

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 10, 2018

**ADMA BIOLOGICS, INC.**

(Exact name of registrant as specified in its charter)

Delaware

001-36728

56-2590442

(State or other jurisdiction  
of incorporation)

(Commission  
File Number)

(IRS Employer  
Identification No.)

465 State Route 17, Ramsey, New Jersey

07446

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: (201) 478-5552

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

**Item 2.02. Results of Operations and Financial Condition.**

On August 10, 2018, ADMA Biologics, Inc. issued a press release announcing its financial results for the three and six months ended June 30, 2018. A copy of the press release is furnished herewith as Exhibit 99.1.\*

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">ADMA Biologics, Inc. Press Release, dated August 10, 2018.</a>

\* The information in Item 2.02 of this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

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SIGNATURE

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

August 10, 2018

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer



## **ADMA Biologics Reports Second Quarter 2018 Financial Results**

### *Key Regulatory & Manufacturing Milestones Achieved*

RAMSEY, N.J. and BOCA RATON, FL., – August 10, 2018 – ADMA Biologics, Inc. (NASDAQ: ADMA) (“ADMA” or the “Company”) today announced its financial results for the quarter ended June 30, 2018 and provided an update on its operations and corporate objectives.

“During the quarter we strengthened our balance sheet by completing a \$46 million financing with well-known healthcare institutions and insider participation. This financing, coupled with our previously existing cash balance, provides funding for ADMA through several key regulatory and commercial milestones. We are pleased with our quarter-over-quarter revenue growth attributed to the commercial assets that we received as part of the Biotest Therapy Business Unit (“BTBU”) transaction in June 2017,” stated Adam Grossman, President and Chief Executive Officer of ADMA.

“Since announcing the successful close-out of our April 2018 U.S. Food and Drug Administration (“FDA”) compliance inspection, we are now preparing for the resubmission of our Biologics License Application (“BLA”) for RI-002 in the near term. During the first half of 2018, we achieved an important corporate objective of submitting our Prior Approval Supplement (“PAS”) for BIVIGAM®, which is currently under review by the FDA, with a target action date of October 25, 2018 under the Prescription Drug User Fee Act (“PDUFA”). We look forward to what the second half of 2018 can bring to ADMA and its stockholders with several meaningful value-creating regulatory and commercial milestones anticipated, as well as the potential FDA approval of our third plasma center by year-end,” concluded Mr. Grossman.

### **2018 & 2019 Anticipated Goals and Milestones**

- Respond to Complete Response Letter and Resubmit BLA for RI-002
  - BIVIGAM® PDUFA target action date; October 25, 2018 followed by resumption of commercial sales upon positive regulatory outcome
  - Obtain FDA approval for 3<sup>rd</sup> plasma collection center
  - RI-002 PDUFA with initial commercial sales
  - Commercial and promotional launch for RI-002
  - Expand promotional activities for Nabi-HB®
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### **Financial Results for the Three Months Ended June 30, 2018**

ADMA reported total revenues of \$4.7 million for the quarter ended June 30, 2018, as compared to \$3.4 million for the quarter ended June 30, 2017, representing an increase of \$1.3 million, or approximately 37%. The increase in revenues was primarily due to the accretive nature of assets and commercial product rights acquired in the BTBU transaction, which was completed in June 2017.

The consolidated net loss for the quarter ended June 30, 2018 was \$14.7 million, or \$(0.35) per basic and diluted share, as compared to a consolidated net loss of \$9.0 million, or \$(0.55) per basic and diluted share, for the quarter ended June 30, 2017. The increase in net loss of \$5.7 million was primarily attributable to increased cost of product revenue of \$5.3 million, which reflected an increase in unabsorbed manufacturing costs at our plasma fractionation facility acquired in the BTBU transaction (the "Boca Facility"), and an increase in cost of product revenue related to the sales and production of Nabi-HB®, among other product revenue related costs. Other costs attributable to the increased net loss include higher employee related costs of approximately \$1.5 million as part of the BTBU transaction, an increase in interest expense of \$0.7 million and an increase in insurance expense of \$0.4 million, partially offset by \$1.2 million of non-recurring BTBU transaction costs in 2017 and the increase in revenues in 2018. Included in the net loss for the quarter ended June 30, 2018 were non-cash expenses of approximately \$1.6 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

### **Financial Results for the Six Months Ended June 30, 2018**

ADMA reported total revenues of \$8.7 million for the six months ended June 30, 2018, as compared to \$6.0 million for the six months ended June 30, 2017, representing an increase of \$2.7 million, or approximately 44%. The increase in revenues was attributable to the assets acquired in the BTBU transaction, partially offset by lower revenues from our ADMA BioCenters plasma collection business segment due to increased competition from other plasma centers.

The consolidated net loss for the six months ended June 30, 2018 was \$32.6 million, or \$(0.74) per basic and diluted share, as compared to a consolidated net loss of \$15.6 million, or \$(1.06) per basic and diluted share, for the six months ended June 30, 2017. The increase in net loss of \$17.0 million was primarily attributable to increased product revenue costs of \$15.9 million, primarily comprised of an increase in unabsorbed manufacturing costs at the Boca Facility and conformance lot production of RI-002 and BIVIGAM®, among other product revenue related costs. Other costs attributable to the increased net loss include higher employee related costs of approximately \$3.2 million as part of the BTBU transaction, increases in other expenses associated with the Boca Facility of \$1.8 million and an increase in interest expense of \$1.4 million, partially offset by \$3.8 million of non-recurring BTBU transaction costs in 2017 and the increase in revenues in 2018. Included in the net loss for the quarter ended June 30, 2018 were non-cash expenses of \$3.2 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

At June 30, 2018, ADMA had cash and cash equivalents of \$55.2 million, as compared to \$43.1 million at December 31, 2017. ADMA's net working capital as of June 30, 2018 was \$66.7 million, as compared to \$53.7 million as of December 31, 2017. In the second quarter of 2018, the Company completed an underwritten public offering of its common stock and received net proceeds of \$42.9 million.

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## **About ADMA Biologics, Inc. (ADMA)**

ADMA Biologics is a vertically integrated commercial biopharmaceutical company that manufactures, markets and develops specialty plasma-based biologics for the treatment of Primary Immune Deficiency Disease (“PIDD”) and the prevention and treatment of certain infectious diseases. ADMA's mission is to develop and commercialize plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases. The target patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disease, or who may be immune-compromised for other medical reasons. ADMA has received U.S. Patents 9,107,906, 9,714,283, 9,815,886 and 9,969,793 related to certain aspects of its lead product candidate, RI-002. For more information, please visit [www.admabiologics.com](http://www.admabiologics.com).

## **About BIVIGAM®**

BIVIGAM® is an intravenous immune globulin indicated for the treatment of primary humoral immunodeficiency. This includes, but is not limited to, agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These primary immunodeficiencies (“PI”) are a group of genetic disorders. Initially thought to be very rare, it is now believed that as many as 250,000 people in the U.S. have some form of PI. BIVIGAM® contains a broad range of antibodies similar to those found in normal human plasma. These antibodies are directed against bacteria and viruses, and help to protect PIDD patients against serious infections. BIVIGAM® is a purified, sterile, ready-to-use preparation of concentrated polyclonal Immunoglobulin (“IgG”) antibodies. Antibodies are proteins in the human immune system that work to defend against infections and disease. FDA approval for BIVIGAM® was received by Biotest Pharmaceuticals Corporation (“BPC” or “Biotest”) on December 19, 2012, and production of BIVIGAM® was halted by Biotest in December 2016. ADMA Biologics obtained ownership and all rights, title and interest in BIVIGAM® on June 6, 2017 as part of the Biotest Therapy Business Unit (“BTBU”) asset acquisition. ADMA optimized the production process for BIVIGAM® and submitted a Prior Approval Supplement (“PAS”) to the United States Food and Drug Administration (“FDA”) to amend the Biologics License Application (“BLA”) for BIVIGAM® in June of 2018, with a target action date of October 25, 2018 under the Prescription Drug User Fee Act (“PDUFA”). If the PAS is approved by the FDA, ADMA expects to be able to relaunch the product for commercial sale by the end of the first quarter of 2019.

## **About RI-002**

ADMA's lead portfolio product candidate, RI-002, which has demonstrated positive Phase III pivotal clinical trial data, is a specialty plasma-derived, polyclonal, intravenous immune globulin (“IVIG”) derived from human plasma containing naturally occurring polyclonal antibodies (e.g., Streptococcus pneumoniae, H. influenza type B, cytomegalovirus (“CMV”), measles, tetanus, etc.) as well as plasma from donors tested to have high levels of neutralizing antibodies to respiratory syncytial virus (“RSV”). ADMA is pursuing an indication for the use of this specialty IVIG product for treatment of patients diagnosed with PIDD. Polyclonal antibodies are the primary active component of IVIG products. Polyclonal antibodies are proteins that are used by the body's immune system to neutralize microbes, such as bacteria and viruses and prevent against infection and disease. Data review which has been published in peer reviewed journals indicates that the polyclonal antibodies present in RI-002 support its ability to prevent infections in immune-compromised patients. This data and other information about RI-002 or ADMA Biologics products can be found on the Company website at: [www.admabiologics.com/therapies](http://www.admabiologics.com/therapies) and [www.admabiologics.com](http://www.admabiologics.com). RI-002 is protected by U.S. Patents: 9,107,906, 9,714,283, 9,815,886 and 9,969,793, the latter of which affords the Company patent exclusivity for the use of an immune globulin as a prevention and/or treatment for any type of respiratory infection.

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## Cautionary Note Regarding Forward-Looking Statements

*This press release contains "forward-looking statements" pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about ADMA Biologics, Inc. ("we", "our" or the "Company"). Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain the words "estimate," "project," "intend," "forecast," "target," "anticipate," "plan," "planning," "expect," "believe," "will," "is likely," "will likely," "should," "could," "would," "may," or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements also include, but are not limited to, statements concerning our plans to develop, manufacture, market, launch and expand our own commercial infrastructure and commercialize our current products and future products, the safety, efficacy and expected timing of, and our ability to, obtain and maintain regulatory approvals of our current products and product candidates, and the labeling or nature of any such approvals, the success of our work with our third party vendors and the U.S. Food and Drug Administration (the "FDA") in furtherance of and progress towards an approval of our Biologics License Application for specialty plasma-based biologics and the ability of such third parties to respond adequately or in a timely manner to the issues raised by the FDA, our ability to successfully pursue commercialization and prelaunch activities, the timeframe within which we may receive approval from the FDA for specialty plasma-based biologics, if at all, the potential of our specialty plasma-based biologics to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease or other indications, our ability to realize increased prices for plasma growth in the plasma collection industry and our expectations for future capital requirements. Actual events or results may differ materially from those described in this document due to a number of important factors. Current and prospective security holders are cautioned that there also can be no assurance that the forward-looking statements included in this press release will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by ADMA or any other person that the objectives and plans of ADMA will be achieved in any specified time frame, if at all. Except to the extent required by applicable laws or rules, ADMA does not undertake any obligation to update any forward-looking statements or to announce revisions to any of the forward-looking statements. Forward-looking statements are subject to many risks, uncertainties and other factors that could cause our actual results, and the timing of certain events, to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, the risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Form 10-K, 10-Q and 8-K, and any amendments thereto.*

### COMPANY CONTACT:

Brian Lenz

Executive Vice President and Chief Financial Officer | 201-478-5552 | [www.admabiologics.com](http://www.admabiologics.com)

### INVESTOR RELATIONS CONTACT:

Jeremy Feffer

Managing Director, LifeSci Advisors, LLC | 212-915-2568 |

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**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**Three and Six Months Ended June 30, 2018 and 2017**

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
<b>REVENUES:</b>				
Product revenue	\$ 4,620,841	\$ 3,363,692	\$ 8,627,139	\$ 5,956,855
License and other revenue	35,709	35,709	71,417	71,417
<b>Total Revenues</b>	<u>4,656,550</u>	<u>3,399,401</u>	<u>8,698,556</u>	<u>6,028,272</u>
<b>OPERATING EXPENSES:</b>				
Cost of product revenue (exclusive of amortization expense shown below)	9,645,662	4,334,019	21,888,410	5,950,306
Research and development	1,472,100	1,358,409	2,753,806	2,551,136
Plasma center operating expenses	1,738,128	1,600,170	3,571,902	3,079,646
Amortization of intangibles	211,234	73,021	422,469	73,021
Selling, general and administrative	5,006,807	4,435,650	10,011,853	8,713,034
<b>TOTAL OPERATING EXPENSES</b>	<u>18,073,931</u>	<u>11,801,269</u>	<u>38,648,440</u>	<u>20,367,143</u>
<b>LOSS FROM OPERATIONS</b>	<u>(13,417,381)</u>	<u>(8,401,868)</u>	<u>(29,949,884)</u>	<u>(14,338,871)</u>
<b>OTHER INCOME (EXPENSE):</b>				
Interest income	33,070	7,858	59,616	26,426
Interest expense	(1,359,188)	(642,485)	(2,682,340)	(1,261,013)
Other (expense) income	(4,332)	—	2,635	—
<b>OTHER EXPENSE, NET</b>	<u>(1,330,450)</u>	<u>(634,627)</u>	<u>(2,620,089)</u>	<u>(1,234,587)</u>
<b>NET LOSS</b>	<u>\$ (14,747,831)</u>	<u>\$ (9,036,495)</u>	<u>\$ (32,569,973)</u>	<u>\$ (15,573,458)</u>
<b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>	<u>\$ (0.35)</u>	<u>\$ (0.55)</u>	<u>\$ (0.74)</u>	<u>\$ (1.06)</u>
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:</b>				
Basic and Diluted	<u>42,712,168</u>	<u>16,427,054</u>	<u>44,007,409</u>	<u>14,666,677</u>



**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED BALANCE SHEETS:**

	<b>June 30, 2018</b>	<b>December 31, 2017</b>
	(Unaudited)	(Note 2)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 55,153,975	\$ 43,107,574
Accounts receivable, net	3,797,194	3,880,154
Inventories	12,246,968	12,628,181
Prepaid expenses and other current assets	2,431,366	2,050,740
Restricted cash	—	1,500,000
Total current assets	73,629,503	63,166,649
Property and equipment, net	30,337,285	30,466,858
Intangible assets, net	4,426,881	4,849,350
Goodwill	3,529,509	3,529,509
Assets to be transferred under purchase agreement	1,295,392	1,496,410
Restricted cash	4,000,000	4,000,000
Deposits and other assets	533,422	510,057
<b>TOTAL ASSETS</b>	<b>\$ 117,751,992</b>	<b>\$ 108,018,833</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,101,079	\$ 5,920,873
Accrued expenses and other current liabilities	3,644,181	3,376,476
Current portion of deferred revenue	142,834	142,834
Current portion of capital lease obligation	28,992	—
Total current liabilities	6,917,086	9,440,183
Notes payable, net of discount	25,878,081	25,368,458
End of term liability, notes payable	2,760,000	2,760,000
Deferred revenue, net of current portion	2,475,782	2,547,199
Note payable - related party, net of discount	14,857,908	14,842,396
Obligation to transfer assets under purchase agreement	12,621,844	12,621,844
Capital lease obligation	134,323	—
Other non-current liabilities	347,898	105,996
<b>TOTAL LIABILITIES</b>	<b>65,992,922</b>	<b>67,686,076</b>
<b>COMMITMENTS AND CONTINGENCIES</b>	—	—
<b>STOCKHOLDERS' EQUITY</b>		
Preferred Stock, \$0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common Stock - voting, \$0.0001 par value, 75,000,000 shares authorized, 46,349,514 and 36,725,499 shares issued and outstanding	4,635	3,673
Common Stock - non-voting, \$0.0001 par value, 8,591,160 shares authorized, 0 and 8,591,160 shares issued and outstanding	—	859
Additional Paid-In Capital	235,018,201	191,022,018
Accumulated Deficit	(183,263,766)	(150,693,793)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>51,759,070</b>	<b>40,332,757</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 117,751,992</b>	<b>\$ 108,018,833</b>