**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): November 9, 2022

# 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 November 9, 2022, ADMA Biologics, Inc. issued a press release announcing its financial results for the three months ended September 30, 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 November 9, 2022 |
| 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.

November 9, 2022

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz
Title: Executive Vice President and
Chief Financial Officer

**Exhibit 99.1**

*ADMA Biologics Announces Third Quarter 2022 Financial Results and Provides Business Update*

*3Q2022 Total Revenues Were $41.1 Million, a 99% Y-o-Y Increase*

*Grew 3Q2022 Gross Profit to $9.7 Million, a $9.3 Million Y-o-Y Increase*

*Raising FY 2022 Total Revenue Guidance to $145 Million From $130 Million Previously*

*Gross Profit Growth and Narrowing Net Losses Expected into 2023*

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

**RAMSEY, N.J. and BOCA RATON, Fla., November 9, 2022** -- 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 third quarter 2022 financial results and provided a business update.

"We are pleased to again be raising revenue guidance for full-year 2022; the Company now expects to generate total revenue of approximately $145 million, increased from $130 million as previously provided. We believe that the third quarter revenue growth of 99% year-over-year establishes a strong foundation from which ADMA will continue to generate substantial revenue growth and improve margins as we accelerate towards corporate profitability," said Adam Grossman, President and Chief Executive Officer of ADMA.

Mr. Grossman continued, "Enabled by this continued revenue growth, we opportunistically undertook several investments during the quarter which we believe will strengthen commercial initiatives, advance growth opportunities and enhance margins moving forward. Research and development expenditures increased due to accelerated enrollment of the post-marketing clinical study for BIVIGAM. We believe the rapid pace of enrollment and investigator excitement speaks to the reputation ADMA and its products have established in the market. Additionally, during the quarter, we mobilized a robust medical education and conference symposia strategy which is anticipated to solidify ASCENIV's growth outlook and further expand the product's growing customer base to areas not yet penetrated."

"While we are pleased with our reported gross profit expansion, it is important to note that a substantial portion of BIVIGAM revenues during the third quarter consisted of legacy 2,200-liter scale product, which yields a significantly lower margin compared to the current 4,400-liter batch production scale," said Brian Lenz, ADMA's Chief Financial Officer, and General Manager, ADMA BioCenters. "BIVIGAM inventory at the 2,200-liter scale sold during this quarter was produced during 2021, prior to the Company receiving FDA approval of the 4,400L-liter scale production. Encouragingly, ADMA has been exclusively producing BIVIGAM at the 4,400-liter scale since the second half of 2021. The residual, lower margin inventory produced at the 2,200-liter scale is anticipated to be fully exhausted over the coming quarters and once sold, we believe our profit margins will substantially improve."

Mr. Grossman concluded, “As we look to 2023, we believe ADMA is well-positioned in its advancement towards profitability. The immunoglobulin (“IG”) end market remains one of the fastest growing segments in the pharmaceutical sector, and we are proud to have clearly demonstrated ADMA’s staying power within this landscape. The pieces are in place for ADMA to sustain its best-in-class revenue growth profile and deliver on our longstanding commitment of reaching profitability as rapidly as possible.”

**Third Quarter 2022 and Recent Achievements:**

- **Significant Revenue Growth:** Achieved third quarter 2022 total revenues of $41.1 million, as compared to $20.7 million during the third quarter of 2021, an increase of $20.4 million, or approximately 99%.

- **Operating Leverage Materializing.** Excluding the impact associated with the sale of lower margin, 2,200-liter scale BIVIGAM, the Company estimates corporate gross margins for the third quarter would have been approximately 2-4% higher compared to reported results, translating to an approximate 26-28% corporate gross margin in a normalized quarter. As the Company has been exclusively producing BIVIGAM at the expanded 4,400-liter scale since the second half of 2021 and considering the record high BIVIGAM product pull-through realized during the third quarter of 2022, ADMA anticipates this lower margin inventory will be fully monetized over the coming periods. ADMA anticipates further margin enhancements as product throughput transitions throughout the first half of 2023 to exclusively the higher margin 4,400-liter scale product.
    - Accounting for the transient gross margin dynamics amounting to approximately $1.3 million at the midpoint, in addition to approximately $1 million in non-recurring operating expenditures incurred during the quarter, the Company estimates third quarter operating loss would have been approximately $7 million, the equivalent of approximately 50% less than the prior year’s third quarter.

- **Product Mix Continues to Favorably Evolve:** ASCENIV’s prescriber and patient base continued to expand during the third quarter, which drove record utilization and pull-through for the product. These elevated demand trends have sustained into the fourth quarter, and we expect that the product’s rapid growth will continue into 2023 and beyond.

- **Newly Identified Growth Opportunities:** Strong reception to ADMA’s medical education and scientific symposia strategy is anticipated to catalyze penetration into additional targeted growth opportunities. During the third quarter, ADMA expanded educational initiatives on identifying clinical needs in managing respiratory infections in the immunocompromised host, specifically:
    - Case study presentations by nationally recognized clinical experts in areas of transplantation, infectious disease, and immunology at national and regional medical meetings (i.e., Immune Globulin National Society, Infectious Disease Week, and Florida Allergy Asthma & Immunology Society).
    - Full-capacity attendance of symposia discussions of real-world experience of ASCENIV in patients with primary immunodeficiency (“PI”).
    - 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.

- **Advancing Toward Profitability:** The Company maintains and reiterates its previously provided profitability timeline, which is expected no later than the first quarter of 2024, while taking into account current macroeconomic uncertainties. However, should current demand trends and margin dynamics sustain, accelerated profitability timelines may be achievable.

- **On-Track BioCenters Expansion:** The Company's BioCenters segment has ten plasma collection centers under its corporate umbrella: seven centers are United States Food and Drug Administration ("FDA")-licensed, two additional centers are operational and collecting plasma presently under FDA licensing preparation and review and one center is in the construction phase. The Company remains on track to have 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 Company will communicate material developments as required by the U.S. Securities and Exchange Commission ("SEC"). The exploration of value-creating opportunities remains a top corporate priority for ADMA.

**2022 & Long-Term Financial Guidance:**

- **2022 Financial Guidance:** Enabled by the strong year-to-date execution, ADMA anticipates total 2022 revenues will reach approximately $145 million. ADMA reiterates expectations for continued gross profit expansion and narrowing net losses into 2023.

- **2024-2025 Financial Guidance:** The Company continues to anticipate generating approximately $250 million or more in revenue in 2024, and approximately $300 million or more thereafter. At these revenue levels, and based upon current assumptions, ADMA continues to forecast 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.

**Third Quarter 2022 Financial Results:**

Total revenues for the third quarter ended September 30, 2022 were $41.1 million, as compared to $20.7 million during the third quarter of 2021, an increase of $20.4 million, or approximately 99%. The revenue growth for the third quarter of 2022, compared to the third quarter of 2021, was favorably impacted by the continued commercial ramp-up of the Company's intravenous immune globulin (IVIG) product portfolio and expanding the customer base for BIVIGAM and ASCENIV.

Gross profit for the third quarter of 2022 was $9.7 million, compared to gross profit of $0.4 million for the third quarter of 2021. Gross profit growth during the third quarter was driven by a favorable contribution from ASCENIV. Partially offsetting the favorably evolving product mix, ADMA sold a material amount of the remaining 2,200-liter scale, lower margin BIVIGAM product during the third quarter of 2022. Moving forward, this lower margin inventory is anticipated to be exhausted over the coming quarters, after which production throughput and sales recognition is anticipated to be confined exclusively to the higher margin 4,400-liter BIVIGAM product.

Consolidated net loss for the quarter ended September 30, 2022 was $14.9 million, or $(0.08) per basic and diluted share, compared to a consolidated net loss of $17.7 million, or $(0.13) per basic and diluted share, for the quarter ended September 30, 2021.

Net loss decreased by approximately $2.8 million compared to the third quarter of 2021, primarily attributed to higher gross profit of $9.3 million, partially offset by a $2.3 million increase in interest expense as a result of additional debt principal as well as rising interest rates. Additional offsets during the third quarter of 2022 included increased plasma center operating expenses of $1.7 million attributed to having nine plasma centers in operation compared to five operating centers during the same period last year, as well as increased general and administrative expenses of $2.2 million resulting from increased headcount, commercialization, and marketing expenditures.

As of September 30, 2022, ADMA had working capital of approximately $179.7 million, primarily consisting of $162.9 million of inventory, $34.9 million of cash and cash equivalents and net accounts receivable of $20.9 million, partially offset by an aggregate of $43.6 million of accounts payable and accrued expenses.

**Conference Call Information**

To access the conference call on November 9, 2022 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 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," "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; the success of BIVIGAM® and ASCENIV™ in future periods, including certain opportunities for such products; the production scale of BIVIGAM; future growth opportunities; the timeline associated with profitability; the ability to obtain FDA approval of its plasma collection centers and the associated timing in connection therewith; expectations regarding the Company's future gross margins; 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.*

**COMPANY CONTACT:**
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**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF OPERATIONS**
**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| **REVENUES:** | | | | |
| Product revenue | $ 41,054,429 | $ 20,644,842 | $ 103,991,112 | $ 54,452,633 |
| License revenue | 35,708 | 35,708 | 107,125 | 107,125 |
| **Total revenues** | 41,090,137 | 20,680,550 | 104,098,237 | 54,559,758 |
| Cost of product revenue | 31,433,496 | 20,295,213 | 83,010,156 | 56,897,959 |
| **Gross profit (loss)** | 9,656,641 | 385,337 | 21,088,081 | (2,338,201) |
| **OPERATING EXPENSES:** | | | | |
| Research and development | 1,041,947 | 770,557 | 2,539,444 | 2,917,072 |
| Plasma center operating expenses | 4,859,450 | 3,146,221 | 12,755,525 | 8,191,890 |
| Amortization of intangible assets | 178,838 | 178,838 | 536,514 | 536,514 |
| Selling, general and administrative | 12,893,139 | 10,726,797 | 38,563,136 | 31,198,880 |
| **Total operating expenses** | 18,973,374 | 14,822,413 | 54,394,619 | 42,844,356 |
| **LOSS FROM OPERATIONS** | (9,316,733) | (14,437,076) | (33,306,538) | (45,182,557) |
| **OTHER INCOME (EXPENSE):** | | | | |
| Interest income | 7,236 | 4,256 | 42,573 | 32,241 |
| Interest expense | (5,580,366) | (3,298,680) | (13,542,419) | (9,741,110) |
| Loss on extinguishment of debt | - | - | (6,669,941) | - |
| Other expense | (9,641) | 18,546 | (195,942) | (106,772) |
| **Other expense, net** | (5,582,771) | (3,275,878) | (20,365,729) | (9,815,641) |
| **NET LOSS** | $ (14,899,504) | $ (17,712,954) | $ (53,672,267) | $ (54,998,198) |
| **BASIC AND DILUTED LOSS PER COMMON SHARE** | $ (0.08) | $ (0.13) | $ (0.27) | $ (0.44) |
| **WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:** | | | | |
| **Basic and Diluted** | 196,383,935 | 133,770,147 | 196,204,893 | 125,682,400 |

**ADMA BIOLOGICS, INC. AND SUBSIDIARIES**
**CONDENSED CONSOLIDATED BALANCE SHEETS**

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| **ASSETS** | (Unaudited) | |
| Current assets: | | |
| Cash and cash equivalents | $ 34,906,020 | $ 51,089,118 |
| Accounts receivable, net | 20,902,385 | 28,576,857 |
| Inventories | 162,913,633 | 124,724,091 |
| Prepaid expenses and other current assets | 5,372,484 | 4,339,245 |
| Total current assets | 224,094,522 | 208,729,311 |
| Property and equipment, net | 56,946,090 | 50,935,074 |
| Intangible assets, net | 1,192,254 | 1,728,768 |
| Goodwill | 3,529,509 | 3,529,509 |
| Right to use assets | 10,335,873 | 7,262,658 |
| Deposits and other assets | 4,459,322 | 4,067,404 |
| **TOTAL ASSETS** | $ 300,557,570 | $ 276,252,724 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 25,197,806 | $ 12,429,409 |
| Accrued expenses and other current liabilities | 18,378,932 | 17,214,988 |
| Current portion of deferred revenue | 142,834 | 142,834 |
| Current portion of lease obligations | 720,755 | 591,084 |
| Total current liabilities | 44,440,327 | 30,378,315 |
| Senior notes payable, net of discount | 141,365,706 | 94,866,239 |
| Deferred revenue, net of current portion | 1,868,739 | 1,975,865 |
| End of term fee | 1,500,000 | - |
| Lease obligations, net of current portion | 10,636,083 | 7,462,388 |
| Other non-current liabilities | 362,179 | 397,351 |
| **TOTAL LIABILITIES** | 200,173,034 | 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, 196,776,871 and 195,813,817 shares issued and outstanding | 19,678 | 19,581 |
| Additional paid-in capital | 566,149,846 | 553,265,706 |
| Accumulated deficit | (465,784,988) | (412,112,721) |
| **TOTAL STOCKHOLDERS' EQUITY** | 100,384,536 | 141,172,566 |
| **TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY** | $ 300,557,570 | $ 276,252,724 |