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): January 19, 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):

☐ 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

Item 2.02 Results of Operations and Financial Condition.

On January 19, 2021, ADMA Biologics, Inc. (the "Company") issued a press release announcing its preliminary unaudited fourth quarter and full year 2020 revenues. The Company's press release also provided commercial updates for its immune globulin product portfolio, as well as introduced the Company's 2021 strategic and operational outlook. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company, dated January 19, 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.

January 19, 2021

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

ADMA Biologics Announces Preliminary Fourth Quarter and Full Year 2020 Revenues and Provides 2021 Strategic Outlook

Achieved Fourth Quarter 2020 Preliminary Unaudited Total Revenues of $13.9 Million, the Highest Revenue Quarter for the Company Since Inception

Full Year 2020 Preliminary Unaudited Total Revenues of $42.2 Million, a 44% Increase Over Full Year 2019

Multiple Value-Creating FDA Decisions Across All Business Segments Anticipated in 2021 Are Expected to Enhance the Supply Chain, Increase Product Yields and Improve Margins for Revenue Generating Products

RAMSEY, N.J. and BOCA RATON, Fla., January 19, 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 announced its preliminary unaudited fourth quarter and full year 2020 revenues. The Company also provided commercial updates for its immune globulin product portfolio, as well as introduced its 2021 strategic and operational outlook.

Fourth Quarter and Full Year 2020 Highlights

- Achieved record fourth quarter 2020 preliminary unaudited revenues of $13.9 million, compared to $12.0 million during the fourth quarter of 2019, reflecting a 16% increase. The preliminary results for the fourth quarter of 2020 represent the Company's highest revenue generating quarter since its inception.

- Full year 2020 preliminary unaudited total revenues of $42.2 million, compared to $29.3 million for the full year 2019, reflecting a substantial 44% increase over full year 2019.

"We are extremely pleased with our preliminary record fourth quarter and full year 2020 revenue results. ADMA's continued execution through COVID-19 headwinds is a testament to our organization's unwavering commitment to provide patients with products to ensure the continuity of care. Our 2020 full year operating results, we believe, will ultimately unlock significant value for ADMA shareholders," said Adam Grossman, ADMA's President and Chief Executive Officer. "2021 is poised to be a transformative year for ADMA as we continue to execute on our mission of providing specialty immune globulin products to patients and building a highly profitable, end-to-end biologics manufacturing company."

Mr. Grossman continued, “Throughout 2021 and beyond, we anticipate delivering ongoing quarter-over-quarter revenue growth. We also anticipate realizing robust operating efficiencies as early as mid-2021, pending United States Food and Drug Administration (FDA) decisions regarding ADMA’s submissions for its supply chain enhancement initiatives, most notably consisting of our Intravenous Immune Globulin (IVIG) production scale increase and for our in-house aseptic fill-finish production line. Additionally, we expect to potentially obtain FDA approvals in 2021 for two new plasma collection centers located in Knoxville and Maryville, TN as well as file Biologics License Applications (BLAs) for an additional two plasma collection centers. COVID-19 notwithstanding, ADMA remained on track in 2020 and achieved all its stated 2020 strategic and operating objectives. We anticipate 2021 will be another year of achieving value-creating milestones, including executing on the ongoing production ramp up and inventory build to support annual revenue generation in excess of $250 million by 2024 which will provide for substantial profitability.”

ADMA executed on all of its 2020 strategic objectives, including:

- Navigated COVID-19 operating headwinds evidenced by preliminary total revenues of approximately $42.2 million generated for the first full calendar year of commercialization, in addition to significantly building inventory balances throughout the year, establishing a solid basis for continued quarter-over-quarter revenue growth.

- Expanded ADMA BioCenters’ plasma collection center network on schedule with the construction of two new collection centers which are currently operational and collecting plasma, as well as initiated the establishment of three additional collection centers. The Company currently has six plasma collection centers under its corporate umbrella at various stages of approval and development.

- Refinanced ADMA’s senior secured term loan with Perceptive Advisors, which among other things, consolidated ADMA’s long term debt and provided for a two year extension of the interest-only period through March 2024, which we believe will allow ADMA to reach profitability prior to maturity. As part of the refinancing transaction, the Company negotiated a $1 million principal reduction to the payoff of ADMA’s subordinated debt facility prior to maturity without any prepayment penalty.

- Advanced supply chain enhancements and capacity expansion initiatives in-line with Company provided timelines and maintained anticipated regulatory decisions and FDA interactions.

- Expanded the Company’s IP portfolio with new patents and developed the ImmunoRank™ Neutralization MICRO-ELISA to detect the presence and levels of COVID-19 antibodies.

- Entered into a manufacturing and supply agreement to produce and sell plasma-derived intermediate fractions which is expected to contribute $10-20 million in revenues at full scale.

- Hosted an exclusive educational event at IDWeek 2020 on respiratory viral infections and novel treatment modalities, as well as presented new data on *Streptococcus pneumonia* in an on-demand poster session.

ADMA is focused on the following key strategic priorities in 2021:

- Generate ongoing quarter-over-quarter and year-over-year revenue growth throughout 2021 and beyond as the Company progresses towards achieving profitability with peak revenues of $250 million or greater by 2024.

- Continue building ADMA's inventory balance to support anticipated ongoing revenue growth and solidify ADMA's position as a reliable supplier for the growing U.S. immune globulin marketplace ultimately ensuring the continuity of immune globulin supply for our patients and customers.

- Complete certain supply chain enhancements and capacity expansion programs as early as mid-2021. Once FDA approved, the Company's newly installed fill-finish machine as well as the IVIG manufacturing scale increase should allow ADMA to realize significant operating efficiencies and improved gross margins beginning potentially as early as mid-2021. These projects will ultimately position the Company to be fully vertically integrated with in-house control over the Company's most critical manufacturing functions.

- Expand ADMA's plasma collection center network to achieve the goal of building up to 10 plasma collection centers in the U.S. by 2024. During 2021, ADMA expects two regulatory approval decisions for the Company's Knoxville and Maryville, TN plasma collection centers. ADMA also anticipates filing BLAs for two additional plasma collection centers during 2021.

Fourth Quarter and Full Year 2020 Financial Results Conference Call

ADMA plans to host a conference call and webcast to discuss its fourth quarter and full year 2020 financial results during the first quarter of 2021 in conjunction with filing its Annual Report on Form 10-K, which is expected to be filed with the U.S. Securities and Exchange Commission in the first quarter of 2021.

The financial information included in this press release is preliminary, unaudited and subject to adjustment. It does not present all information necessary for an understanding of the Company's fourth quarter and full year financial results for 2020.

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 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 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. ("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; timing of revenue and profitability; execution of corporate objectives and achievement of goals, including but not limited to, the Company's key strategic priorities for 2021; receipt of future regulatory approvals; realization of shareholder value; and future appreciation of the asset value of manufactured plasma and plasma collection centers. 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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