

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): November 8, 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 November 8, 2018, ADMA Biologics, Inc. issued a press release announcing its financial results for the three and nine months ended September 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	<u>ADMA Biologics, Inc. Press Release, dated November 8, 2018.</u>

* 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.

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.

November 8, 2018

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief
Financial Officer



ADMA Biologics Reports Third Quarter 2018 Financial Results

RAMSEY, N.J. and BOCA RATON, FL., – November 8, 2018 – ADMA Biologics, Inc. (NASDAQ: ADMA) (“ADMA” or the “Company”), a vertically integrated commercial biopharmaceutical company that develops, manufactures and markets specialty plasma-based biologics for the treatment of Primary Immune Deficiency Disease (“PIDD”) and the prevention and treatment of certain infectious diseases, today announced its financial results for the quarter and nine months ended September 30, 2018 and provided an update on its operations and upcoming milestones.

“We have made substantial progress executing on our key initiatives throughout 2018. Most importantly, we improved the U.S. Food and Drug Administration (“FDA”) compliance status for our manufacturing facility in Boca Raton, Florida, which allowed us to submit applications for approval for the relaunch of BIVIGAM® and the approval and launch of RI-002,” stated Adam Grossman, President and Chief Executive Officer of ADMA. “We have two upcoming Prescription Drug User Fee Act (“PDUFA”) dates for these products: BIVIGAM® on December 18, 2018 and RI-002 on April 2, 2019.”

“We were also pleased to obtain FDA approval for our third plasma collection center, which was announced during the third quarter and occurred ahead of expectations. We look forward to the coming months as we continue working with the FDA and commercialize our intravenous immune globulin products, which are expected to grow our top line in 2019,” concluded Mr. Grossman.

Recent Achievements and Upcoming Milestones

- PDUFA target action date of December 18, 2018 for BIVIGAM®
 - PDUFA target action date of April 2, 2019 for RI-002
 - Boca facility compliance status improved to Voluntary Action Indicated
 - Obtained FDA approval for 3rd plasma collection center
 - Increased revenues by approximately 20% for the nine months ended September 30, 2018 as compared to the same period in 2017
 - Continue to produce, release and market commercial product for Nabi-HB® in the U.S.
 - Expand promotional activities for Nabi-HB®
-

Financial Results for the Three Months Ended September 30, 2018

ADMA reported total revenues of \$4.2 million for the quarter ended September 30, 2018, as compared to \$4.7 million for the quarter ended September 30, 2017, representing a decrease of \$0.5 million. The decrease in revenues was primarily due to the timing of shipments of normal source plasma to certain customers in accordance with their agreements from our ADMA Bio Centers plasma collection business segment, partially offset by an increase in revenues from commercial product produced at our plasma manufacturing facility (the "Boca Facility").

The consolidated net loss for the quarter ended September 30, 2018 was \$15.1 million, or \$(0.33) per basic and diluted share, as compared to a consolidated net loss of \$15.2 million, or \$(0.59) per basic and diluted share, for the quarter ended September 30, 2017. The net loss in 2018 includes approximately \$7.0 million in unabsorbed manufacturing costs at the Boca Facility and non-cash expenses of \$1.7 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

Financial Results for the Nine Months Ended September 30, 2018

ADMA reported total revenues of \$12.9 million for the nine months ended September 30, 2018, as compared to \$10.8 million for the nine months ended September 30, 2017, representing an increase of \$2.1 million, or approximately 20%. The increase in revenues was attributable to the sales of our FDA licensed product Nabi-HB®, which was acquired in June 2017, partially offset by lower revenues from our ADMA Bio Centers business segment due to the timing of shipments of normal source plasma to certain customers in accordance with their agreements along with increased competition from other local plasma donation centers which have opened in close proximity to our more established centers.

The consolidated net loss for the nine months ended September 30, 2018 was \$47.7 million, or \$(1.06) per basic and diluted share, as compared to a consolidated net loss of \$30.8 million, or \$(1.67) per basic and diluted share, for the nine months ended September 30, 2017. The increase in net loss of \$16.9 million was primarily attributable to increased product revenue costs of \$13.8 million, which reflects a full nine months of operations at the Boca Facility as compared to four months of operating activity at the Boca Facility in 2017, as well as conformance lot production of RI-002 and BIVIGAM®, which can be used for commercial sales upon FDA approval, as well as higher selling, general and administrative expenses attributed to increased headcount along with initiating marketing and commercial activities, partially offset by higher revenues. Included in the net loss for the nine months ended September 30, 2018 were non-cash expenses of \$5.0 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

At September 30, 2018, ADMA had cash and cash equivalents of \$42.4 million, as compared to \$43.1 million at December 31, 2017. ADMA's net working capital as of September 30, 2018 was \$52.6 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.

About ADMA Biologics, Inc. (ADMA)

ADMA 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, including 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.

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 December 18, 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 during the first half 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 polyclonal 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. In September 2018, ADMA resubmitted its BLA for RI-002 and in October 2018 the FDA provided a target action date under PDUFA of April 2, 2019. If the BLA is approved by the FDA, ADMA anticipates the commercial launch of RI-002 to occur during the second half of 2019. This data and other information about RI-002 or ADMA Biologics products can be found on the Company website at: 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.

About Primary Immune Deficiency Disease (PIDD)

PIDD is a class of inherited genetic disorders that causes an individual to have a deficient or absent immune system. According to the World Health Organization, there are approximately 350 different genetic mutations encompassing PIDD. Some disorders present at birth or in early childhood, the disorders can affect anyone regardless of age or gender. Some affect a single part of the immune system, others may affect one or more components of the system. PIDD patients are vulnerable to infections and more likely to suffer complications from these infections as compared to individuals with a normal functioning immune system. The infections may occur in any part of the body. As patients suffering from PIDD lack a properly functioning immune system, they typically receive monthly treatment with polyclonal immune globulin products. Without this exogenous antibody replacement, these patients would remain vulnerable to persistent and chronic infections. PIDD has an estimated prevalence of 1:1,200 in the United States, or approximately 250,000 people in the U.S.

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

INVESTOR RELATIONS CONTACT:

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Three and Nine Months Ended September 30, 2018 and 2017

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
REVENUES:				
Product revenue	\$ 4,194,602	\$ 4,693,703	\$ 12,821,741	\$ 10,650,558
License and other revenue	35,708	35,708	107,125	107,125
Total Revenues	<u>4,230,310</u>	<u>4,729,411</u>	<u>12,928,866</u>	<u>10,757,683</u>
OPERATING EXPENSES:				
Cost of product revenue (exclusive of amortization expense shown below)	9,164,109	11,291,116	31,052,519	17,241,422
Research and development	1,317,234	1,814,069	4,071,040	4,365,205
Plasma center operating expenses	1,973,338	1,582,694	5,545,240	4,662,340
Amortization of intangibles	211,235	273,828	633,704	346,849
Selling, general and administrative	5,355,794	4,195,464	15,367,647	12,908,498
TOTAL OPERATING EXPENSES	<u>18,021,710</u>	<u>19,157,171</u>	<u>56,670,150</u>	<u>39,524,314</u>
LOSS FROM OPERATIONS	<u>(13,791,400)</u>	<u>(14,427,760)</u>	<u>(43,741,284)</u>	<u>(28,766,631)</u>
OTHER INCOME (EXPENSE):				
Interest income	75,581	8,014	135,197	34,440
Interest expense	(1,402,475)	(782,969)	(4,084,815)	(2,043,982)
Other expense	(17,191)	—	(14,556)	—
OTHER EXPENSE, NET	<u>(1,344,085)</u>	<u>(774,955)</u>	<u>(3,964,174)</u>	<u>(2,009,542)</u>
NET LOSS	<u>\$ (15,135,485)</u>	<u>\$ (15,202,715)</u>	<u>\$ (47,705,458)</u>	<u>\$ (30,776,173)</u>
BASIC AND DILUTED LOSS PER COMMON SHARE	<u>\$ (0.33)</u>	<u>\$ (0.59)</u>	<u>\$ (1.06)</u>	<u>\$ (1.67)</u>
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic and Diluted	<u>46,350,392</u>	<u>25,790,805</u>	<u>44,796,986</u>	<u>18,415,468</u>

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

	September 30, 2018	December 31, 2017
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 42,367,489	\$ 43,107,574
Accounts receivable, net	4,126,794	3,880,154
Inventories	13,877,434	12,628,181
Prepaid expenses and other current assets	2,131,035	2,050,740
Restricted cash	—	1,500,000
Total current assets	62,502,752	63,166,649
Property and equipment, net	30,362,629	30,466,858
Intangible assets, net	4,215,646	4,849,350
Goodwill	3,529,509	3,529,509
Assets to be transferred under purchase agreement	1,204,391	1,496,410
Restricted cash	4,000,000	4,000,000
Deposits and other assets	530,173	510,057
TOTAL ASSETS	\$ 106,345,100	\$ 108,018,833
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,267,683	\$ 5,920,873
Accrued expenses and other current liabilities	4,453,027	3,376,476
Current portion of deferred revenue	142,834	142,834
Current portion of capital lease obligation	29,443	—
Total current liabilities	9,892,987	9,440,183
Notes payable, net of discount	26,153,543	25,368,458
End of term liability, notes payable	2,760,000	2,760,000
Deferred revenue, net of current portion	2,440,074	2,547,199
Note payable - related party, net of discount	14,865,981	14,842,396
Obligation to transfer assets under purchase agreement	12,621,844	12,621,844
Capital lease obligation	126,765	—
Other non-current liabilities	277,692	105,996
TOTAL LIABILITIES	69,138,886	67,686,076
COMMITMENTS AND CONTINGENCIES	—	—
STOCKHOLDERS' EQUITY		
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, 46,351,243 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	235,600,830	191,022,018
Accumulated Deficit	(198,399,251)	(150,693,793)
TOTAL STOCKHOLDERS' EQUITY	37,206,214	40,332,757
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 106,345,100	\$ 108,018,833