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

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 September 30, 2017

OR

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

For the transition period from _____ to _____

Commission file number 001-36728

ADMA BIOLOGICS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company ý
(Do not check if a smaller reporting company)	Emerging growth company ý

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

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

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

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This quarterly report on Form 10-Q includes our trademarks, trade names and service marks, such as "Nabi-HB®" and "Bivigam®" which are protected under applicable intellectual property laws and are the property of ADMA Biologics, Inc., or its subsidiaries. Solely for convenience, trademarks, trade names and service marks referred to in this report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks.

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Special Note Regarding Forward-Looking Statements

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

- our ability to successfully leverage the anticipated benefits and synergies of our recent acquisition of certain assets from Biotest Pharmaceuticals Corporation ("BPC") , including optimization of the combined businesses, operations and products and services, as well as the nature, strategy and focus of the combined company and the management and governance structure of the combined company;

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

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

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

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

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

- our dependence upon our third-party and related party customers and vendors and their compliance with regulatory bodies;

- our ability to obtain adequate quantities of FDA-approved plasma with proper specifications;

- our plans to increase our supplies of plasma;

- the potential indications for our product candidates;

- potential investigational new product applications;

- the acceptability of any of our products as well as RI-002 for any purpose by physicians, patients or payers;

- concurrence by the FDA with our conclusions and the satisfaction by us of its guidance;

- the comparability of results of our immune globulin products to other comparably run intravenous immunoglobulin ("IVIG") clinical trials;

- the potential of RI-002 and Bivigam to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease ("PIDD");

- our ability to market and promote Nabi-HB in the competitive environment and to generate meaningful revenues;

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

These statements may be found under the “Risk Factors“ and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this quarterly report on Form 10-Q. Forward-looking statements typically are identified by the use of terms such as “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “should,” or “will” or the negative thereof or other variations thereof or comparable terminology. You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to the factors referenced above. Any forward-looking statement included or incorporated by reference in this quarterly report on Form 10-Q reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions related to our operations, results of operations, industry and future growth. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements speak only as of the dates such statements are made.

In addition to the foregoing, you should also consider carefully the statements under the section entitled “Risk Factors” and other sections of this quarterly report on Form 10-Q, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements. Any forward-looking statements that we make in this quarterly report on Form 10-Q speak only as of the date of such statements and we undertake no obligation to publicly update any forward-looking statements or to publicly announce revisions to any of the forward-looking statements, whether as a result of new information, future events or otherwise.

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PART I
FINANCIAL INFORMATION

Item 1. Financial Statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2017 (Unaudited)	December 31, 2016 (Note 2)
ASSETS		
Current assets:		
Cash and cash equivalents	$13,601,391	$9,914,867
Short-term investments	—	5,390,184
Accounts receivable, net	1,499,809	1,018,027
Inventories	13,418,971	5,020,146
Prepaid expenses and other current assets	2,078,509	313,914
Assets held for sale	845,389	—
Total current assets	31,444,069	21,657,138
Property and equipment, net	29,755,541	2,000,784
Intangible assets, net	5,737,175	—
Goodwill	3,529,509	—
Assets to be transferred under purchase agreement	1,596,493	—
Deposits and other assets	750,693	27,163
TOTAL ASSETS	$72,813,480	$23,685,085
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$9,156,341	$2,564,681
Accrued expenses	3,860,121	2,385,356
Current portion of notes payable	—	6,111,111
Current portion of deferred revenue	145,154	145,154
Other current liabilities	177,250	16,559
Total current liabilities	13,338,866	11,222,861
Notes payable, net of discount	14,534,340	12,321,640
End of term liability, notes payable	1,790,000	1,790,000
Deferred revenue, net of current portion	2,582,908	2,690,033
Note payable - related party, net of discount	14,834,696	—
Obligation to transfer assets under purchase agreement	12,621,844	—
Other non-current liabilities	118,318	117,813
TOTAL LIABILITIES	59,820,972	28,142,347

COMMITMENTS AND CONTINGENCIES	—	—
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred Stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common Stock - voting, $0.0001 par value, 75,000,000 shares authorized, 17,202,244 and 12,886,741 shares issued and outstanding	1,722	1,289
Common Stock - non-voting, $0.0001 par value, 8,591,160 shares authorized, 8,591,160 and 0 shares issued and outstanding	859	—
Additional Paid-In Capital	150,700,918	102,476,267
Accumulated Deficit	(137,710,991)	(106,934,818)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	12,992,508	(4,457,262)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$72,813,480	$23,685,085

See notes to (unaudited) condensed consolidated financial statements.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

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

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 (DEFICIT)
(Unaudited)

For the Nine Months Ended September 30, 2017

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

See notes to (unaudited) condensed consolidated financial statements.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(30,776,173)	$(14,956,043)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,231,265	351,702