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): May 8, 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):

o 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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ADMA	Nasdaq Capital Market

Item 2.02 Results of Operations and Financial Condition.

On May 8, 2019, ADMA Biologics, Inc. issued a press release announcing its financial results for the three months ended March 31, 2019 and provided an update on its recent achievements and upcoming milestones. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	ADMA Biologics, Inc. Press Release, dated May 8, 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.

May 8, 2019

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

ADMA Biologics Reports First Quarter 2019 Financial Results

RAMSEY, N.J. and BOCA RATON, FL., – May 8, 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 of certain infectious diseases, today announced its financial results for the first quarter ended March 31, 2019, and provided an update on its recent achievements, operations and upcoming milestones.

"We had a strong and productive start to 2019, most notably due to the United States Food and Drug Administration ("FDA") approval of ASCENIV™, the announcement of our fifth patent, which expands our proprietary hyperimmune immunotechnology product and product candidate portfolio, along with entering into a favorable credit facility with Perceptive Advisors ("Perceptive"). As a result of ASCENIV's™ FDA approval, we recently accessed the available second tranche of funding from the credit facility in the principal amount of $27.5 million and also announced Perceptive's additional financial commitment to ADMA by upsizing the original amount of the credit facility by $12.5 million, which is predicated on BIVIGAM's® FDA approval. This second tranche of funding received from Perceptive will be used to support our commercial launch of ASCENIV™, procurement of additional raw material plasma inventory and to initiate the project planning and buildout of another plasma center," stated Adam Grossman, President and Chief Executive Officer of ADMA Biologics.

Recent Achievements and Upcoming Milestones

- Obtained FDA approval for ASCENIV™ (formerly RI-002)
- Granted U.S. patent for the treatment and prevention of pneumococcal infections, which provides coverage for expanding the Company's hyperimmune intravenous immune globulin through 2037, bringing our total number of hyperimmune focused patents to five
- Completed a debt refinancing with Perceptive in the aggregate principal amount of $72.5 million and subsequently upsized this credit facility by an additional $12.5 million
- Obtained Department of Health and Human Services ("DHHS") U.S. License to manufacture and sell ASCENIV™ in the U.S. (DHHS License No. 2019)
- Ongoing communications with the FDA to obtain approval of the BIVIGAM® drug substance Prior Approval Supplement ("PAS") required to relaunch the product
- Potential commercial sales of ASCENIV™ and BIVIGAM®
- Continue to produce, release and market commercial product for Nabi-HB® in the U.S.
- Expand promotional activities for Nabi-HB®
- Expand our ADMA Bio Centers plasma collection network

Financial Results for the First Quarter Ended March 31, 2019

ADMA reported total revenues of $3.5 million for the first quarter ended March 31, 2019, as compared to $4.0 million for the first quarter ended March 31, 2018, representing a decrease of $0.5 million. The decrease in revenues is primarily attributable to the Company generating revenues from one plasma collection center during the first quarter of 2019, as compared to generating revenues from two plasma collection centers during the first quarter of 2018. In accordance with the June 2017 purchase agreement for the Biotest Therapy Business Unit ("BTBU"), on January 1, 2019, the Company transferred ownership of two of its FDA approved plasma collection centers to Biotest Pharmaceuticals Corporation ("BPC"). The decrease in quarterly revenues is also attributable to the timing of certain customers' shipment requests for Nabi-HB®.

The consolidated net loss for the first quarter of 2019 was $13.1 million, or $(0.28) per basic and diluted share, as compared to a consolidated net loss of $17.8 million, or $(0.39) per basic and diluted share, for the first quarter of 2018. The decrease in net loss of $4.7 million was mainly due to the Company recording a non-cash gain of $11.5 million pertaining to the value of its two plasma centers transferred to BPC on January 1, 2019 and a decrease in total operating expenses of $3.8 million in the first quarter of 2019 as compared to the first quarter of 2018, partially offset by a $10.0 million loss on the extinguishment of debt pertaining to the refinancing of the Company's senior credit facility during the first quarter of 2019. Included in the net loss for the quarter ended March 31, 2019 were non-cash expenses of $1.7 million for stock-based compensation, depreciation and amortization, and amortization of debt discount.

At March 31, 2019, ADMA had cash and cash equivalents of $16.5 million, as compared to $22.8 million at December 31, 2018. ADMA's net working capital was $30.0 million as of March 31, 2019, as compared to $34.9 million as of December 31, 2018. Subsequent to March 31, 2019, ADMA accessed $27.5 million of additional funding from Perceptive Advisors, with another $12.5 million of funding from Perceptive available upon FDA approval of BIVIGAM®.

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 ("PI") 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, 9,969,793 and 10,259,865 related to certain aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

About ASCENIV™ (Formerly referred to as RI-002)
ASCENIV™, Immune Globulin Intravenous, Human – slra 10% Liquid, is a plasma-derived, polyclonal, intravenous immune globulin ("IVIG"). ASCENIV™ is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886. ASCENIV™ is manufactured using our unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and plasma from donors tested using our proprietary microneutralization assay. ASCENIV™ contains naturally occurring polyclonal antibodies. ASCENIV™ is indicated for the treatment of Primary Humoral Immunodeficiency ("PI") in adults and adolescents (12 to 17 years of age). ADMA received FDA approval for ASCENIV™ on April 1, 2019. 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. ASCENIV™ prevented serious bacterial infection among fifty-nine patients treated for twelve months during the pivotal investigation. The most common adverse reactions to ASCENIV™ (≥5% of study subjects) were headache, sinusitis, diarrhea, gastroenteritis viral, nasopharyngitis, upper respiratory tract infection, bronchitis, and nausea. ADMA anticipates the commercial launch of ASCENIV™ during the second half of 2019. Certain data and other information about ASCENIV™ or ADMA Biologics and its products can be found on the Company's website at: 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 PIs 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 PI 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. The FDA's initial approval for BIVIGAM® was received by BPC in December 2012, and production of BIVIGAM® was halted by BPC in December 2016. ADMA obtained ownership and all rights, title and interest in BIVIGAM® in June 6, 2017 as part of the Biotest Therapy Business Unit asset acquisition (the "Biotest Transaction") and resumed the production of BIVIGAM® during the fourth quarter of 2017.

About Nabi-HB®
Nabi-HB® is a hyperimmune globulin that is rich in antibodies to the Hepatitis B virus. Nabi-HB® is a purified human polyclonal antibody product collected from plasma donors who have been previously vaccinated with a Hepatitis B vaccine. Nabi-HB® is indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen ("HBsAg"), prenatal exposure to infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute Hepatitis B virus infection. Hepatitis B is a potentially life-threatening liver infection caused by the Hepatitis B virus. It is a major global health problem and can cause chronic infection and put people at high risk of death from cirrhosis and liver cancer. Nabi-HB® has a well-documented record of long-term safety and effectiveness since its initial market introduction. FDA approval for Nabi-HB® was received on March 24, 1999. Biotest acquired Nabi-HB® from Nabi Biopharmaceuticals in 2007. ADMA resumed production of Nabi-HB® in the third quarter of 2017, as substantially all of the Nabi-HB® inventory received as part of the Biotest Transaction has been sold in the normal course of business.

About Primary Immune Deficiency Disease (“PI”)
PI 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 PI. 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. PI 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. Because patients suffering from PI 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. PI 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, product expansions into new fields of use, indications and product candidates, and the labeling or nature of any such approvals, our ability to successfully pursue commercialization and prelaunch activities for our products, the potential of our specialty plasma-based biologics products and product candidates 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:
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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

	Three Months Ended March 31,	
	2019	**2018**
REVENUES:		
Product revenue	$ 3,492,881	$ 4,006,298
License revenue	35,708	35,708
Total Revenues	3,528,589	4,042,006
OPERATING EXPENSES:		
Cost of product revenue (exclusive of amortization expense shown below)	9,405,179	12,242,748
Research and development	870,635	965,571
Plasma center operating expenses	654,486	1,833,774
Amortization of intangible assets	211,235	211,235
Selling, general and administrative	5,595,470	5,321,181
Total operating expenses	16,737,005	20,574,509
LOSS FROM OPERATIONS	(13,208,416)	(16,532,503)
OTHER INCOME (EXPENSE):		
Interest and other income	127,399	26,546
Interest expense	(1,540,507)	(1,323,152)
Loss on extinguishment of debt	(9,962,495)	—
Gain on transfer of plasma center assets	11,527,421	
Other (expense) income	(11,357)	6,967
Other income (expense), net	140,461	(1,289,639)
NET LOSS	$ (13,067,955)	$ (17,822,142)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.28)	$ (0.39)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic and Diluted	46,353,068	45,317,042

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

	March 31, 2019	December 31, 2018
ASSETS	(Unaudited)	Note 2
Current assets:		
Cash and cash equivalents	$ 16,534,278	$ 22,754,852
Accounts receivable, net	1,310,404	1,392,441
Inventories	18,439,912	18,616,169
Prepaid expenses and other current assets	2,049,552	1,766,163
Total current assets	38,334,146	44,529,625
Property and equipment, net	29,694,764	30,115,730
Intangible assets, net	3,793,177	4,004,412
Goodwill	3,529,509	3,529,509
Assets to be transferred under purchase agreement	—	1,153,508
Restricted cash	—	4,000,000
Deposits and other assets	2,768,374	1,543,737
TOTAL ASSETS	$ 78,119,970	$ 88,876,521
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,479,791	$ 5,900,394
Accrued expenses and other current liabilities	2,505,996	3,551,835
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	209,506	29,983
Total current liabilities	8,338,127	9,625,046
Notes payable, net of discount	40,885,103	26,440,830
End of term liability, notes payable	—	2,760,000
Deferred revenue, net of current portion	2,368,657	2,404,365
Note payable - related party, net of discount	14,882,337	14,874,184
Obligation to transfer assets under purchase agreement	—	12,621,844
Lease obligations	1,461,452	119,080
Other non-current liabilities	145,340	260,734
TOTAL LIABILITIES	68,081,016	69,106,083
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 shares issued and outstanding	4,635	4,635
Additional paid-in capital	239,539,512	236,203,041
Accumulated deficit	(229,505,193)	(216,437,238)
TOTAL STOCKHOLDERS' EQUITY	10,038,954	19,770,438
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 78,119,970	$ 88,876,521