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 12, 2021

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 Global Market
Preferred Share Purchase Rights	-	Nasdaq Global Market

Item 2.02 Results of Operations and Financial Condition

On May 12, 2021, ADMA Biologics, Inc. issued a press release announcing its financial results for the three months ended March 31, 2021 and providing an overview of recent progress and accomplishments. 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 May 12, 2021

* 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 12, 2021

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

ADMA Biologics Reports First Quarter 2021 Financial Results and Highlights Recent Company Progress and Accomplishments

Achieved First Quarter 2021 Total Revenues of $16.0 Million, a 57% Increase Over First Quarter 2020

Significantly Expanded Total Asset Value to $235.7 Million, Including $94.1 Million in Inventories

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

RAMSEY, NJ and BOCA RATON, FL – May 12, 2021 – 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 first quarter 2021 and provided an overview of recent progress and accomplishments.

"ADMA has successfully transformed its business in the early months of 2021 and in doing so set the stage for what the Company expects to be a strong year of growth and achievements. We remain on track to deliver on several strategic and financial objectives over the near term, and visibility is improving on the Company's path to profitability," said Adam Grossman, President and Chief Executive Officer of ADMA Biologics. "We achieved multiple milestones across business segments during the quarter, while at the same time delivered on operating commitments to shareholders, specifically, generating record quarterly revenues of $16.0 million, a 57% increase over the same period last year. Also on the financial front, ADMA successfully narrowed both gross losses as well as net losses compared to the prior quarter, an encouraging trend the Company will strive to continue in the coming quarters and accelerate throughout 2022."

ADMA additionally grew its total asset value to a quarter-end balance of $235.7 million, up approximately 13% compared to the year-end 2020 total asset value of $207.7 million. The growth in asset value notably includes approximately $94.1 million in inventories recorded at the Company's cost, which ADMA expects will support continued production ramp-up as well as quarter-over-quarter revenue growth throughout 2021, and to ensure continuity of product supply into an increasingly supply-constrained immune globulin market.

Mr. Grossman continued, "ADMA substantially strengthened its supply chain during the first quarter of 2021, making significant progress towards its objective to establish end-to-end control of its production operations. Of note, the recent U.S. Food and Drug Administration ("FDA") approval of the Company's Intravenous Immune Globulin ("IVIG") production scale expansion is expected to increase total manufacturing production capacity by up to 50% compared to the Company's prior expectations, ADMA BioCenters remains on track to have 10 or more plasma collection facilities in operation by 2024, and the two fiscal quarter extension of ADMA's existing third-party plasma supply commitment to year-end 2022 is expected to further supplement ADMA's growing internal plasma collections and support the Company in meeting all ongoing, as well as the forecasted, peak IVIG production requirements."

“The milestones achieved during the first quarter of 2021 establish a strong foundation for ADMA’s continued execution as the year progresses. We believe the multi-year remediation and production enhancement objectives will enable ADMA to yield significant returns in the way of margin improvements, and to generate anticipated quarter-over-quarter revenue growth which we expect should continue throughout 2021 and beyond. The pathway to profitability is clearly in focus. We believe that we have executed on all stated commitments to our shareholders and to a large extent de-risked future growth prospects as a result of the Company’s achievements during the first quarter. These achievements could not have been completed without the dedication and focus of ADMA’s staff and we commend the entire team for their extraordinary efforts,” concluded Mr. Grossman.

Select First Quarter 2021 Achievements & Recent Corporate Developments:

- **Continued Commercial Execution:** Achieved first quarter 2021 total revenues of $16.0 million, compared to $10.2 million for the first quarter of 2020, reflecting a 57% increase.

- **Inventories Continued to Increase to Support Anticipated Quarter-Over-Quarter Revenue Growth.** Grew inventories to a first quarter 2021 ending balance of $94.1 million compared to $52.3 million in the first quarter of 2020, which supports our anticipated quarter-over-quarter revenue growth in 2021 and beyond. This inventory consists of raw materials, including source plasma, work-in-process and finished goods.

- **Strengthened Internal and Externally Sourced Plasma Supply.** ADMA currently has seven plasma collection facilities under its corporate umbrella at various stages of approval and development, including four facilities that are currently operational and collecting plasma, and remains on track to achieve its stated goal of operating 10 or more plasma collection centers by 2024. Over the remainder of 2021, ADMA anticipates to receive approval for one facility presently pending a Biologics License Application (“BLA”), and expects filing BLAs for two additional plasma collection centers. The Company additionally announced an extension of its existing third-party source plasma supply agreement from June 2022 previously through December 2022. We believe ADMA’s growing internal plasma collection network coupled with its contractually committed third-party supply obligations position the company well to ensure sufficient quantities of plasma supply to meet both ongoing production requirements as well as the supply needs associated with the upwardly revised peak annual production capacity expectations of up to 600,000-liters.

- **Advanced Supply Chain Enhancement Initiative.** The recent FDA approval of the 4,400-liter IVIG plasma pool scale increase for BIVIGAM® will enable ADMA to potentially ramp-up to 600,000-liters of annual production throughput, realize meaningful gross margin improvement as production throughput flows through the standard 7 to 12-month manufacturing cycle for plasma-derived therapies, and allow ADMA to offer BIVIGAM® in two vial sizes, both the 50 mL and 100 mL configurations. The next anticipated regulatory decision as a part of ADMA's supply chain enhancement initiative will be for the installed VanRx SA25 Workcell aseptic fill-finish machine ("VanRx"). Based on recent correspondence with the FDA, a facility site inspection (virtual or in-person per current published FDA guidance) will be required prior to approval, the timing of which will be contingent on COVID-19 policies. ADMA is actively working with the FDA to find a way to expedite the plant inspection, and the Company sees a potential pathway for receiving approval during the fourth quarter of 2021. Importantly, the potential regulatory delay has no impact on the Company's near-term or ongoing operating targets, and ADMA remains confident in its ability to receive FDA approval of its in-house fill-finish machine.

- **Improved ASCENIV's Coverage and Patient Access.** Permanent J-code was implemented April 1, 2021, which will provide for a streamlined and permanent reimbursement process in outpatient treatment settings.

- **Launched ADvantage Ig Comprehensive Patient Support Program.** ADvantage Ig is a comprehensive patient support program designed to help prevent potential barriers to providers obtaining access to ADMA's therapies for their patients. The launch of this comprehensive patient support program allows for a singular point of contact for patients and providers.

- **Lobbied Stakeholders in the Fight Against Sexually Transmitted Diseases.** Presented a poster highlighting the pharmacoeconomic burden of human immunodeficiency virus ("HIV") and Hepatitis B virus ("HBV") infection in sexual assault patients at the 2021 Academy of Managed Care Pharmacy virtual annual meeting. The Company's analysis suggests that amending U.S. Centers for Disease Control and Prevention guidelines in this at-risk population for HBV to mirror those of HIV and specifically mandating a Hepatitis B Globulin intervention such as ADMA's Nabi-HB® hyperimmune, will provide a cost-effective strategy for prophylactic seroprotection of these vulnerable patients.

First Quarter 2021 Financial Results

Total revenues for the quarter ended March 31, 2021 were $16.0 million, compared to $10.2 million for the quarter ended March 31, 2020, representing an increase of approximately $5.8 million, or 57%. The revenue growth for the first quarter of 2021, compared to the first quarter of 2020, was favorably impacted by the continued commercial ramp up of our IVIG product portfolio.

Consolidated net loss for the quarter ended March 31, 2021 was $18.4 million, or $(0.16) per basic and diluted share, compared to a consolidated net loss of $19.2 million, or $(0.26) per basic and diluted share, for the quarter ended March 31, 2020. The $0.8 million narrowing in net loss compared to the prior year period was primarily attributable increased revenues and improved gross margins.

At March 31, 2021, ADMA had cash and cash equivalents of approximately $62.0 million and accounts receivable of $15.4 million, compared to cash and cash equivalents of $55.9 million and accounts receivable of $13.2 million as of December 31, 2020. ADMA's net working capital as of March 31, 2021 was $156.1 million, compared to $133.8 million as of December 31, 2020.

Conference Call Information

ADMA will host a conference call today, May 12, 2021, at 4:30 p.m. Eastern Time, to discuss the fiscal first quarter 2021 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 1063675. 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 antibodies. Certain data and other information about BIVIGAM® or ADMA Biologics and its products can be found on the Company's website at www.admabiologics.com.

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 in April 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 respiratory syncytial virus (RSV) plasma obtained 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. 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 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 operates FDA-licensed facilities 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 safe, professional and pleasant donation environment. ADMA BioCenters strictly follows FDA regulations and guidance and enforces current good manufacturing practices (cGMP) in all of its facilities. For more information about ADMA BioCenters, please visit www.admabiocenters.com.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is an end-to-end American 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 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 BioCenters 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. and its subsidiaries (collectively, "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 our anticipated timing for reaching profitability and meaningful gross margin improvement; BIVIGAM® production capacity; the goal of building and opening new plasma collection centers by 2024; the Company's plasma collections and production; our ability to maintain plasma supply; the outcome and timing of our BLA application for our new plasma centers and for FDA inspection and approval of our VanRx aseptic fill finish machine; and our continued evaluation of opportunities to expand our pipeline and future product offerings. Actual events or results may differ materially from those described in this press release 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 March 31,	
	2021	**2020**
REVENUES:		
Product revenue	$ 16,012,910	$ 10,164,036
License revenue	35,708	35,708
Total revenues	16,048,618	10,199,744
OPERATING EXPENSES:		
Cost of product revenue (exclusive of amortization expense shown below)	17,770,122	16,829,226
Research and development	987,649	1,528,738
Plasma center operating expenses	2,242,343	500,644
Amortization of intangible assets	178,838	178,838
Selling, general and administrative	10,033,915	7,932,084
Total operating expenses	31,212,867	26,969,530
LOSS FROM OPERATIONS	(15,164,249)	(16,769,786)
OTHER INCOME (EXPENSE):		
Interest income	22,059	248,068
Interest expense	(3,195,750)	(2,717,091)
Other expense	(42,001)	(6,421)
Other expense, net	(3,215,692)	(2,475,444)
NET LOSS	$ (18,379,941)	$ (19,245,230)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.16)	$ (0.26)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic and Diluted	115,661,937	73,781,507

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2021	December 31, 2020
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,965,709	$ 55,921,152
Accounts receivable, net	15,362,030	13,237,290
Inventories	94,146,200	81,535,599
Prepaid expenses and other current assets	5,802,608	3,046,466
Total current assets	177,276,547	153,740,507
Property and equipment, net	44,175,613	41,593,090
Intangible assets, net	2,265,283	2,444,121
Goodwill	3,529,509	3,529,509
Right to use assets	6,197,295	4,259,191
Deposits and other assets	2,222,781	2,106,976
TOTAL ASSETS	$ 235,667,028	$ 207,673,394
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,152,852	$ 11,073,708
Accrued expenses and other current liabilities	8,592,142	8,365,143
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	317,910	365,682
Total current liabilities	21,205,738	19,947,367
Senior notes payable, net of discount	93,412,660	92,968,866
Deferred revenue, net of current portion	2,082,990	2,118,698
Lease obligations, net of current portion	6,419,589	4,334,151
Other non-current liabilities	41,965	54,886
TOTAL LIABILITIES	123,162,942	119,423,968
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, 150,000,000 shares authorized, 123,044,981 and 104,902,888 shares issued and outstanding	12,304	10,490
Additional paid-in capital	471,336,826	428,704,039
Accumulated deficit	(358,845,044)	(340,465,103)
TOTAL STOCKHOLDERS' EQUITY	112,504,086	88,249,426
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 235,667,028	$ 207,673,394