Over Financial Reporting

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

PART II
OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 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.

None.

Item 6. Exhibits.

The following is a list of exhibits filed as part of this Form 10-Q:

Exhibit Number	Description
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

- 32.1 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.
- 32.2 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.

- 101 The following materials from ADMA Biologics, Inc. Form 10-Q for the quarter ended September 30, 2015, formatted in Extensible Business Reporting Language (XBRL):
- (i) Condensed Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014, (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2015 and 2014, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity for the nine months ended September 30, 2015, (iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014, and (v) Notes to Unaudited Condensed Consolidated Financial Statements.

SIGNATURES

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

ADMA Biologics, Inc.

Date: November 10, 2015

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

Date: November 10, 2015

By: /s/ Brian Lenz
Name: Brian Lenz
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	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.
32.2	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.
101	The following materials from ADMA Biologics, Inc. Form 10-Q for the quarter ended September 30, 2015, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014, (ii) Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2015 and 2014, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity for the nine months ended September 30, 2015, (iv) Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014, and (v) Notes to Unaudited Condensed Consolidated Financial Statements.