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 8, 2024

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 8, 2024, ADMA Biologics, Inc. (the "Company") issued a press release announcing the Company's preliminary unaudited fourth quarter and full year 2023 revenues and providing a business update.*

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	ADMA Biologics, Inc. Press Release, dated January 8, 2024
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 8, 2024

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

Exhibit 99.1

ADMA Biologics Announces Preliminary Fourth Quarter 2023 Revenue and Provides Business Update

4Q 2023 Preliminary Unaudited Total Revenue of $72-74 Million

FY 2023 Preliminary Unaudited Total Revenue of $256-258 Million

FY 2024 and 2025 Total Revenue Guidance Increased to More than $320 Million and $370 Million, Respectively

FY 2024 Net Income Expected to Exceed $60 Million and Adjusted EBITDA(1) Expected to be $85 Million

Growth Opportunities Targeting Manufacturing and New Pipeline Hyperimmune Globulin to Advance During 2024

RAMSEY, N.J. and BOCA RATON, FL, January 8, 2024 - ADMA Biologics, Inc. (Nasdaq: ADMA) ("ADMA" or the "Company"), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty biologics, today announced its preliminary unaudited fourth quarter and full year 2023 revenues and provided a business update. Based on unaudited financial information, ADMA preliminarily estimates that its total revenue for the quarter- and year-ended December 31, 2023 will be between $72 million and $74 million and $256 million and $258 million, respectively.

"Entering 2024 from a position of strength, we're increasing both top and bottom-line financial guidance due to robust business trends and strong forward-looking product demand indicators. Additionally, we've identified new growth opportunities that we believe have the potential to approximately double currently provided peak revenue and earnings by the end of this decade," said Adam Grossman, President and Chief Executive Officer of ADMA. "These growth opportunities, such as manufacturing yield enhancement and the commencement of pre-clinical development for our new *S. pneumonia* hyperimmune pipeline program, are expected to be capital-efficient and will not impact the upwardly revised 2024-2025 profitability guidance."

Mr. Grossman continued, "We anticipate 2024 will be defined by continued top tier revenue and earnings growth, commitment to capital allocation strategies that we believe will maximize stockholder value, and further de-risking growth initiatives that have the potential to provide transformative upside to ADMA's currently provided peak revenue and earnings potential. The combination of our continued success with ASCENIV and BIVIGAM, in addition to the potential contribution from new growth opportunities, we believe positions us to continue to make a difference in patients' lives and generate durable top and bottom-line growth for years to come."

2024-2025 Financial Guidance:

- FY 2024-2025 Total Revenue expected to be in the range of $320 Million to $370 Million, respectively, increased from $290 Million and $335 Million previously.
- FY 2024-2025 Net Income expected to exceed $60 Million to $110 Million, respectively, increased from $55 Million and $100 Million previously.
- FY 2024 Adjusted EBITDA anticipated to reach $85 Million or more.

(1) Adjusted EBITDA is a non-GAAP financial measure. The estimated Adjusted EBITDA amounts included herein are preliminary and reconciliations cannot be produced at this time without unreasonable effort. The Company expects to provide a reconciliation of Adjusted EBITDA to the most comparable GAAP measure in its earnings release relating to the fourth quarter and full year 2023 financial results.

New Growth Opportunities: These initiatives, if successful, represent upside to newly provided guidance ranges:

Biologic Production Yield Enhancement: The Company continues to make progress with development scale and laboratory analyses, advancing ADMA's initiative to capture additional IG production yields with the same quantities of starting raw material. These initiatives are subject to further evaluation, validation of commercial-scale production and requisite regulatory review. If proven successful, these yield enhancements will potentially provide significant upside to the Company's peak financial targets.

New Pipeline Introduction - *S. pneumonia* Hyperimmune Globulin:

- *S. pneumonia* is the predominant cause of community-acquired pneumonia (CAP) in the United States, ranking as the ninth leading cause of overall mortality. We believe the strategic importance and unmet need are evident in both the prophylactic and therapeutic settings where documented anti-infective resistance is on the rise. Annually, approximately one million U.S. adults contract pneumococcal pneumonia, resulting in 400,000 hospitalizations and a 5-7% mortality rate, of which approximately 7,000 deaths annually are attributable to anti-infective resistance. Despite vaccine availabilities, vaccine-naive and immune-compromised patient populations remain at risk and could potentially benefit from the immediately available neutralizing antibodies conferred with a hyperimmune globulin in both the in-patient and out-patient treatment settings. We estimate that an *S. pneumonia* hyperimmune globulin, if approved, has the potential to generate peak revenue of $300-500 Million.
- ADMA holds multiple U.S. and foreign patents and patent applications encompassing various aspects of its proprietary pneumococcal hyperimmune technology. These include U.S. Patent Nos. 10,259,865 and 11,084,870, EP Patent No. 3375789, and other patents, each with patent term through 2037, as well as numerous pending U.S. and foreign applications. Issued and pending claims encompass ADMA's hyperimmune anti-pneumococcal immune globulin, methods of preparing the immune globulin, and methods of using the immune globulin (e.g., to treat *S. pneumonia* infection or to provide immunotherapy to a patient).

ASCENIV Label Expansion: The ongoing post-marketing pediatric clinical study for ASCENIV is progressing and may provide label expansion opportunities, further strengthening ADMA's product portfolio compared to peers, if successful.

About ASCENIV™

ASCENIV (immune globulin intravenous, human – slra 10% liquid) is a plasma-derived, polyclonal, intravenous immune globulin (IVIG). ASCENIV was approved by the United States Food and Drug Administration (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 can be found by visiting www.asceniv.com. Information about ADMA and its products can be found on the Company's website at www.admabiologics.com.

Additional Important Safety Information About ASCENIV™

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

Thrombosis may occur with immune globulin intravenous (IGIV) products, including ASCENIV. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.

Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with the administration of IGIV products in predisposed patients.

Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. ASCENIV does not contain sucrose.
For patients at risk of thrombosis, renal dysfunction or renal failure, administer ASCENIV at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

ASCENIV™ Contraindications:

History of anaphylactic or severe systemic reactions to human immunoglobulin.

IgA deficient patients with antibodies to IgA and a history of hypersensitivity.

ASCENIV™ Warnings and Precautions:

IgA-deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions. Have medications such as epinephrine available to treat any acute severe hypersensitivity reactions. [4, 5.1]

Thrombotic events have occurred in patients receiving IGIV treatments. Monitor patients with known risk factors for thrombotic events; consider baseline assessment of blood viscosity for patients at risk of hyperviscosity. [5.2, 5.4]

In patients at risk of developing acute renal failure. monitor renal function, including blood urea nitrogen (BUN), serum creatinine, and urine output. [5.3, 5.9]

Hyperproteinemia, increased serum viscosity, and hyponatremia or pseudohyponatremia can occur in patients receiving IGIV treatment.

Aseptic meningitis syndrome (AMS) has been reported with IGIV treatments, especially with high doses or rapid infusion. [5.5]

Hemolytic anemia can develop subsequent to IGIV treatment. Monitor patients for hemolysis and hemolytic anemia. [5.6]

Monitor patients for pulmonary adverse reactions (Transfusion-related acute lung injury [TRALI]). If transfusion related acute lung injury is suspected, test the product and patient for antineutrophil antibodies. [5.7]

Because this product is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

ASCENIV™ Adverse Reactions:

The most common adverse reactions to ASCENIV (≥5% of study subjects) were headache, sinusitis, diarrhea, gastroenteritis viral, nasopharyngitis, upper respiratory tract infection, bronchitis, and nausea

To report SUSPECTED ADVERSE REACTIONS, contact ADMA Biologics at (800) 458-4244 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty 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 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 holds numerous U.S. and foreign patents related to and encompassing various 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," "is likely," "will likely," "should," "could," "would," "may," or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements include, but are not limited to, statements about the Company's fourth quarter and full-year 2023 total revenue; revenue, net income and Adjusted EBITDA guidance in future periods; additional growth opportunities; and statements regarding the effectiveness and revenue potential for the Company's newly announced hIG pipeline program targeting S. pneumonia. 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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