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 5, 2020

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))

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, par value $0.0001 per share	ADMA	Nasdaq Global Market

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 5, 2020, ADMA Biologics, Inc. issued a press release announcing its financial results for the three and nine months ended September 30, 2020 and provided an overview of recent progress and accomplishments. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 **Financial Statements and Exhibits.**
(d)

Exhibit No.	Description
99.1	ADMA Biologics, Inc. Press Release, dated November 5, 2020

* 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 5, 2020

ADMA BIOLOGICS, INC.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

ADMA Biologics Reports Third Quarter 2020 Financial Results and Business Highlights

Generated Total Revenues of $28.3 Million for the First Nine Months of 2020, Reflecting a 63% Increase Over the Same Prior Year Period

Successfully Opened Newest ADMA BioCenters Plasma Collection Facility; On Track to Achieve Stated Goal of Opening Five to 10 New Collection Centers Over the Next Three to Five Years

Management to Host Conference Call and Webcast Today at 4:30 p.m. ET

RAMSEY, NJ and BOCA RATON, FL – November 5, 2020 – ADMA Biologics, Inc. (Nasdaq: ADMA) ("ADMA" or the "Company"), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics, today reported financial results for its fiscal third quarter and nine months ended September 30, 2020, and provided an overview of recent progress and accomplishments.

"On the commercial front, demand for immune globulins and our marketed products remained robust with our product portfolio generating sales of $28.3 million year-to-date ('YTD') in 2020, an increase of 63% compared to the same period in 2019. The third quarter was our strongest quarter of the year, even in the face of continued COVID-19 operating headwinds, as we generated $10.3 million in revenue, representing quarterly year-over-year growth of 42%," said Adam Grossman, President and Chief Executive Officer of ADMA. "We continue to build our inventory balance in support of anticipated revenue growth in the fourth quarter and into 2021. Our supply chain robustness initiatives continue as planned and the expansion of our Company-owned plasma collection center network is ahead of schedule. We now have six centers under our corporate umbrella at various stages of approval and development, including two that are fully operational and collecting plasma. We are confident in our continued ability to successfully navigate the Company against the backdrop of COVID-19, and anticipate a strong fourth quarter and ultimately achieving considerable growth in the second half of 2020 versus the first half."

Third Quarter 2020 and Recent Highlights

- **Expansion of ADMA BioCenters Plasma Collection Center Network Ahead of Schedule** – ADMA BioCenters, a wholly-owned subsidiary of ADMA Biologics, successfully opened, began donor collections and submitted a Biologics License Application to the U.S. Food and Drug Administration ("FDA") seeking FDA approval for this second plasma collection center, which we anticipate receiving in mid-2021. The Company currently has six plasma collection centers at various stages of approval and development, including two that are fully operational and collecting plasma, three that are under construction with favorable long-term leases, and one in the planning stage. ADMA remains on track to achieve its stated goal of opening five to 10 new, FDA-approved plasma collection centers over the next three to five years.

- **Manufacturing Capacity Expansion Initiatives** – ADMA continues to invest in and make progress with supply chain robustness enhancements, including the successful onboarding of aseptic fill-finish capabilities with our newly installed Vanrx SA25 Workcell, in addition to advancing regulatory efforts for the planned capacity expansion to the 4,400 liter BIVIGAM plasma pool. These important initiatives are designed to reduce operating costs, improve margins, increase scale and provide for faster production cycle turnaround time, ultimately providing increased control and independence from third-party vendors and contractors. ADMA remains on track to submit the appropriate applications to the FDA during the second half of 2020, and expects to begin benefitting from these initiatives as early as mid-2021.

- **Developed COVID-19 ImmunoRank™ Neutralization MICRO-ELISA** – The COVID-19 ImmunoRank Neutralization MICRO-ELISA is a proprietary, fully-validated ELISA assay for the detection of SARS-CoV-2 neutralizing antibodies in plasma. ImmunoRank, which was developed in collaboration with Leinco Technologies, Inc., is intended for use as an aid to identify individuals who produce an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, and specifically for the detection of circulating SARS-CoV-2 neutralizing antibodies in human plasma of all immune globulin classes. ImmunoRank is important because it offers a potentially faster, simpler, more cost effective way to identify high titer convalescent plasma for use in both treating COVID-19 patients and for creating COVID-19 hyperimmune globulins.

Financial Results for the Three Months Ended September 30, 2020

Total revenues for the quarter ended September 30, 2020 were $10.3 million, compared to $7.2 million for the quarter ended September 30, 2019, representing an increase of approximately $3.1 million, or 42%. The revenue growth for the third quarter of 2020, compared to the third quarter of 2019, was favorably impacted by the continued commercial ramp up of BIVIGAM and ASCENIV, and by the manufacturing and supply agreement ADMA entered into in January 2020 to produce and sell intermediate fractions.

Consolidated net loss for the quarter ended September 30, 2020 was $16.9 million, or $(0.19) per basic and diluted share, compared to a consolidated net loss of $11.4 million, or $(0.19) per basic and diluted share, for the quarter ended September 30, 2019. The $5.5 million increase in net loss compared to the prior year period was primarily attributable to a $3.9 million increase in cost of product revenue resulting from the higher product revenues generated from our immunoglobulin products portfolio, and to increases in selling, general and administrative expenses of $1.9 million related to employee compensation, new hires and other costs to support the commercialization efforts of BIVIGAM and ASCENIV, as well as a $1.2 million increase in research and development expenses related to the validation of a new filling line at one of our contracted third party fill-finishers. Research and development expenses were also impacted by costs associated with developing our neutralization MICRO-ELISA proprietary assay to detect SARS-CoV-2 neutralizing antibodies in plasma in collaboration with a third-party. The increase in net loss also includes a $0.8 million increase in plasma center operating expenses due to the opening of additional plasma centers during 2020. Included in the net loss for the third quarter of 2020 were non-cash expenses of approximately $2.3 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

Financial Results for the Nine Months Ended September 30, 2020

Total revenues for the nine months ended September 30, 2020 were $28.3 million, compared to $17.3 million for the nine months ended September 30, 2019, representing an increase of $11.0 million, or approximately 63%. The increase in revenues was primarily attributable to increased sales of our immunoglobulin products portfolio: BIVIGAM®, ASCENIV™, Nabi-HB® and intermediate fractions.

Consolidated net loss for the nine months ended September 30, 2020 was $56.3 million, or $(0.68) per basic and diluted share, compared to a consolidated net loss of $37.7 million, or $(0.72) per basic and diluted share, for the nine months ended September 30, 2019. The increase in net loss of $18.6 million was primarily attributable to a $14.4 million increase in cost of product revenue related to production costs incurred for the manufacture of BIVIGAM conformance lots at an increased plasma pool production scale that pertains to our planned capacity expansion at our Boca Raton, FL plasma fractionation facility, as well as higher product revenues generated from our immunoglobulin products portfolio. The increase in net loss during the first nine months of 2020 was also attributable to increased selling, general administrative expenses of $6.9 million in connection with the overall growth in the size and scope of the Company's operations, including the commercialization efforts of BIVIGAM® and ASCENIV™, and a $3.0 million increase in research and development expenses associated with the validation of a new line at one of our third party fill-finishers, and increases in various clinical research activities, some of which are required by the FDA. Included in the net loss for the first nine months of 2020 were non-cash expenses of approximately $6.2 million for stock-based compensation, depreciation and amortization and non-cash interest expense.

At September 30, 2020, ADMA had cash and cash equivalents of $59.7 million and accounts receivable of $6.3 million, compared to cash and cash equivalents of $26.8 million and accounts receivable of $3.5 million at December 31, 2019. ADMA's net working capital as of September 30, 2020 was $123.1 million, compared to $71.8 million as of December 31, 2019.

Conference Call Information

ADMA will host a conference call today, Thursday, November 5, 2020, at 4:30 p.m. Eastern Time, to discuss the third quarter 2020 financial results and recent corporate updates. To access the conference call, please dial (855) 884-8773 (local) or (615) 622-8043 (international) at least 10 minutes prior to the start time and refer to conference ID 8185674. A live audio webcast of the call will be available under "Events & Webcasts" in the Investor section of the Company's website, https://ir.admabiologics.com/events-webcasts. An archived webcast will be available on the Company's website approximately two hours after the event.

About BIVIGAM®

BIVIGAM (immune globulin intravenous, human – 10% liquid) is a plasma-derived, polyclonal, intravenous immune globulin (IVIG). BIVIGAM was approved by the FDA in May 2019 and is indicated for the treatment of primary humoral immunodeficiency (PI), including, but not limited to the following group of genetic disorders: X-linked and congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. 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 human Immunoglobulin (IgG) antibodies.

About ASCENIV™

ASCENIV (immune globulin intravenous, human – slra 10% liquid) is a plasma-derived, polyclonal, intravenous immune globulin (IVIG). ASCENIV was approved by the FDA on April 1, 2019 and is indicated for the treatment of primary humoral immunodeficiency (PI), also known as primary immune deficiency disease (PIDD), in adults and adolescents (12 to 17 years of age). ASCENIV is manufactured using ADMA's unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and plasma from donors tested using the Company's proprietary microneutralization assay. ASCENIV contains naturally occurring polyclonal antibodies, which 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 is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886.

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. Certain data and other information about Nabi-HB® or ADMA Biologics and its products can be found on the Company's website at www.admabiologics.com.

About ADMA BioCenters

ADMA BioCenters is an FDA licensed facility specializing in the collection of human plasma used to make special medications for the treatment and prevention of diseases. Managed by a team of experts who have decades of experience in the specialized field of plasma collection, ADMA BioCenters provides a safe, professional and pleasant donation environment. ADMA BioCenters strictly follows FDA regulations and guidance and enforces cGMP (current good manufacturing practices) in all of its facilities. For more information about ADMA BioCenters, please visit www.atlantaplasma.com.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and others at risk for certain infectious diseases. ADMA currently manufactures and markets three United States Food and Drug Administration (FDA) approved plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases: BIVIGAM® (immune globulin intravenous, human) for the treatment of primary humoral immunodeficiency (PI); ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) for the treatment of PI; and NABI-HB® (hepatitis B immune globulin, human) to provide enhanced immunity against the hepatitis B virus. ADMA manufactures its immune globulin products at its FDA-licensed plasma fractionation and purification facility located in Boca Raton, Florida. Through its ADMA Bio Centers subsidiary, ADMA also operates as an FDA-approved source plasma collector in the U.S., which provides a portion of its blood plasma for the manufacture of its products. ADMA's mission is to manufacture, market and develop specialty plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases and management of immune compromised patient populations who suffer from an underlying immune deficiency, 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.

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 such words as "estimate," "project," "intend," "forecast," "target," "anticipate," "plan," "planning," "expect," "believe," "will," "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 about ADMA's future results of operations; the goal of opening new collection centers over the next three to five years; our supply chain robustness initiatives and their intended outcome, expected benefits, and timing thereof; the outcome and timing of our BLA application for our new plasma center; the expected benefits from the new aseptic fill-finish machine installed at our Boca Raton facility; the intended outcome and expected benefits from our several manufacturing and supply chain enhancement initiatives, and the expected timing for realizing those benefits, and our plan to submit appropriate applications to the FDA related thereto; and the expected benefits relating to the development of the COVID-19 ImmunoRank Neutralization MICRO-ELISA. 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. 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.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
REVENUES:				
Product revenue	$ 10,240,650	$ 7,186,795	$ 28,156,571	$ 17,204,909
License revenue	35,708	35,708	107,125	107,125
Total Revenues	10,276,358	7,222,503	28,263,696	17,312,034
OPERATING EXPENSES:				
Cost of product revenue (exclusive of amortization expense shown below)	11,855,464	7,916,220	42,180,319	27,812,635
Research and development	1,708,391	491,404	4,893,549	1,879,025
Plasma center operating expenses	1,218,898	456,899	2,597,444	1,705,498
Amortization of intangible assets	178,838	211,235	536,514	633,704
Selling, general and administrative	9,115,744	7,197,173	25,750,458	18,878,690
Total operating expenses	24,077,335	16,272,931	75,958,284	50,909,552
LOSS FROM OPERATIONS	(13,800,977)	(9,050,428)	(47,694,588)	(33,597,518)
OTHER INCOME (EXPENSE):				
Interest and other income	1,164	281,896	268,643	619,103
Interest expense	(3,091,200)	(2,649,404)	(8,875,597)	(6,262,489)
Loss on extinguishment of debt	—	—	—	(9,962,495)
Gain on transfer of plasma center assets	—	—	—	11,527,421
Other expense, net	(26,440)	(20,523)	(39,232)	(42,308)
Other expense, net	(3,116,476)	(2,388,031)	(8,646,186)	(4,120,768)
NET LOSS	$ (16,917,453)	$ (11,438,459)	$ (56,340,774)	$ (37,718,286)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.19)	$ (0.19)	$ (0.68)	$ (0.72)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic and Diluted	87,698,258	59,317,830	82,627,753	52,673,190

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2020	December 31, 2019
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 59,675,045	$ 26,752,135
Accounts receivable, net	6,334,536	3,469,919
Inventories	69,752,528	53,064,734
Prepaid expenses and other current assets	3,786,421	2,533,593
Total current assets	139,548,530	85,820,381
Property and equipment, net	39,622,510	31,741,317
Intangible assets, net	2,622,959	3,159,474
Right to use assets	2,782,987	1,245,029
Goodwill	3,529,509	3,529,509
Deposits and other assets	1,869,548	1,595,015
TOTAL ASSETS	$ 189,976,043	$ 127,090,725
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,979,772	$ 9,174,591
Accrued expenses and other current liabilities	8,074,989	4,481,395
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	275,988	229,073
Total current liabilities	16,473,583	14,027,893
Senior notes payable, net of discount	82,108,633	68,291,163
Deferred revenue, net of current portion	2,154,407	2,261,532
Subordinated note payable, net of discount	14,934,926	14,908,053
Lease obligations, net of current portion	2,860,732	1,302,361
Other non-current liabilities	67,808	106,574
TOTAL LIABILITIES	118,600,089	100,897,576
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred Stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common Stock, $0.0001 par value, 150,000,000 shares authorized, 89,616,176 and 59,318,355 shares issued and outstanding	8,960	5,932
Additional paid-in capital	392,424,323	290,903,772
Accumulated deficit	(321,057,329)	(264,716,555)
TOTAL STOCKHOLDERS' EQUITY	71,375,954	26,193,149
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 189,976,043	$ 127,090,725