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): <u>August 11, 2021</u>

ADMA BIOLOGICS, INC.

(Exac	ct name of registrant as specified in its chart	er)			
Delaware	001-36728	56-2590442			
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)			
465 State Route 17, Ramsey, New Jerse	у	07446			
(Address of principal executive offices		(Zip Code)			
Registrant's to	elephone number, including area code: (201) 478-5552			
(Former na	ame or former address, if changed since last	report.)			
Check the appropriate box below if the Form 8-K filing is following provisions (see General Instruction A.2. below)		g obligation of the registrant under any of the			
\square 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 \square					
If an emerging growth company, indicate by che any new or revised financial accounting standards provide		ise the extended transition period for complying with e Act. \Box			
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 August 11, 2021, ADMA Biologics, Inc. issued a press release announcing its financial results for the three months ended June 30, 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 August 11, 2021

104 Cover Page Interactive Data File (embedded with the Inline XBRL document)

^{*} 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 11, 2021 ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial

Officer



ADMA Biologics Reports Record Second Quarter 2021 Financial Results and Highlights Recent Progress and Accomplishments

Achieved Record Total Revenues of \$17.8 Million in Second Quarter 2021, a 129% Increase Over Second Quarter 2020

Narrowed Gross and Net Losses Year-over-Year

ADMA Now Anticipates Exiting 2021 Approaching an Annualized Revenue Run Rate of Approximately \$100 Million or More; Reiterates All Previously Communicated Strategic and Financial Objectives

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

RAMSEY, NJ and BOCA RATON, FL – August 11, 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 the three months ended June 30, 2021, its fiscal second quarter, and provided an overview of recent progress and accomplishments.

"ADMA continues to achieve milestones and execute on its commercial and operational strategies as evidenced by the strong second quarter financial results and regulatory successes. The totality of the year-to-date accomplishments across business segments has the Company well-positioned to sustain quarter-over-quarter revenue growth with improving margins for the foreseeable future," said Adam Grossman, President and Chief Executive Officer of ADMA.

"Less than two years into ADMA's commercial launch of its intravenous immune globulin ("IVIG") product portfolio, the Company generated record quarterly revenues of \$17.8 million, representing an increase of 129% year-over-year. This top-line growth is particularly impressive in light of the pandemic-related headwinds that continue to persist throughout the product launch period, which impacted industry supply chains and limited engagement with physicians and providers. Additionally, these results do not reflect the substantial benefits anticipated from the recently approved BIVIGAM® expanded production scale, increasing our facility's total annual peak production capacity from 400,000 liters to 600,000 liters, as well as the expected approval of the VanRx SA25 Workcell aseptic fill-finish machine ("VanRx") in the second half of 2021. We are confident that our underlying business trends have demonstrated strength and resilience year-to-date and can continue improving in the second half of 2021 and beyond as operating efficiencies materialize and production ramp-up further progresses.

"ADMA has also seen a substantial strengthening of its supply chain in the first half of the year. The recent receipt of zero Form 483 observations as a part of the pre-approval inspection ("PAI") for the VanRx machine paves the way for an anticipated approval over the coming months. When approved, it will cap a multi-year remediation and end-to-end supply chain initiative at the Boca Raton, FL manufacturing facility, and will propel ADMA into an elite group of U.S.-based drug manufacturers with comprehensive in-house control of a majority of its critical manufacturing functions.

"The ADMA BioCenters team, through its year-to-date accomplishments, has made significant strides towards ensuring uninterrupted raw material plasma supply. The enhanced yield anticipated from the recent implementation of Haemonetics' Persona® technology, the extension of the Company's primary third-party plasma supply contract to the end of 2022 and the continued expansion of the BioCenters plasma collection network establishes a solid foundation for ADMA to ensure continuity of product supply into an increasingly supply-constrained immune globulin market. With the current industry-wide pressures on plasma collection operations, ADMA's strategic emphasis on building an internal collection network and solidifying third-party supplemental supply should yield significant returns in the periods ahead and largely insulate the Company from supply and pricing fluctuations.

"Over the past 4 years, ADMA has also been diligently building a vertically integrated commercial biologics manufacturing organization since acquiring its manufacturing facility and assets in June 2017 and is now successfully emerging from its multi-year investment, regulatory and remediation phase. The majority of substantive investments are now in the rearview, the wholly owned manufacturing plant is now fully remediated and collectively, positions the Company to meet or exceed all longer-term financial targets. These accomplishments could not have been realized without the dedication and focus of ADMA's staff, leadership and advisors. We commend the entire team for their extraordinary efforts focused on improving healthcare for U.S. patients," concluded Mr. Grossman.

Select Second Quarter 2021 Achievements & Recent Corporate Developments:

- **Continued Commercial Execution:** Achieved second quarter 2021 total revenues of \$17.8 million, compared to \$7.8 million for the second quarter of 2020, reflecting a 129% increase.
- Successful PAI Paves the Way for Second Half 2021 VanRx Approval. We anticipate the successfully completed PAI, during which the U.S. Food and Drug Administration (FDA) issued no Form 483 observations, will facilitate a VanRx approval over the coming months. In addition to the significant operating efficiencies expected to result from the expected VanRx approval, the fill-finish capabilities will propel ADMA into an elite class of U.S. drug manufacturers with complete end-to-end control of critical manufacturing functions. As previously stated, we are actively evaluating new business opportunities with these fill-finish capabilities and intend to update the market as appropriate.
- On Track BioCenters Network Expansion. ADMA currently has eight plasma collection facilities under its corporate umbrella at various stages of approval and development, including five facilities that are currently operational and collecting plasma. The Company 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 receiving approval for one facility presently pending a Biologics License Application ("BLA") and expects to file BLAs for two additional plasma collection centers.

• Expanded Suite of IG Product Offerings with Introduction of Additional Vial Sizes. The availability of the additional NABI-HB® and BIVIGAM® vial sizes meaningfully enhance ADMA's go-to-market offering for its immunoglobulin product portfolio and allows for more versatile utilization by providers and patients.

Second Quarter 2021 Financial Results

Total revenues for the quarter ended June 30, 2021, were approximately \$17.8 million, compared to approximately \$7.8 million for the quarter ended June 30, 2020, representing an increase of approximately \$10.0 million, or 129%. The revenue growth for the quarter ended June 30, 2021, compared to the quarter ended June 30, 2020, was favorably impacted by the continued commercial ramp-up of ADMA's IVIG product portfolio.

Consolidated net loss for the quarter ended June 30, 2021 was approximately \$18.9 million, or \$(0.15) per basic and diluted share, compared to a consolidated net loss of approximately \$20.2 million, or \$(0.23) per basic and diluted share, for the quarter ended June 30, 2020. The \$1.3 million narrowing in net loss compared to the prior year period was primarily attributable to increased revenues and improved gross margins. The net loss incurred during the second quarter of 2021 includes a one-time, non-recurring charge related to a separation and transition agreement in the amount of approximately \$0.8 million.

At June 30, 2021, ADMA had cash and cash equivalents of approximately \$42.4 million and accounts receivable of approximately \$23.5 million, compared to cash and cash equivalents of approximately \$75.8 million and accounts receivable of approximately \$6.5 million as of June 30, 2020. ADMA's net working capital as of June 30, 2021 was approximately \$153.2 million, compared to approximately \$130.1 million as of June 30, 2020.

Conference Call Information

ADMA will host a conference call today, August 11, 2021, at 4:30 p.m. Eastern Time, to discuss the fiscal second 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 8992329. 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 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 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 a 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 is an end-to-end American commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasmaderived 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 our expected revenue run rates, meaningful gross margin improvement and operating efficiencies; the impact of COVID-19 on the Company's financial results and business operations; expected benefits from the VanRx aseptic fill-finish machine, including cost efficiencies and contract manufacturing opportunities; the anticipated benefits from the recent implementation of Haemonetics' Persona® technology combined with our plasma collection network; BIVIGAM®'s 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 approval of our VanRx aseptic fill-finish machine; and the expected benefits of additional NABI-HB® and BIVIGAM® vial sizes. 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.

COMPANY CONTACT:

Skyler Bloom

Director, Investor Relations and Corporate Strategy | 201-478-5552 | sbloom@admabio.com

INVESTOR RELATIONS CONTACT:

Michelle Pappanastos

Senior Managing Director, Argot Partners | 212-600-1902 | michelle@argotpartners.com



ADMA BIOLOGICS, INC. AND SUBSIDIARIES

$\frac{\textbf{CONSOLIDATED STATEMENTS OF OPERATIONS}}{(\underline{\textbf{Unaudited}})}$

	Three Months E	Three Months Ended June 30,		
	2021	2020		
REVENUES:				
Product revenue	\$ 17,794,881	\$ 7,751,885		
License revenue	35,709	35,709		
Total revenues	17,830,590	7,787,594		
OPERATING EXPENSES:				
Cost of product revenue (exclusive of amortization expense shown below)	18,832,624	13,495,629		
Research and development	1,158,866	1,656,420		
Plasma center operating expenses	2,803,326	877,902		
Amortization of intangible assets	178,838	178,838		
Selling, general and administrative	10,438,168	8,702,630		
Total operating expenses	33,411,822	24,911,419		
LOSS FROM OPERATIONS	(15,581,232)	(17,123,825)		
OTHER INCOME (EXPENSE):				
Interest income	5,926	19,411		
Interest expense	(3,246,680)	(3,067,306)		
Other expense	(83,317)	(6,371)		
Other expense, net	(3,324,071)	(3,054,266)		
NET LOSS	\$ (18,905,303)	\$ (20,178,091)		
BASIC AND DILUTED LOSS PER COMMON SHARE	\$ (0.15)	\$ (0.23)		
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic and Diluted	127,416,126	86,347,467		

ADMA BIOLOGICS, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(<u>Unaudited)</u>

	June 30, 		December 31, 2020	
ASSETS		_		
Current assets:				
Cash and cash equivalents	\$	42,408,958	\$	55,921,152
Accounts receivable, net		23,544,594		13,237,290
Inventories		99,699,743		81,535,599
Prepaid expenses and other current assets		5,701,863		3,046,466
Total current assets		171,355,158		153,740,507
Property and equipment, net		46,486,980		41,593,090
Intangible assets, net		2,086,445		2,444,121
Goodwill		3,529,509		3,529,509
Right to use assets		6,829,040		4,259,191
Deposits and other assets	_	2,526,660		2,106,976
TOTAL ASSETS	\$	232,813,792	\$	207,673,394
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	6,167,465	\$	11,073,708
Accrued expenses and other current liabilities	Ψ	11,490,239	Ψ	8,365,143
Current portion of deferred revenue		142,834		142,834
Current portion of lease obligations		385,858		365,682
Total current liabilities	_	18,186,396		19,947,367
Senior notes payable, net of discount		93,877,017		92,968,866
Deferred revenue, net of current portion		2,047,281		2,118,698
Lease obligations, net of current portion		7,073,415		4,334,151
Other non-current liabilities		36,151		54,886
TOTAL LIABILITIES		121,220,260		119,423,968
	_	111,110,100		110, 120,000
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, 300,000,000 and 150,000,000 shares authorized, 131,872,026 and		_		_
104,902,888 shares issued and outstanding		13,187		10,490
Additional paid-in capital		489,330,692		428,704,039
Accumulated deficit		(377,750,347)	((340,465,103)
TOTAL STOCKHOLDERS' EQUITY		111,593,532		88,249,426
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	232,813,792	\$	207,673,394