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): March 13, 2019

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 March 13, 2019, ADMA Biologics, Inc. issued a press release announcing its financial results for the year ended December 31, 2018 and provided an update on its operations and upcoming milestones. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	ADMA Biologics, Inc. Press Release, dated March 13, 2019.

* 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.

March 13, 2019

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

ADMA Biologics Reports Full Year 2018 Financial Results

RAMSEY, N.J. and BOCA RATON, FL., – March 13, 2019 – ADMA Biologics, Inc. (NASDAQ: ADMA) ("ADMA" or the "Company"), a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-derived biologics for the treatment of immune deficiencies and the prevention and treatment of certain infectious diseases, today announced its financial results for the year ended December 31, 2018, and provided an update on its operations and upcoming milestones.

"During 2018, we achieved several key objectives, most notably the improvement of our Boca Raton, FL manufacturing facility's FDA compliance status to Voluntary Action Indicated ("VAI"). This improved VAI classification has afforded us the opportunity to submit regulatory applications to the U.S. Food and Drug Administration (the "FDA") for potential approval of new drug product candidates," stated Adam Grossman, President and Chief Executive Officer of ADMA.

"As part of our compliance enhancement upgrades to our Boca Raton, FL facility, we optimized the intravenous immunoglobulin ("IVIG") manufacturing process for BIVIGAM®. We continue to work with the FDA to finalize our BIVIGAM Prior Approval Supplement ("PAS") for drug substance, with the goal of reintroducing BIVIGAM® to the market this year. We are also working closely with the FDA on the pending application for RI-002's initial approval, and the FDA action date is scheduled for April 2, 2019," continued Mr. Grossman.

"Other notable accomplishments include: retiring approximately 8.6 million shares of our non-voting common stock from Biotest Pharmaceuticals Corporation, receiving FDA approval of our plasma collection center in Kennesaw, GA, obtaining FDA approval for the BIVIGAM® drug product PAS and completing a debt refinancing of up to $72.5 million with Perceptive Advisors."

Mr. Grossman concluded, "We look forward to continuing to work with the FDA during 2019 as we seek FDA approval for the pending applications for both RI-002 and BIVIGAM®. FDA approval for RI-002 and BIVIGAM®, if received, along with Nabi-HB®, our presently commercially available hyperimmune globulin, would give us three commercial immune globulin products and would make ADMA one of the few globally recognized plasma manufacturers offering a portfolio of novel immune globulin products."

Recent Achievements and Upcoming Milestones

- Improved compliance status for the Boca Raton, FL facility to VAI, enabling ADMA to submit regulatory applications for FDA review and potential approval
- Obtained FDA approval for our Kennesaw, GA plasma collection center
- Completed a debt refinancing of up to $72.5 million with Perceptive Advisors

- Ongoing work with the FDA to obtain approval of the BIVIGAM® drug substance PAS in order to relaunch the product
- Prescription Drug User Fee Act action date of April 2, 2019 for RI-002
- Potential commercial sales of BIVIGAM® and RI-002
- 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 Year Ended December 31, 2018

ADMA reported total revenues of $17.0 million for the year ended December 31, 2018, as compared to $22.8 million for the year ended December 31, 2017, representing a decrease of $5.8 million. The decrease in revenues is primarily due to $7.0 million of non-recurring revenue generated in 2017 that was related to an amendment to our contract manufacturing agreement and a decrease in the sale of normal source plasma of $1.6 million in 2018 due to increased competition from other plasma donation centers which have opened in close proximity to the plasma collection centers we transferred to Biotest on January 1, 2019, partially offset by an increase in Nabi-HB revenues of $2.8 million.

The consolidated net loss for the year ended December 31, 2018 was $65.7 million, or $(1.45) per basic and diluted share, as compared to a consolidated net loss of $43.8 million, or $(1.91) per basic and diluted share for the year ended December 31, 2017. The increase in net loss of $22.0 million was primarily attributable to an increase in cost of product revenue from the manufacture of conformance lots production of RI-002 and BIVIGAM®, which can be used for commercial sales upon FDA approval, higher operational expenses reflecting a full year of operations at the Boca Raton, FL facility for 2018, as compared to just seven months of operating activity at the Boca Raton, FL facility in 2017, as well as the initiation of marketing and commercial activities and the decrease in revenues. Included in the net loss for the year ended December 31, 2018 were non-cash expenses of $6.8 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

At December 31, 2018, ADMA had cash and cash equivalents of $22.8 million, as compared to $43.1 million at December 31, 2017. ADMA's net working capital was $34.9 million as of December 31, 2018, as compared to $52.9 million as of December 31, 2017.

About ADMA Biologics, Inc. (ADMA)
ADMA Biologics is a vertically integrated commercial biopharmaceutical and specialty immunoglobulin company that manufactures, markets and develops specialty plasma-based biologics for the treatment of immune deficiencies and the prevention of and treatment 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-suppressed for 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 Primary Immune Deficiency Disease ("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's initial approval for BIVIGAM® was received by Biotest Pharmaceuticals Corporation on December 19, 2012, and production of BIVIGAM® was halted by Biotest in December 2016. ADMA obtained ownership and all rights, title and interest in BIVIGAM® on June 6, 2017 as part of the Biotest Therapy Business Unit asset acquisition and resumed the production of BIVIGAM® during the fourth quarter of 2017.

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. 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 manufactured with novel technology protected by U.S. Patents: 9,107,906, 9,714,283, 9,815,886 and 9,969,793, the latter of which affords ADMA 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 and availability of future capital. 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:
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INVESTOR RELATIONS CONTACT:
Jeremy Feffer
Managing Director, LifeSci Advisors, LLC | 212-915-2568 |

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Years Ended December 31, 2018 and 2017

	Years Ended December 31,	
	2018	**2017**
REVENUES:		
Product revenue	$ 16,842,456	$ 15,617,726
License revenue	142,834	142,834
Other revenue	—	7,000,000
Total Revenues	16,985,290	22,760,560
OPERATING EXPENSES:		
Cost of product revenue (exclusive of amortization expense shown below)	42,194,635	29,164,321
Research and development	3,926,120	5,570,029
Plasma center operating expenses	7,805,619	6,503,750
Asset impairment charge	—	845,389
Amortization of intangible assets	844,938	1,234,674
Selling, general and administrative	22,502,922	18,752,393
Total operating expenses	77,274,234	62,070,556
LOSS FROM OPERATIONS	(60,288,944)	(39,309,996)
OTHER INCOME (EXPENSE):		
Interest income	195,403	57,228
Interest expense	(5,522,783)	(3,285,847)
Loss on extinguishment of debt	—	(1,210,216)
Other expense	(127,121)	(10,144)
Other expense, net	(5,454,501)	(4,448,979)
NET LOSS	$ (65,743,445)	$ (43,758,975)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (1.45)	$ (1.91)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic and Diluted	45,188,899	22,896,042

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

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,754,852	$ 43,107,574
Accounts receivable, net	1,392,441	3,880,154
Inventories	18,616,169	12,628,181
Prepaid expenses and other current assets	1,766,163	1,225,654
Restricted cash	—	1,500,000
Total current assets	44,529,625	62,341,563
Property and equipment, net	30,115,730	30,466,858
Intangible assets, net	4,004,412	4,849,350
Goodwill	3,529,509	3,529,509
Assets to be transferred under purchase agreement	1,153,508	1,496,410
Restricted cash	4,000,000	4,000,000
Deposits and other assets	1,543,737	1,335,143
TOTAL ASSETS	$ 88,876,521	$ 108,018,833
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,900,394	$ 5,920,873
Accrued expenses and other current liabilities	3,551,835	3,376,476
Current portion of deferred revenue	142,834	142,834
Current portion of capital lease obligation	29,983	—
Total current liabilities	9,625,046	9,440,183
Notes payable, net of discount	26,440,830	25,368,458
End of term liability, notes payable	2,760,000	2,760,000
Deferred revenue, net of current portion	2,404,365	2,547,199
Note payable - related party, net of discount	14,874,184	14,842,396
Obligation to transfer assets under purchase agreement	12,621,844	12,621,844
Capital lease obligation	119,080	—
Other non-current liabilities	260,734	105,996
TOTAL LIABILITIES	69,106,083	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, 46,353,068 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	236,203,041	191,022,018
Accumulated deficit	(216,437,238)	(150,693,793)
TOTAL STOCKHOLDERS' EQUITY	19,770,438	40,332,757
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 88,876,521	$ 108,018,833