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): March 23, 2023

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))

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

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 March 23, 2023, ADMA Biologics, Inc. issued a press release announcing its financial results for the three months and year ended December 31, 2022 and providing a business update. 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 March 23, 2023
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.

March 23, 2023

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

Exhibit 99.1

ADMA Biologics Announces Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

4Q2022 Total Revenues of $50 Million, a 90% Y-o-Y Increase

4Q2022 Gross Profit of $14 Million, an $11 Million Y-o-Y Increase

FY 2023 Total Revenue Expected to Exceed $210 Million

First-Time Positive EBITDA Expected No Later than Second Half of 2023

Conference Call Scheduled for Today at 4:30 p.m. ET

RAMSEY, N.J. and BOCA RATON, Fla., March 23, 2023 -- 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 fourth quarter and full year 2022 financial results and provided a business update.

"We achieved year-over-year revenue growth of 90% during 2022, advancing ADMA's position as the fastest growing provider of Immunoglobulin (IG) in the U.S. market. We believe our continued commercial success is in large part attributable to ADMA's exclusive focus on targeting the immune deficient patient segment, the fastest growing cohort in the IG market, where we treated a record number of patients and achieved strong market share gains. We believe our innovative business model and success in this subsector position us well for the future," said Adam Grossman, President and Chief Executive Officer of ADMA.

Mr. Grossman continued, "We remain highly committed to driving profitability in the periods ahead and have now identified several opportunities to potentially grow peak revenues and earnings to levels exceeding prior guidance. The persistence of encouraging business trends since the start of 2023 gives us confidence in our ability to meet or potentially exceed previously provided financial targets. We anticipate 2023 to be an inflection point for ADMA: our organization aims to sustain top-tier revenue growth, achieve first-time EBITDA profitability and shortly thereafter, solidify the pathway to an ultimate margin profile at the upper bound of ADMA's plasma peer group."

2023 Milestones & Objectives:

- **Unlock New Growth Opportunities:** ADMA has identified several growth opportunities that can potentially increase revenue and improve margins beyond previously provided financial targets. With an unwavering emphasis on achieving near term profitability, the incremental investments required to pursue these initiatives are not significant and are not expected to impact ADMA's strong funding position.
    - **Expanded ASCENIV Production Scale:** In 2023, ADMA will commence manufacturing of ASCENIV at the 4,400 Liter production scale for the first time in corporate history. We expect that this expansion should meaningfully improve the product's margin profile and increase plant production capacity as fewer batches will be needed to support revenue goals. The Company's successful experience in ramping up BIVIGAM to this production scale over the last two years lends confidence to its ability to leverage these same processes for ASCENIV. We believe these benefits could be realized as early as the second half of 2023.

- **Yield Enhancement Opportunities:** The Company is pursuing new initiatives to capture additional IG production yields, which could meaningfully increase both peak revenues as well as margin potential if successful.

- **Label Expansion:** The ongoing post-marketing clinical studies may provide for label expansion opportunities for both BIVIGAM and ASCENIV to include pediatric-aged PI patients as well as additional publications supporting product safety.

- **Accelerated Sales of Legacy, Lower Margin BIVIGAM.** ADMA's estimated fourth quarter 2022 corporate gross margins would have been approximately 200-300 basis points higher if the impact of selling lower margin, 2,200-liter scale BIVIGAM were excluded. At the midpoint, the estimated operating loss for the quarter would have been approximately $4.7 million, which is 64% improved compared to the prior year's fourth quarter when accounting for transient gross margin dynamics amounting to approximately $1.3 million. Due to record product demand, ADMA expects to monetize a substantial portion of the remaining lower margin inventory in the first quarter of 2023, incrementally earlier than previous expectations of mid-year 2023.

- **Product Mix Continues to Favorably Evolve:** ASCENIV's prescriber and patient base continued to expand during the fourth quarter of 2022, which drove record utilization and pull-through for the product. These elevated demand trends have sustained into 2023, and ADMA currently expects the product's rapid growth will continue throughout 2023 and beyond.

- **On-Track BioCenters Expansion:** The Company's BioCenters segment now has eight U.S. Food and Drug Administration (FDA)-licensed collection centers with two additional centers operational and collecting plasma pending FDA licensure. The Company remains on track to have all ten BioCenters FDA-licensed by year-end 2023 and, in the same period, forecasts raw material plasma supply self-sufficiency. ADMA anticipates its strong plasma supply position will support its upwardly revised production and revenue forecasts.

- **Ongoing Strategic Review.** ADMA continues to evaluate a variety of strategic alternatives through its ongoing engagement with Morgan Stanley. The exploration of value-creating opportunities remains a top corporate priority for ADMA.

2023 & Long-Term Financial Guidance:

- **2023 Financial Guidance:** ADMA anticipates full year 2023 total revenues to exceed $210 million. As a result, ADMA anticipates generating first-time positive EBITDA no later than the second half of 2023. The guidance framework considers several macroeconomic uncertainties; however, should ADMA's current demand trends and margin dynamics sustain, accelerated profitability timelines may be achievable.

- **2024-2025 Financial Guidance:** The Company anticipates generating approximately $250 million or more in topline revenue in 2024, and approximately $300 million or more thereafter. At these revenue levels, ADMA forecasts achieving corporate gross margins in the range of 40-50% and net income margins in the range of 20-30%. These assumptions translate to potential annual gross profit and net income in the range of $100-150 million and $50-100 million, respectively, during the 2024-2025 time period and beyond.

Fourth Quarter 2022 Financial Results:

Total revenues for the quarter ended December 31, 2022 were $50.0 million, as compared to $26.4 million during the fourth quarter of 2021, an increase of $23.6 million, or approximately 90%. The revenue growth for the fourth quarter of 2022, compared to the fourth quarter of 2021, was favorably impacted by the continued commercial ramp-up of the Company's intravenous immune globulin (IVIG) product portfolio and the expanding customer base for BIVIGAM and ASCENIV.

Gross profit for the fourth quarter of 2022 was $14.2 million, compared to gross profit of $3.5 million for the fourth quarter of 2021. Gross profit growth during the fourth quarter was driven by a favorable contribution from ASCENIV. Partially offsetting the favorably evolving product mix, ADMA sold a significant amount of the remaining 2,200-liter scale, lower margin BIVIGAM product during the fourth quarter of 2022. Moving forward, this lower margin inventory is anticipated to be exhausted over the coming months, and production throughput and sales recognition is anticipated to be confined exclusively to the higher margin 4,400-liter BIVIGAM product, along with ASCENIV.

Consolidated net loss for the quarter ended December 31, 2022 was $12.2 million, or $(0.06) per basic and diluted share, compared to a consolidated net loss of $16.6 million, or $(0.09) per basic and diluted share, for the quarter ended December 31, 2021. Net loss decreased by approximately $4.4 million compared to the fourth quarter of 2021, primarily attributable to the higher gross profit driven by sales of ASCENIV.

Full Year 2022 Financial Results:

Total revenues for the year ended December 31, 2022 were $154.1 million, as compared to $80.9 million during the year ended December 31, 2021, an increase of $73.1 million, or approximately 90%. The increase is mainly due to increased sales of our immunoglobulin products and intermediate fractions generated by our Boca Raton, FL manufacturing operations in 2022 totaling $69.2 million. The Company also experienced a $4.0 million increase in plasma revenues generated by its Plasma Collection Centers business segment due to increased sales of source plasma through spot market opportunities beyond its long-term supply agreement.

Consolidated net loss was $65.9 million for the year ended December 31, 2022, as compared to $71.6 million for the year ended December 31, 2021. The decrease in net loss of $5.7 million was mainly due to the decrease in operating loss, largely offset by the higher interest expense and loss on extinguishment of debt resulting from the refinancing of our senior credit facility in March of 2022.

As of December 31, 2022, ADMA had working capital of approximately $231.0 million, primarily consisting of $163.3 million of inventory, $86.5 million of cash, and cash equivalents and $15.5 million of net accounts receivable, partially offset by an aggregate of $38.3 million of accounts payable and accrued expenses.

Conference Call Information
To access the conference call on March 23, 2023 at 4:30 PM ET, participants may register for the call here to receive the dial-in numbers and unique PIN to access the call seamlessly. It is recommended that you join 10 minutes prior to the event starting (although you may register and dial in at any time during the call). 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 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 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 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 cGMP (current good manufacturing practices) in all of its facilities. For more information about ADMA BioCenters, please visit www.admabiocenters.com.

About Primary Immunodeficiency Disease (PI) or Inborn Errors of Immunity (IEI)

PI or IEI are a class of inherited genetic disorders that causes an individual to have a deficient or absent immune system due to either a lack of necessary antibodies or a failure of these antibodies to function properly. PI has an estimated prevalence of 1:1,200 in the United States, or approximately 250,000 people. According to the World Health Organization, there are over 400 different presentations of PI.

PI patients are more vulnerable to infections and more likely to suffer complications from these infections. As patients suffering from PI lack a properly functioning immune system, they typically receive monthly, outpatient infusions of IVIG therapy. Without this exogenous antibody immune support, these patients would be susceptible to a wide variety of infectious diseases.

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: 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 and European Patent No. 3375789, among others, related to certain aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

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, "our", "ADMA" 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 "anticipates," "believes," "could," "can," "estimates," "expects," "forecasts," "intends," "may," "plans," "predicts," "projects," "should," "targets," "will," "would," 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 and pro forma results, as well as certain underlying assumptions in connection therewith; the success of BIVIGAM® and ASCENIV™ in future periods, including certain opportunities for such products; the production scale of BIVIGAM and ASCENIV; future growth opportunities; the timeline associated with profitability; the ability to obtain FDA approval of our ninth and tenth plasma collection centers and the associated timing in connection therewith; and the ability to achieve source plasma self-sufficiency and the associated timing in connection therewith, as well as benefits thereof. 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 SEC, 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 December 31,		Years Ended December 31,	
	2022	2021	2022	2021
REVENUES:				
Product revenue	$ 49,945,746	$ 26,347,158	$ 153,936,858	$ 80,799,791
License revenue	35,709	35,709	142,834	142,834
Total revenues	49,981,455	26,382,867	154,079,692	80,942,625
Cost of product revenue	35,804,379	22,871,382	118,814,535	79,769,341
Gross profit	14,177,076	3,511,485	35,265,157	1,173,284
OPERATING EXPENSES:				
Research and development	1,074,320	728,988	3,613,764	3,646,060
Plasma center operating expenses	5,087,571	4,096,833	17,843,096	12,288,723
Amortization of intangible assets	178,839	178,839	715,353	715,353
Selling, general and administrative	13,894,888	11,698,009	52,458,024	42,896,889
Total operating expenses	20,235,618	16,702,669	74,630,237	59,547,025
LOSS FROM OPERATIONS	(6,058,542)	(13,191,184)	(39,365,080)	(58,373,741)
OTHER INCOME (EXPENSE):				
Interest income	2,260	2,291	44,833	34,532
Interest expense	(5,736,954)	(3,315,724)	(19,279,373)	(13,056,834)
Loss on extinguishment of debt	-	-	(6,669,941)	-
Other expense	(438,447)	(144,803)	(634,389)	(251,575)
Other expense, net	(6,173,141)	(3,458,236)	(26,538,870)	(13,273,877)
NET LOSS	$ (12,231,683)	$ (16,649,420)	$ (65,903,950)	$ (71,647,618)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.06)	$ (0.09)	$ (0.33)	$ (0.51)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic and Diluted	202,830,446	180,813,817	197,874,895	139,578,538

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 86,521,542	$ 51,089,118
Accounts receivable, net	15,505,048	28,576,857
Inventories	163,280,047	124,724,091
Prepaid expenses and other current assets	5,095,146	4,339,245
Total current assets	270,401,783	208,729,311
Property and equipment, net	58,261,481	50,935,074
Intangible assets, net	1,013,415	1,728,768
Goodwill	3,529,509	3,529,509
Right to use assets	10,485,447	7,262,658
Deposits and other assets	4,770,246	4,067,404
TOTAL ASSETS	$ 348,461,881	$ 276,252,724
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 13,229,390	$ 12,429,409
Accrued expenses and other current liabilities	24,989,349	17,214,988
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	905,369	591,084
Total current liabilities	39,266,942	30,378,315
Senior notes payable, net of discount	142,833,063	94,866,239
Deferred revenue, net of current portion	1,833,031	1,975,865
End of term fee	1,500,000	-
Lease obligations, net of current portion	10,704,176	7,462,388
Other non-current liabilities	350,454	397,351
TOTAL LIABILITIES	196,487,666	135,080,158
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 shares authorized, 221,816,930 and 195,813,817 shares issued and outstanding	22,182	19,581
Additional paid-in capital	629,968,704	553,265,706
Accumulated deficit	(478,016,671)	(412,112,721)
TOTAL STOCKHOLDERS' EQUITY	151,974,215	141,172,566
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 348,461,881	$ 276,252,724