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 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 August 5, 2020, ADMA Biologics, Inc. issued a press release announcing its financial results for the three and six months ended June 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 August 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.

August 5, 2020

ADMA BIOLOGICS, INC.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

ADMA Biologics Reports Business Highlights and Second Quarter 2020 Financial Results

Generated Total Revenues of $18.0 Million for the First Half of 2020, Reflecting a 78% Increase Over First Half of 2019

Joined CoVIg-19 Plasma Alliance and Successfully Opened New ADMA BioCenters Plasma Collection Center

Company Anticipates Generating $250 Million or More in Annual Revenues Within Next Three to Five Calendar Years

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

RAMSEY, NJ and BOCA RATON, FL – August 5, 2020 – ADMA Biologics, Inc. (Nasdaq: ADMA) ("ADMA"), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics, today reported business highlights and financial results for its fiscal second quarter and six months ended June 30, 2020, and provided an overview of recent progress and accomplishments.

"The first half of 2020 was marked by several achievements and challenges as we navigate through these unprecedented macro-market conditions," said Adam Grossman, President and Chief Executive Officer of ADMA. "Total revenues for the first half of 2020 increased approximately 78% compared to the same prior year period. While the second quarter 2020 revenues were approximately 19% higher than second quarter 2019 revenues, ADMA, and certain of its third-party vendors, experienced impacts from the global COVID-19 pandemic which resulted in unforeseen supply chain disruptions. These COVID-19 disruptions were primarily related to delays with final product Current Good Manufacturing Practice ("cGMP") release testing by third-party vendors. This means that a few of our production batches were finished on schedule but we were unable to submit for U.S. Food and Drug Administration ("FDA") lot release authorization due to delayed test results.

These delays were mainly experienced during the latter part of the second quarter and have since been resolved during July. In response to these delays, and in partnership with the FDA, we added additional release testing laboratories to our approved consortium and believe we have completely resolved the issue and do not anticipate additional testing or batch release delays going forward.

Market demand for our immunoglobulin product portfolio remains strong and we anticipate considerable revenue growth for the second half of the year and are excited for the anticipated production volume increases from our capacity expansion efforts in 2021 and beyond. We also believe we remain on track to achieve our stated goal of generating $250 million or more in annual revenues within the next three to five calendar years."

“In accordance with our stated corporate objectives, during the quarter we completed construction of a new plasma collection center, initiated donor collections and submitted a Biologics License Application (“BLA”) to the FDA, with an approval decision expected in mid-2021. We also installed and qualified a new aseptic fill-finish machine at our Boca Raton facility, and manufactured conformance batches of BIVIGAM® at an increased scale that will ultimately allow us to manufacture at twice the volume as the process that is in place today. And finally, we joined the CoVIg-19 Plasma Alliance and began collection of plasma from COVID-19 convalesced patients. We are proud of these important achievements and milestones and believe we have set the stage to now be in a position to ensure the U.S. market has a continuous supply of BIVIGAM®, ASCENIV™ and NABI-HB®. We are on target for positioning our operations to capitalize on the continued forecasted growth of the plasma products industry. Our production throughput and finished product supply remains on track to begin realizing the benefits from these initiatives as early as mid-2021,” concluded Mr. Grossman.

Second Quarter 2020 Highlights and Recent Events

- **Plasma Collection Centers** – ADMA BioCenters, a wholly-owned subsidiary of ADMA Biologics, successfully opened, began donor collections and filed a BLA to receive FDA approval for its second plasma collection center. ADMA expects to open a third U.S. collection center and commence construction on a fourth center by the end of 2020 and remains on track to deliver on its stated milestone of opening five to ten new plasma collection centers over the next three to five years.

- **Plasma Industry Alliance** – ADMA recently joined the CoVIg-19 Plasma Alliance, an unprecedented plasma industry collaboration established to accelerate the development of a plasma-derived hyperimmune globulin therapy for COVID-19. As an Alliance member company, ADMA, through its ADMA BioCenters subsidiary, has initiated collecting and providing COVID-19 plasma from convalesced patients. This plasma will be used by the CoVIg-19 Plasma Alliance to produce a COVID-19 targeted hyperimmune globulin, as well as for internal research and development purposes.

- **Manufacturing Capacity Expansion Initiatives** – ADMA successfully implemented several manufacturing and supply chain enhancements, including the purchase and installation of a new Vanrx SA25 Workcell aseptic filling machine and manufacturing of four conformance batches of BIVIGAM® at an increased scale. These important initiatives are designed to reduce operating costs, improve margins and provide for faster production cycle turnaround time, ultimately providing increased control and independence from third-party vendors and contractors. ADMA plans 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.

COVID-19 Impacts

- **Final Product Release Testing** – ADMA experienced delays with final product release testing for its commercial products due to COVID-19's impact on third-party laboratories that perform the FDA-required cGMP release testing. These testing delays prevented ADMA from receiving FDA authorization to sell additional completed production batches during the second quarter. ADMA believes this delay was completely resolved in July 2020. In response to these delays, and in collaboration with the FDA, ADMA secured additional third-party laboratories, which has completely resolved this specific testing backlog. ADMA received FDA authorized product releases with data from its new third-party testing laboratories during July. Going forward, ADMA believes access to these additional laboratories will provide more rapid final product release testing as well as more consistent receipt of testing results to submit to the FDA for final product releases.

- **Supply Chain Impacts Due to COVID-19** – As a result of previous state and local "shelter-in-place" orders, ADMA experienced lower than normal donor collections at its FDA-licensed plasma collection center during the second quarter of 2020. ADMA also experienced delayed timing of shipments of source plasma from its contracted third-party suppliers, as well as delays in deliveries of personal protective equipment, reagents and other non-plasma raw materials and supplies used in the manufacture of its products.

- **Commercial Engagement Opportunities** – ADMA observed impacts to its customer engagement initiatives as its sales and medical affairs field forces experienced difficulty communicating directly with physicians and other healthcare professionals. In addition, a number of key scientific and medical meetings were either canceled or postponed, further limiting ADMA's ability to communicate with potential customers. ADMA has implemented a comprehensive suite of virtual engagement initiatives; however, clinician engagement has been reduced due to rapidly evolving COVID-19 priorities at U.S. medical centers.

Financial Results for the Three Months Ended June 30, 2020

Total revenues for the quarter ended June 30, 2020 were $7.8 million, compared to $6.6 million for the quarter ended June 30, 2019, representing an increase of approximately $1.2 million, or approximately 19%. The increase is primarily due to sales of BIVIGAM, ASCENIV and intermediates, compared to no sales from these products during the same prior year period. ADMA's revenues for the second quarter of 2020, compared to the second quarter of 2019, were favorably impacted by the FDA approvals of BIVIGAM and ASCENIV on May 9, 2019 and April 1, 2019, respectively, and by the manufacturing and supply agreement ADMA entered into in January 2020 to produce and sell intermediate fractions to a certain customer.

Consolidated net loss for the quarter ended June 30, 2020 was $20.2 million, or $(0.23) per basic and diluted share, compared to a consolidated net loss of $13.2 million, or $(0.25) per basic and diluted share, for the quarter ended June 30, 2019. The increase in net loss of $7.0 million was primarily due to increased cost of product revenue of $3.0 million related to sales of FDA-approved immunoglobulin products not present in the same prior year period, along with the remaining costs associated with the manufacturing of BIVIGAM's increased plasma pool conformance lots as part of our planned capacity expansion, partially offset by a decrease in unabsorbed manufacturing expense at the Boca Raton, FL production facility. The increase in net loss during the second quarter of 2020 is also attributable to higher research and development expenses of $1.1 million, largely due to costs associated with the testing and development of a new filling line at one of our third-party fill finishers, and to increased selling, general and administrative expenses of $2.6 million, mainly due to increases in employee compensation expenses and other costs in support of our commercialization efforts for BIVIGAM and ASCENIV. In addition, interest expense for the quarter increased by $1.0 million due to our accessing additional debt during the second quarter of 2019 and first quarter of 2020. Included in the net loss for the second quarter of 2020 were non-cash expenses of approximately $2.0 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

Financial Results for the Six Months Ended June 30, 2020

Total revenues for the six months ended June 30, 2020 were $18.0 million, compared to $10.1 million for the six months ended June 30, 2019, representing an increase of $7.9 million, or approximately 78%. The increase in revenues was primarily attributable to sales of BIVIGAM, ASCENIV and intermediates, compared to no sales from these products during the same prior year period.

Consolidated net loss for the six months ended June 30, 2020 was $39.4 million, or $(0.49) per basic and diluted share, compared to a consolidated net loss of $26.3 million, or $(0.53) per basic and diluted share, for the six months ended June 30, 2019. The increase in net loss of $13.1 million was primarily attributable to increased cost of product revenue of $10.4 million related to sales of BIVIGAM, ASCENIV and intermediates not present during the first half of 2019, along with the costs associated with the manufacturing of BIVIGAM's increased plasma pool conformance lots as part of our planned capacity expansion, along with other production initiatives and investments at the Boca Raton facility. Other factors contributing to the increase in net loss include: higher research and development expenses attributed to costs associated with testing and development of a new fill line at our third-party fill finisher and costs incurred for a study we commenced to potentially extend ASCENIV's approved and labeled expiration dating, higher selling, general administrative expenses in support of our commercialization efforts of BIVIGAM's relaunch and ASCENIV's launch and the overall growth in the size and scope of the Company's operations along with higher interest expense due to accessing additional debt during the second quarter of 2019 and first quarter of 2020. Included in the net loss for the first half of 2020 were non-cash expenses of approximately $3.9 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

At June 30, 2020, ADMA had cash and cash equivalents of $75.8 million and accounts receivable of $6.5 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 June 30, 2020 was $130.1 million, compared to $71.8 million as of December 31, 2019.

Conference Call Information

ADMA will host a conference call today, Wednesday, August 5, 2020, at 4:30 p.m. Eastern Time, to discuss the second 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 8992308. 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: ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) for the treatment of primary humoral immunodeficiency (PI); BIVIGAM® (immune globulin intravenous, human) 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, including the goal of generating $250 million or more in annual revenues within the next three to five calendar years; our belief that we have corrected third-party release testing delay issues through the addition of release testing laboratories to our FDA-approved consortium; 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 continued forecasted growth of the plasma products industry and our expectation to capitalize thereon; the construction and opening of plasma collection centers and the timing thereof; the expected and intended use by the CoVIg-19 Plasma Alliance of plasma that we collect; the benefits expected from our several manufacturing and supply chain enhancement, the expected timing for realizing those benefits, and our plan to submit appropriate applications to the FDA related thereto; and the expected benefits from securing additional third-party laboratories to perform cGMP release testing. 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.

COMPANY CONTACT:

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INVESTOR RELATIONS CONTACT:

Sam Martin

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
REVENUES:				
Product revenue	$ 7,751,885	$ 6,525,233	$ 17,915,921	$ 10,018,114
License revenue	35,709	35,709	71,417	71,417
Total Revenues	7,787,594	6,560,942	17,987,338	10,089,531
OPERATING EXPENSES:				
Cost of product revenue (exclusive of amortization expense shown below)	13,495,629	10,491,236	30,324,855	19,896,415
Research and development	1,656,420	516,986	3,185,158	1,387,621
Plasma center operating expenses	877,902	594,113	1,378,546	1,248,599
Amortization of intangible assets	178,838	211,234	357,676	422,469
Selling, general and administrative	8,702,630	6,086,047	16,634,714	11,681,517
Total operating expenses	24,911,419	17,899,616	51,880,949	34,636,621
LOSS FROM OPERATIONS	(17,123,825)	(11,338,674)	(33,893,611)	(24,547,090)
OTHER INCOME (EXPENSE):				
Interest and other income	19,411	209,808	267,479	337,207
Interest expense	(3,067,306)	(2,072,578)	(5,784,397)	(3,613,085)
Loss on extinguishment of debt	—	—	—	(9,962,495)
Gain on transfer of plasma center assets	—	—	—	11,527,421
Other expense, net	(6,371)	(10,428)	(12,792)	(21,785)
Other expense, net	(3,054,266)	(1,873,198)	(5,529,710)	(1,732,737)
NET LOSS	$ (20,178,091)	$ (13,211,872)	$ (39,423,321)	$ (26,279,827)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.23)	$ (0.25)	$ (0.49)	$ (0.53)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic and Diluted	86,347,467	52,206,204	80,064,641	49,295,805

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2020	December 31, 2019
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 75,781,122	$ 26,752,135
Accounts receivable, net	6,514,165	3,469,919
Inventories	56,001,348	53,064,734
Prepaid expenses and other current assets	4,693,427	2,533,593
Total current assets	142,990,062	85,820,381
Property and equipment, net	37,373,366	31,741,317
Intangible assets, net	2,801,797	3,159,474
Goodwill	3,529,509	3,529,509
Deposits and other assets	4,846,834	2,840,044
TOTAL ASSETS	$ 191,541,568	$ 127,090,725
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,909,659	$ 9,174,591
Accrued expenses and other current liabilities	5,616,666	4,481,395
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	210,870	229,073
Total current liabilities	12,880,029	14,027,893
Senior notes payable, net of discount	81,648,187	68,291,163
Deferred revenue, net of current portion	2,190,115	2,261,532
Subordinated note payable, net of discount	14,925,760	14,908,053
Lease obligations, net of current portion	2,937,292	1,302,361
Other non-current liabilities	80,730	106,574
TOTAL LIABILITIES	114,662,113	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, 86,349,981 and 59,318,355 shares issued and outstanding	8,635	5,932
Additional paid-in capital	381,010,696	290,903,772
Accumulated deficit	(304,139,876)	(264,716,555)
TOTAL STOCKHOLDERS' EQUITY	76,879,455	26,193,149
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 191,541,568	$ 127,090,725