ADMA BIOLOGICS, INC.
Form 10-Q
August 12, 2016

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

¨ 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	56-2590442
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
465 State Route 17, Ramsey, New Jersey	07446
(Address of Principal Executive Offices)	(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 ý 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 ý 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 company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company ý
(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 ý

The number of shares outstanding of the issuer's common stock as of August 12, 2016 was 12,886,741.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

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PART I

FINANCIAL INFORMATION

Item 1. Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2016 (Unaudited)	December 31, 2015 (Note 2)
ASSETS		
Current Assets:		
Cash and Cash Equivalents	$ 12,549,173	$ 10,440,959
Short-Term Investments	11,270,963	6,368,177
Accounts Receivable	826,715	924,468
Inventories	4,209,326	3,445,773
Prepaid Expenses	638,059	111,027
Total Current Assets	29,494,236	21,290,404
Property and Equipment at Cost, Net	2,220,590	2,396,950
Other Assets:		
Deposits	27,163	27,163
Total Other Assets	27,163	27,163
TOTAL ASSETS	$ 31,741,989	$ 23,714,517
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts Payable	$ 3,317,052	$ 2,087,855
Accrued Expenses	1,604,500	1,968,384
Current Portion of Deferred Revenue	145,154	145,154
Current Portion of Leasehold Improvement Loan	15,833	15,139
Total Current Liabilities	5,082,539	4,216,532
Notes Payable, Net of Debt Discount	18,050,306	14,247,212
End of Term Liability, Notes Payable	1,790,000	1,432,000
Deferred Revenue	2,761,450	2,832,867
Deferred Rent Liability	113,396	128,676
Leasehold Improvement Loan	28,162	36,256
TOTAL LIABILITIES	27,825,853	22,893,543
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Common Stock $0.0001 par value 75,000,000 shares authorized, and 12,886,741 and 10,713,087 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively	1,289	1,072
Additional Paid-In Capital	101,959,318	88,239,569
Accumulated Deficit	(98,044,471)	(87,419,667)
TOTAL STOCKHOLDERS' EQUITY	3,916,136	820,974
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 31,741,989	$ 23,714,517

See Notes to Unaudited Condensed Consolidated Financial Statements.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
REVENUES:				
Product revenue	$ 2,236,035	$ 1,291,044	$ 4,324,213	$ 2,775,261
License and other revenue	35,709	18,889	71,417	37,778
Total Revenues	2,271,744	1,309,933	4,395,630	2,813,039
OPERATING EXPENSES:				
Cost of product revenue	1,344,241	786,315	2,610,662	1,695,944
Research and development	3,399,889	1,505,909	5,427,601	2,907,633
Plasma centers	1,294,301	1,096,878	2,574,720	2,144,972
General and administrative	1,724,163	1,437,436	3,432,033	2,783,432
TOTAL OPERATING EXPENSES	7,762,594	4,826,538	14,045,016	9,531,981
LOSS FROM OPERATIONS	(5,490,850)	(3,516,605)	(9,649,386)	(6,718,942)
OTHER INCOME (EXPENSE):				
Interest income	12,017	9,795	25,525	14,776
Interest expense	(537,998)	(453,411)	(1,005,439)	(929,450)
Other income	4,496	-	4,496	-
Change in fair value of stock warrants	-	-	-	67,860
Loss on extinguishment of debt	-	(719,097)	-	(719,097)
OTHER EXPENSE, NET	(521,485)	(1,162,713)	(975,418)	(1,565,911)
NET LOSS	$ (6,012,335)	$ (4,679,318)	$ (10,624,804)	$ (8,284,853)
NET LOSS PER COMMON SHARE, Basic and Diluted	$ (0.50)	$ (0.44)	$ (0.93)	$ (0.81)
WEIGHTED AVERAGE SHARES OUTSTANDING, Basic and Diluted	12,121,500	10,705,573	11,407,918	10,283,239

See Notes to Unaudited Condensed Consolidated Financial Statements.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

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

For the Six Months Ended June 30, 2016

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance - January 1, 2016	10,713,087	$1,072	$88,239,569	$(87,419,667)	$820,974
Stock-based compensation	-	-	733,125	-	733,125
Restricted shares	(2,500)	-	-	-	-
Issuance of common stock, net	2,176,154	217	12,900,324	-	12,900,541
Warrants issued in connection with note payable	-	-	86,300	-	86,300
Net loss	-	-	-	(10,624,804)	(10,624,804)
Balance - June 30, 2016	12,886,741	$1,289	$101,959,318	$(98,044,471)	$3,916,136

See Notes to Unaudited Condensed Consolidated Financial Statements.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Six Months Ended June 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (10,624,804)	$ (8,284,853)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	234,394	234,699
Stock-based compensation	733,125	773,730
Warrant liability	-	(67,860)
Amortization of debt discount	294,498	94,862
Amortization of deferred financing costs	-	39,717
Payment-in-kind interest	-	124,536
Amortization of license revenue	(71,417)	(37,778)
Loss on extinguishment of debt	-	719,097
Changes in operating assets and liabilities:		
Accounts receivable	97,753	(138,538)
Inventories	(763,553)	(744,133)
Prepaid expenses	(527,032)	(255,741)
Accounts payable	1,034,093	(305,506)
Accrued expenses	(363,884)	(774,452)
Accrued interest	-	(105,664)
Deferred rent liability	(15,280)	60,742
Net cash used in operating activities	(9,972,107)	(8,667,142)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of short-term investments	(4,902,786)	(11,277,678)
Purchase of property and equipment	(58,034)	(21,694)
Net cash used in investing activities	(4,960,820)	(11,299,372)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net	13,072,741	10,393,383
Proceeds from Oxford note payable	4,000,000	16,000,000
Repayment of Hercules note payable	-	(15,300,781)
Prepayment penalty of early extinguishment of note payable	-	(229,512)
Payment of debt issuance costs	(24,200)	(134,500)
Payment of Hercules end of term fee	-	(132,500)
Payments of leasehold improvement loan	(7,400)	(6,765)
Net cash provided by financing activities	17,041,141	10,589,325
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,108,214	(9,377,189)
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	10,440,959	17,199,030
CASH AND CASH EQUIVALENTS - END OF PERIOD	$ 12,549,173	$ 7,821,841
SUPPLEMENTAL INFORMATION:		
Cash paid for interest	$ 681,470	$ 790,252
Supplemental Disclosure of Noncash Financing Activities:		

Elimination of warrant liability	$	-	$	408,900
Reclassification of equity issuance costs to additional paid-in capital	$	-	$	12,000
Accrued equity issuance costs	$	172,200	$	154,003
Accrued debt issuance costs	$	22,904		
Noncash deferred financing fees	$	-	$	88,878
End of term liability for Oxford Note Payable	$	358,000	$	1,432,000
Warrants issued in connection with note payable	$	86,300	$	367,700

See Notes to Unaudited Condensed Consolidated Financial Statements.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2016 AND 2015

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 through 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. Each facility holds certifications from the German Health Authority ("GHA") and the Korean Ministry of Food and Drug Safety ("MFDS"). ADMA BioCenters supplies ADMA with a portion of its raw material plasma for the manufacture of RI-002, ADMA's lead product candidate, which the Company is currently developing for the treatment of Primary Immune Deficiency Disease ("PIDD"). A Biologics License Application ("BLA") for RI-002 was submitted to the FDA and accepted for review during the third quarter of 2015. In July 2016, the FDA issued a Complete Response Letter ("CRL") to the Company's BLA for RI-002. The CRL did not cite any concerns with the clinical safety and efficacy data for RI-002, nor has the FDA requested any additional clinical studies be conducted prior to FDA approval of RI-002 for PIDD. In its letter, among other things, the FDA focused on outstanding inspection issues and deficiencies at ADMA's third-party vendors, including the Company's contract drug substance and product manufacturer, its contract fill and finish provider and compliance issues with a third-party contract testing laboratory, and requested documentation of corrections for a number of those issues. The FDA indicated that it cannot grant final approval of the BLA until, among other things, these deficiencies are resolved.

In October 2013, the Company completed an Initial Public Offering ("IPO") that resulted in gross proceeds of approximately $29.1 million. In March 2015, ADMA completed an underwritten public offering of its common stock, raising gross proceeds of approximately $11.3 million. 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 approximately $15.7 million was used to repay a prior loan balance of approximately $15.0 million to Hercules Technology Growth Capital, Inc. ("Hercules"), along with approximately $0.4 million of interest and approximately $0.3 million of prepayment premium and other fees, under its prior loan and security agreement, dated December 21, 2012, with Hercules (the "Prior Loan Agreement"), as amended on February 24, 2014, (see Note 3). In May 2016 the Company amended its LSA with Oxford (the "Amended LSA"). This amendment provided ADMA with an additional $4.0 million term loan, the availability of which was contingent on completing an equity financing of its common stock of at least $10.0 million in gross proceeds no later than May 31, 2016. In May 2016, the Company completed an underwritten public offering of its common stock, raising gross proceeds of approximately $14.1 million, and subsequently borrowed an additional $4.0 million from Oxford under the Amended LSA, which brought the total principal borrowed to $20.0 million.

As of June 30, 2016, the Company had working capital of $24.4 million, consisting primarily of $12.5 million of cash and cash equivalents, $11.3 million of short-term investments, $4.2 million of inventories, $0.8 million of accounts receivable and $0.6 million of prepaid expenses, offset primarily by $3.3 million of accounts payable, $1.6 million of accrued expenses and $0.1 million of deferred revenue. Based upon the Company's projected revenue and expenditures for 2016 and 2017, including regulatory and consulting fees for RI-002 associated with third-party manufacturers and ongoing discussions with the FDA, continuing implementation of the Company's commercialization and expansion activities, management currently believes that its cash, cash equivalents, short-term investments and accounts receivable as of the date of this report are sufficient to fund ADMA's operations, as currently conducted, into the second half of 2017. These estimates may change based upon whether or when the FDA approves

RI-002 and the timing of any required commercial manufacturing scale up activities. The Company has the option to borrow an additional $5.0 million through its current LSA with Oxford, if RI-002 is approved by the FDA prior to January 31, 2017, which funding would also extend its interest only period for an additional six months pursuant to the May 2016 amendment to the LSA. Other than this additional $5.0 million, the Company does not have any existing commitments for future external funding. In addition to traditional debt financing, the Company may also sell additional equity or convertible debt securities, each of which 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, and delay or abandon potential commercialization efforts of the Company's lead or other product candidates. 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 raised capital from the sales of its equity securities and debt financings to sustain operations. The Company has reported losses since inception in June 2004 through June 30, 2016 of $98.0 million. ADMA's long-term liquidity will be dependent upon on its ability to obtain FDA approval for RI-002, generate sales of RI-002 and potentially raise additional capital, to fund its research and development and commercial programs and to meet its obligations on a timely basis, if at all.

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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 and third-party manufacturers, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with FDA and other governmental regulations and approval requirements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation 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 June 30, 2016 and its results of operations for the three and six months ended June 30, 2016 and 2015, change in stockholders' equity for the six months ended June 30, 2016 and cash flows for the six months ended June 30, 2016 and 2015. 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, 2015 on Form 10-K, filed with the U.S. Securities and Exchange Commission (the "SEC") on March 23, 2016. The accompanying condensed consolidated balance sheet as of December 31, 2015, was derived from the 2015 audited consolidated financial statements.

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

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Inventories

Plasma inventories (both plasma intended for resale and plasma intended for internal use in the Company's research and development and future anticipated commercialization activities of which certain quantities are labeled as normal source and Respiratory Syncytial Virus, ("RSV") high titer) are carried at the lower of cost or market value determined by the first-in, first-out method. Research and development plasma used in clinical trials was processed to a finished product and subsequently expensed to research and development. Inventory at June 30, 2016 and December 31, 2015 consists of high titer RSV 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. The Company 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 six months ended June 30, 2016 are comprised of product revenues from the sale of normal source human plasma collected from the Company's plasma collection centers segment and license and other revenues are primarily attributable to the out-licensing of RI-002 to Biotest Aktiengesellschaft ("Biotest AG") to market and sell in Europe and selected countries in North Africa and the Middle East. Biotest AG and Biotest Pharmaceuticals Corporation ("Biotest"), a subsidiary of Biotest AG, have provided the Company with certain services and financial payments in accordance with the related Biotest AG 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 Biotest AG license agreement. Deferred revenue is recognized over the term of the Biotest AG license. Deferred revenue is amortized into income for a period of approximately 20 years, the term of the Biotest AG 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.

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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 1.8 million and 1.5 million as of June 30, 2016 and 2015, respectively.

Stock-based compensation

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

During the three and six months ended June 30, 2016, the Company granted stock options to purchase 15,000 and 100,984 shares of common stock, respectively, to its directors and employees. During the three and six months ended June 30, 2015, the Company granted stock options to purchase 1,000 and 231,000 shares of common stock, respectively, to its directors and employees.

3. DEBT

Loan and Security Agreement

On June 19, 2015, the Company entered into the LSA with Oxford for up to $21.0 million of debt financing in two tranches, and refinanced its then existing loan with Hercules. The first tranche of $16.0 million from the Oxford loan was primarily used to repay the Company's previous facility with Hercules and the remaining $5.0 million is available at ADMA's option if RI-002's BLA is approved by the FDA on or before January 31, 2017, which funding would also extend the interest only period for an additional six months pursuant to the May 2016 amendment to the LSA.

The LSA bears interest at a rate per annum equal to the greater of (i) 7.80% and (ii) the sum of (a) the three (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. 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 prepays a loan for any reason, the Company is

obligated to pay a prepayment charge corresponding to a percentage of the principal amount of the applicable loan prepaid, with such percentage being: 3.0% if prepayment occurs through the first anniversary of its funding, 2.0% if prepayment occurs after the first anniversary through the second anniversary of the applicable funding date, and 1.0% if prepayment occurs after the second anniversary of its funding date and prior to its maturity date. 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 owed under the LSA and taking immediate possession of, and selling, any collateral securing the loan.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES
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In connection with the LSA, on June 19, 2015, the Company issued to Oxford a seven-year warrant, expiring on June 19, 2022, to purchase 74,309 shares of common stock at an exercise price of $8.51 per share. The Company recorded $367,700 as the fair value of the warrant to additional paid-in capital and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included: 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 seven 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 and unamortized debt discount related to the warrants issued to Hercules, along with a prepayment penalty.

In May 2016, the Company amended its LSA with Oxford, referred to as the Amended LSA, which provided ADMA with an additional $4.0 million term loan (the "Term B Loan"), the availability of which was conditioned on completing an equity financing of its common stock of at least $10.0 million in gross proceeds no later than May 31, 2016. On May 3, 2016, the Company completed an underwritten public offering of its common stock, raising gross proceeds of approximately $14.1 million and subsequently borrowed the additional $4.0 million from Oxford under the Amended LSA, which brings the total principal borrowed to $20.0 million. Under the Amended LSA, the Company may borrow an additional aggregate amount up to $5.0 million (the "Term C Loan"), at its option during the period commencing on the date the Company's BLA for RI-002 is approved by the FDA and ending on the earlier of (i) January 31, 2017, (ii) thirty (30) days after the occurrence of such FDA approval and (iii) the occurrence of an event of default under the Amended LSA, in which case the additional loan amount would not be available while the event of default continues. Upon the Company accessing the additional $5.0 million, the interest only period will be extended from February 1, 2017 to August 1, 2017. The Amended LSA further modified the fees payable by the Company on mandatory or voluntary prepayment of a term loan prior to its maturity date as follows: (i) for a prepayment made on or after the funding date of the applicable term loan through and including the first anniversary of its funding date, an amount equal to 3.00% of the principal amount of the term loan prepaid; (ii) for a prepayment made after the first anniversary of the funding date of the applicable term loan through and including the second anniversary of such funding date, an amount equal to 2.00% of the principal amount of such term loan prepaid; and (iii) for a prepayment of a term loan made after the second anniversary of its funding date and prior to its maturity date, an amount equal to 1.00% of the principal amount of the term loan prepaid.

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Pursuant to the Amended LSA, (i) the Company paid a total facility fee of $125,000, consisting of $105,000 previously paid and an additional $20,000 paid on the date the Term B Loan was funded; (ii) certain adjustments were made to the time periods for any applicable prepayment fees; and (iii) certain defined terms were adjusted, including a new Amortization Date that is defined as (a) February 17, 2017, if the Term C Loan is not made and (b) August 1, 2017 if the Term C Loan is made. The Amended LSA further provides for customary representations, warranties and covenants for the Company. Except as otherwise amended, the Amended LSA does not alter the terms of the LSA.

In addition, on May 13, 2016, pursuant to the terms and conditions of the LSA as modified by the Amended LSA, the Company agreed to issue the lenders warrants to purchase shares of its common stock, upon its draw of each tranche of the term loans. The aggregate number of shares of common stock issuable upon exercise of the warrants is equal to 3.95% of the amount drawn of such tranche, divided by the average reported closing price per share of common stock for the ten (10) consecutive trading days prior to the applicable draw.

In connection with the Amended LSA, on May 13, 2016, the Company issued to Oxford a seven- year warrant, expiring on May 23, 2023, to purchase 24,800 shares of common stock at an exercise price of $6.37 per share, in accordance with the Company's drawdown of the Term B Loan. The Company recorded $86,300 as the fair value of the warrant to additional paid-in capital and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included: volatility of 53.5% on the Company's common stock based upon a pro rata percentage of the Company's common stock's volatility and similar public companies' volatilities for comparison, an expected dividend yield of 0.0%, a risk-free interest rate of 1.51% and a term of seven years.

A summary of the Oxford loan balance as of June 30, 2016 and December 31, 2015 is as follows:

	June 30, 2016	December 31, 2015
Gross proceeds	$ 20,000,000	$ 16,000,000
Less: debt discount, net		
End of term fee	(1,412,056)	(1,250,194)
Warrants	(335,558)	(310,196)
Financing fees	(202,080)	(192,398)
Note payable	$ 18,050,306	$ 14,247,212

4. STOCKHOLDERS' EQUITY

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

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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 thereof, 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.

Oxford Debt Financing Warrant Issuance

In May 2016, the Company entered into an Amended LSA with Oxford and accessed an additional $4.0 million Term B Loan under the amended credit facility. In connection therewith, the Company issued to Oxford warrants to purchase an aggregate of up to 24,800 shares of the Company’s common stock at an exercise price equal to $6.37 per share. The warrants became exercisable on or after May 13, 2016 for cash or by net exercise and will expire seven years after their issuance on May 13, 2023.

Equity incentive plan

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

	Six Months Ended June 30, 2016	Six Months Ended June 30, 2015
Expected term	5.8 - 6.3 years	5.8 - 6.3 years
Volatility	51-52%	56-57%
Dividend yield	0.0	0.0
Risk-free interest rate	1.54-1.79%	1.49-1.90%

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 June 30, 2016 is 6.9 years. The weighted average remaining contractual life of stock options exercisable at June 30, 2016 is 6.0 years.

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

	Six Months Ended June 30, 2016	
	Shares	Weighted Average Exercise Price
Outstanding at beginning of period	1,464,203	$ 8.02
Forfeited	(21,334)	$ 8.02
Expired	(8,666)	$ 7.88
Granted	100,984	$ 6.20
Outstanding at end of period and expected to vest	1,535,187	$ 7.90
Options exercisable	1,038,762	$ 7.45

Stock-based compensation expense for the three and six months ended June 30, 2016 and 2015 is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and development	$ 132,277	$ 165,737	$ 288,833	$ 329,805
Plasma centers	11,745	12,323	24,755	23,356
General and administrative	166,923	208,601	419,537	420,569
Total stock-based compensation expense	$ 310,945	$ 386,661	$ 733,125	$ 773,730

As of June 30, 2016, the total compensation expense related to unvested options not yet recognized totaled $2,133,286. The weighted average vesting period over which the total compensation expense will be recorded related to unvested options not yet recognized at June 30, 2016 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 of which terms were amended by the Company's Board of Directors in June 2016 as a result of the Company accessing additional office space related to the expansion and hiring activities in preparation for a potential commercial launch of RI-002. Rent expense amounted to $71,888 and $24,112 for the three months ended June 30, 2016 and 2015, respectively, and $96,000 and $48,224 for the six months ended June 30, 2016 and 2015, respectively. The Company also reimburses its landlord for office related expenses, equipment and certain other operational expenses, which have been insignificant to the condensed consolidated financial statements for the six months ended June 30, 2016 and 2015. The Company maintains deposits and other accounts at a bank which was less than 5%-owned by related parties through January 2016, and where a stockholder and Company director was a member of the bank's board of directors through January 2016, and is now a member of its Corporate Advisory

Council.

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

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

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

Three Months Ended June 30, 2016	Plasma Collection Centers	Research and Development	Corporate	Consolidated
Revenues	$ 2,236,035	$ -	$ 35,709	$ 2,271,744
Cost of product revenue	1,344,241	-	-	1,344,241
Gross profit	891,794	-	35,709	927,503
Loss from operations	(402,507)	(3,399,889)	(1,688,454)	(5,490,850)
Other expense	-	-	(521,485)	(521,485)
Net loss	(402,507)	(3,399,889)	(2,209,939)	(6,012,335)
Total assets	2,509,903	-	29,232,086	31,741,989
Depreciation and amortization expense	102,330	-	13,671	116,001

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Three Months Ended June 30, 2015	Plasma Collection Centers	Research and Development	Corporate	Consolidated
Revenues	$ 1,291,044	$ -	$ 18,889	$ 1,309,933
Cost of product revenue	786,315	-	-	786,315
Gross profit	504,729	-	18,889	523,618
Loss from operations	(592,149)	(1,505,909)	(1,418,547)	(3,516,605)
Other expense	-	-	(1,162,713)	(1,162,713)
Net loss	(592,149)	(1,505,909)	(2,581,260)	(4,679,318)
Total assets	3,152,144	-	26,647,628	29,799,772
Depreciation and amortization expense	105,100	-	12,477	117,577

Six Months Ended June 30, 2016	Plasma Collection Centers	Research and Development	Corporate	Consolidated
Revenues	$ 4,324,213	$ -	$ 71,417	$ 4,395,630
Cost of product revenue	2,610,662	-	-	2,610,662
Gross profit	1,713,551	-	71,417	1,784,968
Loss from operations	(861,169)	(5,427,601)	(3,360,616)	(9,649,386)
Other expense	-	-	(975,418)	(975,418)
Net loss	(861,169)	(5,427,601)	(4,336,034)	(10,624,804)
Total assets	2,509,903	-	29,232,086	31,741,989
Depreciation and amortization expense	207,519	-	26,875	234,394

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Six Months Ended June 30, 2015	Plasma Collection Centers	Research and Development	Corporate	Consolidated
Revenues	$ 2,775,261	$ -	$ 37,778	$ 2,813,039
Cost of product revenue	1,695,944	-	-	1,695,944
Gross profit	1,079,317	-	37,778	1,117,095
Loss from operations	(1,065,655)	(2,907,633)	(2,745,654)	(6,718,942)
Other expense	-	-	(1,565,911)	(1,565,911)
Net loss	(1,065,655)	(2,907,633)	(4,311,565)	(8,284,853)
Total assets	3,152,144	-	26,647,628	29,799,772
Depreciation and amortization expense	210,017	-	24,682	234,699

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

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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 six months ended June 30, 2016 and 2015 and our Annual Report for the year ended December 31, 2015 on Form 10-K, filed with the U.S. Securities and Exchange Commission, or the SEC, on March 23, 2016.

Forward-Looking Statements

This quarterly report 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. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning our business strategy, outlook, objectives, future milestones, plans, intentions, goals, and future financial condition, including the period of time for which our existing resources will enable us to fund our operations. Forward-looking statements also include our financial, clinical, manufacturing and distribution plans and our expectations and timing related to the U.S. Food and Drug Administration, or FDA, approval and commercialization of RI-002.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause actual results to differ materially from any future results expressed or implied by the forward-looking statements. We caution you therefore against relying on any of these forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. Examples of the risks and uncertainties include, but are not limited to:

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

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

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

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

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- our dependence upon one manufacturer for RI-002 and the effect any adverse events on such manufacturer could have on us or our business,
- our dependence upon our third-party contract manufacturers and vendors,
- our ability to obtain adequate quantities of FDA-approved normal source plasma and Respiratory Syncytical Virus, or RSV, high-titer plasma with proper specifications,
- our plans to increase our supplies of plasma,
- the potential indications for our product candidates,
- potential investigational new product applications,
- the acceptability of RI-002 for any purpose by physicians, patients or payers,
- concurrence by FDA with our conclusions and the satisfaction by us of its guidance,
- the comparability of results of RI-002 to other comparably run injectable immune globulin trials,
- the potential of RI-002 to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease, or PIDD,
- our intellectual property position, including our expectations of the scope of patent protection with respect to RI-002, or other future pipeline product candidates,
- our manufacturing capabilities, third-party contractor capabilities and strategy,
- our plans relating to manufacturing, supply and other collaborative agreements,
- our estimates regarding expenses, capital requirements and needs for additional financing,
- possible or likely reimbursement levels, if any, if and when RI-002 is approved for marketing,
- estimates regarding market size, projected growth and sales as well as our expectations of market acceptance of RI-002,
- expectations for future capital requirements.

Pharmaceutical, biotechnology and medical device technology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. After gaining approval of a drug product, pharmaceutical and biotechnology companies face considerable challenges in marketing and distributing their products, and may never become profitable. You should read carefully the factors described in the "Risk Factors" in our Annual Report for the year ended December 31, 2015 on Form 10-K as filed with the SEC on March 23, 2016, our Current Report on Form 8-K, as filed with the SEC on April 27, 2016 and in other filings with the SEC to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this report and you should not place undue reliance on any

forward-looking statements.

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Any forward-looking statements that we make in this quarterly report on Form 10-Q speak only as of the date of such statements and we do not undertake any obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

In addition to the risks identified under the heading “Risk Factors” in the SEC filings referenced previously, 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 or at risk for certain infectious diseases.

Our Lead Product Candidate – RI-002

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

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In the third quarter of 2015, the FDA accepted for review a BLA for RI-002 for the treatment of PIDD. In July 2016, the FDA issued a CRL to the BLA. The CRL did not cite any concerns with the clinical safety or efficacy data for RI-002 submitted in the BLA, nor did the FDA request any additional clinical studies be completed prior to FDA approval of RI-002. The FDA identified in the CRL, among other things, certain outstanding inspection issues and deficiencies at our third-party contract manufacturers/vendors and requested documentation of corrections for a number of those issues. The FDA indicated in the CRL that it cannot grant final approval of the BLA until, among other things, these deficiencies are resolved. We are working with our third-party contract manufacturers/vendors to monitor their efforts in addressing and resolving outstanding issues. If RI-002 is approved by the FDA, we intend to commercialize RI-002 for the treatment of PIDD and explore an alternative process to evaluate and seek approval for RI-002 for additional indications, patient populations and uses.

Evaluation of PIDD Patients

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

The RI-002 pivotal Phase III clinical trial was conducted as a single arm study in which patients were treated approximately once per month for a period of 12 months plus 90 days for follow up. Fifty-nine patients were enrolled in nine treatment centers in the 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 IVIG. The secondary outcome was safety and included other pharmacokinetic, or PK, data collection points including antibody titers for certain agents, including RSV antibody levels at various time points after infusion.

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

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

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Rationale for the Potential Evaluation in RSV Infected Patients

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

We previously conducted a randomized, double-blind, placebo-controlled Phase II clinical trial to evaluate RI-001, RI-002's predecessor product candidate, in immune-compromised, RSV-infected patients. This trial was conducted with 21 patients in the 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 due to the fact that these patients had failed conventional therapeutic interventions. Serum samples were obtained from 13 patients. Samples showed that patients demonstrated a 4-fold or greater rise in RSV antibody titers from baseline. Serum samples were not obtained from two patients that received Palivizumab. All the patients (11) who received RI-001 within 4.2 days after the onset of the diagnosis of RSV survived. The drug was well-tolerated in all 15 patients and there were no reports of serious adverse events attributable to RI-001. Data from our Phase II trial, compassionate use experience and data obtained from the evaluation of RI-002 in the infected cotton rat animal model has been presented at various conferences during 2014, 2015 and 2016.

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

Commercialization

As part of our current ongoing 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, financial and operational management. If and when we receive FDA approval, we may also use a network of national distributors to fulfill orders for RI-002 for use by healthcare professionals and hospitals.

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Intellectual Property

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 of 2015 our U.S. Patent 9,107,906 was issued by the USPTO. This patent describes methods by which the blending of plasma obtained from normal donors with plasma obtained from donors selected to have high levels of neutralizing titers to RSV form a unique antibody enriched plasma pool and provide for the standardization of the levels of anti-RSV antibodies in the RI-002 final product. Our proprietary microneutralization assay allows us to effectively identify and isolate donor plasma with high-titer RSV antibodies and to standardize RI-002’s antibody profile, which we believe may enable us to garner a premium price.

Plasma Collection Facilities

Our wholly-owned subsidiary, ADMA BioCenters, operates two FDA-licensed, German Health Authority, or GHA, and Korean Ministry of Food and Drug Safety, or MFDS, certified source plasma collection facilities located in Norcross, Georgia and Marietta, Georgia, which provide us with a portion of our blood plasma for the manufacture of RI-002. Our plasma collection center in Marietta, Georgia, received FDA approval in the third quarter of 2015. A typical plasma collection center, such as those operated by ADMA BioCenters, can collect approximately 30,000 to 50,000 liters of source plasma annually, which may be sold for different prices depending upon the type of plasma, quantity of purchase, and market conditions at the time of sale. Plasma collected from ADMA BioCenters' two Georgia facilities that is not used for making RI-002 is sold to third-party customers in the United States, and other locations where we are approved globally under supply agreements or in the open "spot" market. We have entered into long-term manufacturing and licensing agreements with Biotest Aktiengesellschaft, or Biotest AG and their United States subsidiary, Biotest Pharmaceuticals Corporation, or Biotest, that provide for the exclusive manufacture of RI-002. At the same time, we granted Biotest AG an exclusive, royalty-bearing license to market and sell RSV antibody-enriched IVIG in Europe and in other selected territories in North Africa and the Middle East.

Financial Operations Overview

Revenues

Revenues for the three and six months ended June 30, 2016 are comprised of product revenues from the sale of normal source human plasma collected from our plasma collection centers 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 Biotest AG license agreement and is obligated to pay us certain amounts in the future if certain milestones are achieved.

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

Research and Development Expenses

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

The process of conducting preclinical studies, clinical trials and regulatory activities necessary to obtain FDA approval is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among others, the quality of the product candidate's early clinical data, investment in the program, competition, regulatory, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, the 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 and six months ended June 30, 2016 increased due to higher validation, testing and production costs related to RI-002 along with increased regulatory consulting services related to our BLA. We anticipate R&D expenses may continue to increase throughout 2016 as a result of ongoing regulatory activities related to our BLA along with anticipated expenditures for testing and validation services relating to the costs associated with seeking FDA approval for RI-002 and in procuring plasma from donors with high levels of neutralizing titers to RSV as part of our manufacturing of RI-002.

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 and six months ended June 30, 2016 are primarily attributable to marketing, commercial planning, increased headcount, wages and benefits for employees, including stock-based compensation and consulting expenses associated with commercialization activities in preparation for anticipated product launch of RI-002 during the second half of 2016, assuming we receive FDA approval of our BLA during such period. We expect that our G&A expenses may continue to increase throughout 2016 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.

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Other Income and Expense

Interest income consists of interest earned on our cash and cash equivalents and short-term investments. Interest expense consists of interest incurred on our notes payable, as well as the amortization of end of term fees, back end fees, value of warrants issued, facility and financing fees. We anticipate other income and expense to remain consistent throughout 2016 as a result of our current outstanding debt and interest earned on investments.

Results of Operations

Three Months Ended June 30, 2016 Compared to Three Months Ended June 30, 2015

Summary table

The following table presents a summary of the changes in our results of operations for the three months ended June 30, 2016 compared to the three months ended June 30, 2015:

	Three Months Ended June 30,		Percentage Increase/ (Decrease)	
	2016	2015		
Revenues	$ 2,271,744	$ 1,309,933	73	%
Cost of product revenue	$ 1,344,241	$ 786,315	71	%
Research and development expenses	$ 3,399,889	$ 1,505,909	>100	%
Plasma center operating expenses	$ 1,294,301	$ 1,096,878	18	%
General and administrative expenses	$ 1,724,163	$ 1,437,436	20	%
Total operating expenses	$ 7,762,594	$ 4,826,538	61	%
Other expense, net	$ (521,485)	$ (1,162,713)	(55	%)
Net loss	$ (6,012,335)	$ (4,679,318)	28	%
Net loss in plasma collection segment	$ (402,507)	$ (592,149)	(32	%)
Net loss attributable to research and development	$ (3,399,889)	$ (1,505,909)	>100	%

Revenues

We recorded total revenues of $2,271,744 for the three months ended June 30, 2016 and $1,309,933 for the three months ended June 30, 2015. Product revenue was $2,236,035 for the three months ended June 30, 2016, which is attributable to our plasma collection centers segment, derived from the sale of blood plasma collected at our FDA-licensed, GHA and MFDS certified Georgia-based blood plasma collection centers, compared to product revenue of $1,291,044 for the three months ended June 30, 2015. Product revenue for the quarter ended June 30, 2016 was primarily attributable to sales made pursuant to our plasma supply agreement with Biotest under which Biotest purchases normal source plasma from ADMA BioCenters for their manufacturing. The increase in product revenue of $944,991 was primarily attributable to sales from our Marietta, Georgia plasma center, which received FDA approval to sell human source plasma within the U.S. during the third quarter of 2015. License and other revenue was $35,709 for the three months ended June 30, 2016 and $18,889 for the three months ended June 30, 2015 which relates to services and financial payments provided by Biotest and Biotest AG, in accordance with our license agreement. We have not generated any revenue from our therapeutics research and development business.

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Cost of Product Revenue

Cost of product revenue was $1,344,241 for the three months ended June 30, 2016, and $786,315 for the three months ended June 30, 2015. The increase in cost of product revenues of $557,926 for the three months ended June 30, 2016 was directly related to the increase in product revenues for the three months ended June 30, 2016.

Research and Development Expenses

R&D expenses, which are attributable to our R&D segment, were $3,399,889 for the three months ended June 30, 2016, an increase of $1,893,980 from $1,505,909 for the three months ended June 30, 2015. The increase in R&D expenses during the three months ended June 30, 2016, compared to the three months ended June 30, 2015, was primarily attributable to an increase in higher validation, testing and production costs related to RI-002 and an increase in regulatory consulting fees.

Plasma Center Operating Expenses

Operating expenses for our plasma collection centers segment attributed solely to ADMA BioCenters were $1,294,301 for the three months ended June 30, 2016, an increase of $197,423 from $1,096,878 for the three months ended June 30, 2015. 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 the result of ADMA BioCenters Marietta collection facility receiving FDA approval during the third quarter of 2015, which was attributable to the higher costs in wages, rent, maintenance and plasma collection supplies during the second quarter of 2016 compared to the second quarter of 2015. We expect that as plasma collection increases, our operating expenses will also increase accordingly.

General and Administrative Expenses

G&A expenses were $1,724,163 for the three months ended June 30, 2016, an increase of $286,727 from $1,437,436 for the three months ended June 30, 2015. G&A expenses primarily increased as a result of pre-launch, market research activities. We expect that our G&A expenses may increase throughout the remainder of 2016 as a result of pre-launch, commercial planning, 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 $7,762,594 for the three months ended June 30, 2016, an increase of $2,936,056 from $4,826,538 for the three months ended June 30, 2015, for the reasons stated above.

Other Income (Expense); Interest Expense

Other expense, net, was $521,485 for the three months ended June 30, 2016, compared to $1,162,713 for the three months ended June 30, 2015. The decrease of $641,228 is primarily related to a loss on extinguishment of debt of $719,097, which was recorded in the second quarter of 2015 for the refinancing of an existing loan with a new lender, of which costs are comprised of a write-off of deferred financing costs, end of term fees and prepayment penalties for the repayment of debt to our prior lender, offset by increased interest expense due to an increase of $4,000,000 to our current debt in the second quarter of 2016, which includes debt discounts amortization for our new lender’s end of term fees, back end fees, value of warrants issued, facility and financing fees.

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Net Loss

Net loss was $6,012,335 for the three months ended June 30, 2016, an increase of $1,333,017 from $4,679,318 for the three months ended June 30, 2015 for the reasons stated above.

Six Months Ended June 30, 2016 Compared to Six Months Ended June 30, 2015

Summary table

The following table presents a summary of the changes in our results of operations for the six months ended June 30, 2016 compared to the six months ended June 30, 2015:

	Six Months Ended June 30,		Percentage Increase/ (Decrease)
	2016	2015	
Revenues	$ 4,395,630	$ 2,813,039	56 %
Cost of product revenue	$ 2,610,662	$ 1,695,944	54 %
Research and development expenses	$ 5,427,601	$ 2,907,633	87 %
Plasma center operating expenses	$ 2,574,720	$ 2,144,972	20 %
General and administrative expenses	$ 3,432,033	$ 2,783,432	23 %
Total operating expenses	$ 14,045,016	$ 9,531,981	47 %
Other expense, net	$ (975,418)	$ (1,565,911)	(38)
Net loss	$ (10,624,804)	$ (8,284,853)	28 %
Net loss in plasma collection segment	$ (861,169)	$ (1,065,655)	(19)
Net loss attributable to research and development	$ (5,427,601)	$ (2,907,633)	87 %

Revenues

We recorded total revenues of $4,395,630 for the six months ended June 30, 2016 and $2,813,039 for the six months ended June 30, 2015. Product revenue was $4,324,213 for the six months ended June 30, 2016, which is attributable to our plasma collection centers segment derived from the sale of human source plasma collected from our FDA-licensed plasma collection centers, compared to product revenue of $2,775,261 for the six months ended June 30, 2015. The increase in product revenue of $1,548,952 was primarily attributable to sales from our Marietta, Georgia plasma center which received FDA approval to sell human source plasma within the U.S. during the third quarter of 2015. Product revenue for the six months ended June 30, 2016 was primarily attributable to sales made pursuant to our plasma supply agreement with Biotest under which Biotest purchases normal source plasma from ADMA BioCenters for their manufacturing. License and other revenue was $71,417 for the six months ended June 30, 2016 and $37,778 for the six months ended June 30, 2015, which relates to services and financial payments provided by Biotest and Biotest AG in accordance with our license agreement. We have not generated any revenue from our therapeutics research and development business.

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Cost of Product Revenue

Cost of product revenue was $2,610,662 for the six months ended June 30, 2016, and $1,695,944 for the six months ended June 30, 2015. The increased cost of product revenues of $914,718 for the six months ended June 30, 2016 was directly related to the increase in product revenues for the six months ended June 30, 2016.

Research and Development Expenses

R&D expenses, which are attributable to our R&D segment, were $5,427,601 for the six months ended June 30, 2016, an increase of $2,519,968 from $2,907,633 for the six months ended June 30, 2015. R&D expenses increased during the six months ended June 30, 2016, compared to the six months ended June 30, 2015, primarily attributable to an increase in higher validation, testing and production costs related to RI-002 and an increase in regulatory consulting fees.

Plasma Center Operating Expenses

Operating expenses for our plasma collection centers segment attributed solely to ADMA BioCenters were $2,574,720 for the six months ended June 30, 2016, an increase of $429,748 from $2,144,972 for the six months ended June 30, 2015. 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 the result of ADMA BioCenters Marietta collection facility receiving FDA approval during the third quarter of 2015, which was attributable to the higher costs in wages, rent, maintenance and plasma collection supplies during the six months ended June 30, 2016 compared to the six months ended June 30, 2015. We expect that as plasma collection increases, our operating expenses will also increase accordingly.

General and Administrative Expenses

G&A expenses were $3,432,033 for the six months ended June 30, 2016, an increase of $648,601 from $2,783,432 for the six months ended June 30, 2015. G&A expenses primarily increased as a result of fees incurred for consulting services provided to us related to pre-launch, commercial planning, market research. We expect that our G&A expenses may increase throughout the remainder of 2016 as a result of pre-launch, commercial planning, 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 $14,045,016 for the six months ended June 30, 2016, an increase of $4,513,035 from $9,531,981 for the six months ended June 30, 2015, for the reasons stated above.

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Other Income (Expense); Interest Expense

Other expense, net was $975,418 for the six months ended June 30, 2016, compared to $1,565,911 for the six months ended June 30, 2015. The decrease of $590,493 is primarily related to a loss on extinguishment of debt of $719,097, which was recorded in the second quarter of 2015 for the refinancing of an existing loan with a new lender, of which costs are comprised of a write-off of deferred financing costs, end of term fees and prepayment penalties for the repayment of debt to our prior lender, offset by increased interest expense due to an increase of $4,000,000 to our current debt in the second quarter of 2016, which includes debt discounts amortization for our new lender's end of term fees, back end fees, value of warrants issued, facility and financing fees.

Net Loss

Net loss was $10,624,804 for the six months ended June 30, 2016, an increase of $2,339,951 from $8,284,853 for the six months ended June 30, 2015 for the reasons stated above.

Cash Flows

Net Cash Used in Operating Activities

Net cash used in operating activities was $9,972,107 for the six months ended June 30, 2016. The net loss for this period was higher than net cash used in operating activities by $652,697, which was primarily attributable to increased inventories of $763,553 related to collection and purchases of normal source and RSV plasma, an increase in prepaid expenses of $527,032 for vendor payments related to insurance premiums, prepayments to third-party manufacturing vendors for commercial manufacturing of RI-002, an increase in accounts payable of $1,034,093 and a decrease in accrued expenses of $363,884, offset by stock-based compensation of $733,125, and depreciation and amortization of $528,892.

Net cash used in operating activities was $8,667,142 for the six months ended June 30, 2015. The net loss for this period was lower than net cash used in operating activities by $382,289, which was primarily attributable to decreases in accrued expenses of $774,452 related to payments made to vendors and service providers, increased inventories of $744,133 related to allocating additional plasma to inventory in preparation of commercial manufacturing activities anticipated in 2016, offset by stock-based compensation of $773,730 and a loss on extinguishment of debt of $719,097 attributable to the refinancing of previous debt with a new venture debt lender.

Net Cash Used in Investing Activities

Net cash used in investing activities was $4,960,820 for the six months ended June 30, 2016, which was related to the purchase of short-term investments of $4,902,786 and $58,034 in purchases of computers and equipment.

Net cash used in investing activities was $11,299,372 for the six months ended June 30, 2015, which was related to the increase in short-term investments of $11,277,678 and $21,694 in purchases of computers and equipment.

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Net Cash Provided by Financing Activities

Net cash provided by financing activities totaled $17,041,141 for the six months ended June 30, 2016, which primarily consisted of $14,145,000 received from the issuance of common stock during the second quarter of 2016 offset by equity issuance costs of $1,072,259, $4,000,000 received from Oxford during the second quarter of 2016, offset by payment of debt issue costs to Oxford of $24,200 in addition to amortization of our leasehold improvement loan for our ADMA BioCenters subsidiary.

Net cash provided by financing activities totaled $10,589,325 for the six months ended June 30, 2015, which primarily consisted of $16,000,000 received from the loan from Oxford during the second quarter of 2015 and $10,393,383 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 $134,500 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 subsidiary.

Liquidity and Capital Resources

Overview

We have had limited revenue from operations and we have incurred cumulative losses of $98.0 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. During May 2016, we completed an underwritten public offering of our common stock and we received net proceeds of approximately $12.9 million. In May 2016, we amended our LSA with Oxford and borrowed an additional $4.0 million. In March 2015, we received net cash proceeds of approximately $10.2 million from an underwritten public offering from the sale of our common stock. In October 2013, we received net cash proceeds of approximately $26.6 million from our Initial Public Offering, or IPO. In various financings since 2012, we received a total of $20.0 million from venture debt lenders. In February 2012, we received net cash proceeds of approximately $15.3 million from a private placement of our common stock.

As of June 30, 2016, we had working capital of $24.4 million, consisting primarily of $12.5 million of cash and cash equivalents, $11.3 million of short-term investments, $4.2 million of inventories, $0.8 million of accounts receivable, and $0.6 million of prepaid expenses, offset by $3.3 million of accounts payable, $1.6 million of accrued expenses and $0.1 million of deferred revenue. See also “Future Financing Needs” below.

Future Financing Needs

We expect to continue to spend substantial amounts of capital on product development, including commercialization activities, procuring raw material plasma, manufacturing, regulatory, consulting fees in connection with our BLA and the potential approval of RI-002, conducting potential future studies and/or clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. Based upon our projected revenue and expenditures for 2016 and 2017, including the ongoing regulatory activities associated with the BLA for RI-002, implementation of our planned potential commercialization and expansion activities, we currently believe that our cash, cash equivalents, short-term investments and accounts receivable as of the date of this report are sufficient to fund our operations, as currently conducted, into the second half of 2017. This time frame may change based upon our interactions with FDA, potential timing of our commercial manufacturing scale up activities, how aggressively we execute on our regulatory strategy and/or commercial initiatives and when the FDA approves our BLA for RI-002, if at all.

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We cannot predict with certainty that we will not need to raise additional funds in the future or when we will reach profitability, if at all. Furthermore, if our assumptions underlying our estimated expenses, the timing of FDA resubmission or approval for RI-002 and revenues from RI-002 are incorrect, we 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 our product candidate, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures associated with our development activities. Our current estimates may be subject to change as circumstances regarding our business requirements evolve. We may decide to raise capital through public or private equity offerings, such financings may only be available on unattractive terms, resulting in significant dilution of stockholders' interests and, in such event, the value and potential future market price of our common stock may decline, or obtain debt financings, or obtain a bank credit facility or corporate collaboration and licensing arrangements. Other than our option to borrow an additional $5.0 million through our current LSA with Oxford, as amended, based upon receiving BLA approval by the FDA for RI-002 no later than January 31, 2017, 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 or other product candidates. We have reported losses since inception in June 2004 through June 30, 2016 of $98.0 million.

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 flows or cash position.

Recent Accounting Pronouncements

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

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

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

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

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers, which requires that an entity recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to its customers. In order to achieve this core principle, an entity should apply the following steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation. This update will replace existing revenue recognition guidance under 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.

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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 condensed consolidated financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Securities Act Section 7(a)(2)(B), upon issuance of a new or revised accounting standard that applies to our condensed consolidated financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

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

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

Stock-Based Compensation

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

We account for stock options granted to non-employees on a fair value basis using the Black-Scholes option pricing method. The noncash charge to operations for non-employee options with vesting 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.

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For purposes of valuing stock options granted to our employees, non-employees and directors and officers through the three and six months ended June 30, 2016, we used the Black-Scholes option pricing model. We granted options to purchase an aggregate of 15,000 and 100,984 shares of common stock during the three and six months ended June 30, 2016, respectively. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of the grant with a term consistent with the expected term of our awards. The expected term of the options granted is in accordance with Staff Accounting Bulletins 107 and 110, which is based on the average between vesting terms and contractual terms. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. The expected stock price volatility for our stock options was calculated by examining the pro rata historical volatilities for similar publicly traded industry peers and the trading history for our common stock. We will continue to analyze the expected stock price volatility and expected term assumptions. 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, testing, validation and production of RI-002 prior to regulatory approval and the disposition of plasma and equipment for which there is no alternative future use.

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 the Biotest AG 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 the Biotest AG 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 Biotest AG 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 no later than January 31, 2017, which funding would also extend our interest only period for an additional six months pursuant to the May 2016 amendment to the LSA. The LSA bears interest at a rate per annum equal to the greater of (i) 7.80% and (ii) the sum of (a) the three (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. 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 prepay a loan for any reason, we are obligated to pay a prepayment charge corresponding to a percentage of

the principal amount of the loan prepaid, with such percentage being: 3.0% if prepayment occurs through the first anniversary of its funding, 2.0% if prepayment occurs after the first anniversary through the second anniversary of the applicable funding date, and 1.0% if prepayment occurs after the second anniversary of its funding date and prior to its maturity date. 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).

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In connection with the LSA, on June 19, 2015, we issued to Oxford a seven-year warrant, expiring on June 19, 2022, to purchase 74,309 shares of common stock at an exercise price of $8.51 per share. We recorded $367,700 as the fair value of the warrant to additional paid-in capital and as a debt discount to the carrying value of the loan. The key assumptions used to value the warrants included, 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 seven 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 May 2016, we entered into an amendment to our LSA with Oxford, pursuant to which we borrowed an additional $4.0 million, as an extension to the original LSA entered into on June 19, 2015, which brings the total principal borrowed to $20.0 million. In connection therewith, we issued warrants to purchase an aggregate of up to 24,800 shares of our common stock at an exercise price equal to $6.37, which will expire seven years after their issuance on May 13, 2023, and incurred facility fees of $20,000 as part of accessing the additional financing.

In connection with our Prior Loan Agreement and as amended, we issued to Hercules a warrant to purchase 31,750 shares of common stock in December 2012, with an exercise price of $7.56 and in connection with the Prior Loan Agreement and as amended, 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 Agreement and as amended, 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 warrants associated with the Prior Loan Agreement were 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 warrant 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.

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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 $2.8 million through the end of the lease terms.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We designed our disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, to provide reasonable assurance that information required to be disclosed by us in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange 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 six months ended June 30, 2016, 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 June 30, 2016.

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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 1A. Additional Risk Factors

In addition to the risks, uncertainties and other factors set forth below and elsewhere in this Form 10-Q, see the “Risk Factors” section contained in our Annual Report on Form 10-K for the year ended December 31, 2015.

Our pending BLA for RI-002, our primary product candidate which is intended for the treatment of PIDD, may not be approved by the FDA in a timely manner, or at all, which could delay or would prevent our commercializing this product candidate in the United States and have a material adverse impact on our business.

Receipt of the CRL in July 2016 has delayed the FDA’s approval of our BLA for RI-002 for the treatment of PIDD. In its letter, the FDA focused on, among other things, outstanding inspection issues and deficiencies at our third-party vendors, including our contract drug substance and product manufacturer, our contract fill and finish provider and compliance issues with a third-party contract testing laboratory, and requested documentation of corrections for a number of those issues. The FDA indicated that it cannot grant final approval of the BLA until, among other things, these deficiencies are resolved. We have been informed by our manufacturers/vendors that they are working to resolve the outstanding inspection issues. While we will work diligently with our third-party manufacturers/vendors to monitor their efforts in addressing and resolving outstanding issues relating to the observations, we have no control over these third-party vendors, and cannot guarantee the timing of when or whether they will ultimately resolve such identified deficiencies, if at all. If these deficiencies are not resolved by our third party vendors to the satisfaction of the FDA, our BLA may never be approved. If our BLA is not approved by the FDA or if there are further unanticipated delays in the FDA’s review process, our ability to commercialize our product candidate could be delayed or may not occur at all and our ability to continue operations may be impaired.

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A revised BLA submission that satisfies the inspection issues and deficiencies identified in the CRL does not guarantee the approval of RI-002 or the ability to obtain acceptable labeling.

Even if the outstanding inspection issues and deficiencies identified in the CRL are resolved to the satisfaction of the FDA, the agency retains the right not to approve the BLA or to require additional information, or to raise additional issues to support regulatory approval of RI-002, which could further delay or prevent its approval. Furthermore, the FDA has indicated that product labeling for RI-002 has not yet been finalized, which requires further negotiations before the label can be agreed upon. If we are unable to obtain FDA approval for RI-002, or reach an agreement with the FDA regarding the labeling and/or packaging for RI-002, our ability to market, sell, distribute, obtain acceptable reimbursement for, set pricing for, and continue to operate, commercialize or continue the development of RI-002 or any other potential product candidate may be delayed or could be adversely affected.

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.

Amended and Restated Agreement for Services

On August 12, 2016, ADMA Biologics, Inc. ("ADMA" or the "Company") entered into an Amended and Restated Agreement for Services (the "A&R Services Agreement") with Areth LLC. The agreement contains substantially similar terms to the Agreement for Services, dated July 23, 2007, between ADMA and Areth LLC. The scope of the A&R Services Agreement generally covers the provision by Areth LLC of warehousing and distribution/shipping services, office space, shipping, handling, receiving, inventory control, clinical trial drug management and drug sample storage, as well as certain information technology, telephone, mail and other general and administrative services. Areth LLC is a company controlled by Dr. Jerrold B. Grossman, our Vice Chairman. Fees under the A&R Services Agreement are $16,000 per month.

The foregoing description of the A&R Services Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the A&R Services Agreement, a copy of which is filed as Exhibit 10.18 hereto and is incorporated herein by reference.

Item 6. Exhibits.

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

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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: August 12, 2016	By:	/s/ Adam S. Grossman	
		Name:	Adam S. Grossman
		Title:	President and Chief Executive Officer
Date: August 12, 2016	By:	/s/ Brian Lenz	
		Name:	Brian Lenz
		Title:	Chief Financial Officer

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EXHIBIT INDEX

Exhibit Number	Description
10.18	Amended and Restated Agreement for Shared Services Agreement, between ADMA Biologics, Inc. and Areth LLC.
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 June 30, 2016, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets as of June 30, 2016 and December 31, 2015, (ii) Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2016 and 2015, (iii) Condensed Consolidated Statement of Changes in Stockholders' Equity for the six months ended June 30, 2016, (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2016 and 2015, and (v) Notes to Unaudited Condensed Consolidated Financial Statements.