

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): May 6, 2020

ADMA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)	001-36728 (Commission File Number)	56-2590442 (IRS Employer Identification No.)
465 State Route 17, Ramsey, New Jersey (Address of principal executive offices)		07446 (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, par value \$0.0001 per share	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 May 6, 2020, ADMA Biologics, Inc. issued a press release announcing its financial results for the three months ended March 31, 2020 and provided 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	ADMA Biologics, Inc. Press Release, dated May 6, 2020

* 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.

May 6, 2020

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial
Officer



ADMA Biologics Reports First Quarter 2020 Financial Results and Highlights Recent Company Progress

Achieved First Quarter 2020 Total Revenues of \$10.2 Million, a 189% Increase Over First Quarter 2019

Strengthened Balance Sheet Through Successful Completion of Underwritten Public Offering

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

RAMSEY, NJ and BOCA RATON, FL -- May 6, 2020 -- ADMA Biologics, Inc. (Nasdaq: ADMA) (“ADMA”), 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 for the prevention of certain infectious diseases, today reported financial results for the quarter ended March 31, 2020, ADMA’s first fiscal quarter, and provided an overview of recent progress and accomplishments.

“During the first quarter of 2020, we invested in our supply-chain robustness strategy and continued to make progress with reinforcing and expanding our commercial infrastructure by building out our salesforce and medical affairs teams, while generating encouraging year-over-year quarterly revenue growth,” said Adam Grossman, ADMA’s President and Chief Executive Officer. “I am extremely proud of the ADMA Biologics team as they have risen to the challenge of navigating the Company through the COVID-19 pandemic while continuing to provide critical immune globulin (IG) and hyperimmune globulin products that U.S. patients and physicians need. Due to our strong foundation, we believe we are well-positioned to not only weather the current macroeconomic challenges, but to continue to execute on our future growth plans. Most importantly, everyone at ADMA offers our immense gratitude to all of the healthcare personnel, first responders and others working on the front lines during this pandemic.”

2020 Outlook and Objectives Update

- Commercial launches for BIVIGAM and ASCENIV continue to progress. With in-person field opportunities reduced at medical meetings and customer sites due to “shelter-in-place” orders across the U.S., ADMA has successfully implemented virtual engagement initiatives with key opinion leaders, prescribers and other healthcare professionals to facilitate the ongoing commercial rollouts.
 - ADMA continues to ramp its production throughput for its commercial products and build inventory to support continued sales growth, market penetration and increase available market supply. While ADMA has not experienced any significant decreases in its plasma collection operations to date, there have been reports that other plasma collection organizations are experiencing more meaningful declines as a result of the COVID-19 pandemic which could lead to potential plasma product supply constraints. ADMA is working diligently to increase its production throughput to potentially offset a portion of any potential supply shortfall the overall IG market may experience due to the COVID-19 pandemic.
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- Investments in support of our stated supply chain robustness initiatives remain on schedule and within budget and, most notably, the expansion of IG manufacturing capacity continues to be on track:
 - o Aseptic filling machinery installed, Site Acceptance Testing completed and validation testing underway.
 - o Successfully manufactured three BIVIGAM conformance batches at an increased plasma pool scale, which has the potential to increase overall plant production capacity by approximately 50% or more.
 - o Expansion of plasma collection center network continues on track with the commencement of collection center build-outs and the securing of additional locations.

Mr. Grossman continued, “These three substantial objectives and investments, including increased raw material plasma collection, expanded production capacity and aseptic filling capability, are anticipated to change the forward-looking outlook for ADMA in many positive ways, including potentially lowering costs, improving gross margins, providing more flexibility with a reduction to batch production cycle time and ultimately giving ADMA additional end-to-end control previously reserved for only the largest plasma fractionators.”

First Quarter 2020 and Recent Highlights

- Achieved first quarter 2020 total revenues of \$10.2 million, compared to \$3.5 million for the first quarter of 2019, representing a 189% increase.
 - Strengthened the balance sheet through the successful completion of an underwritten public offering of ADMA’s common stock resulting in net proceeds of \$88.7 million to the Company, after deducting underwriting discounts and commissions and other offering expenses.
 - Strengthened the intellectual property estate protecting ASCENIV. The Company recently received a Notice of Allowance from the U.S. Patent and Trademark Office for a patent extension application related to its intellectual property portfolio encompassing immunoglobulin plasma pool compositions used in the manufacturing of ASCENIV. The patent extension is expected to publish during the first half of 2020.
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- Entered into a 5-year manufacturing and supply agreement with a third-party customer to produce and sell plasma-derived intermediate fractions from ADMA's U.S. Food and Drug Administration (FDA) approved IG manufacturing process. This agreement is expected to add \$5-10 million per year in annual revenues for 2020 and 2021, and \$10-20 million per year for 2022 through 2024.
- Received BioNJ 2020 Innovator Award in recognition of the development and approval of ASCENIV, ADMA's novel, proprietary immune globulin product.

First Quarter 2020 Financial Results

Total revenues for the quarter ended March 31, 2020 were \$10.2 million, compared to \$3.5 million for the first quarter ended March 31, 2019, representing an increase of approximately \$6.7 million, or 189%. The increase is mainly due to increased sales and production throughput of our immunoglobulin products generated by our Boca Facility manufacturing operations in 2020 totaling \$6.4 million, and to a \$0.3 million increase in plasma revenues generated by our plasma collection facility in 2020 as compared to the same period of a year ago. Our revenues for the first quarter of 2020 as compared to the first quarter of 2019 were favorably impacted by the FDA approvals of BIVIGAM and ASCENIV on May 9, 2019 and April 1, 2019, respectively, and by the manufacturing and supply agreement we entered into in January 2020 to produce and sell intermediate fractions to a certain customer.

Consolidated net loss for the first quarter of 2020 was \$19.2 million, or \$(0.26) per basic and diluted share, compared to a consolidated net loss of \$13.1 million, or \$(0.28) per basic and diluted share, for the first quarter of 2019. The increase in net loss of \$6.2 million was primarily due to the increase in cost of product revenue of approximately \$7.4 million, which increase is mainly a result of the investment made for the production of BIVIGAM's conformance lots at an increased plasma pool production scale, which pertains specifically to our planned capacity expansion, as well as other production enhancement initiatives and supply chain investments at the Boca Facility. The increase in net loss during the first quarter of 2020 is also attributable to higher selling, general and administrative expenses of \$2.3 million, mainly due to increases in employee compensation expenses in support of our commercialization efforts, increased interest expense of \$1.2 million due to our accessing additional debt during the second quarter 2019, along with higher research and development expenses of \$0.7 million, primarily related to a study we commenced for ASCENIV to potentially extend its approved and labeled expiration dating, partially offset by the increase in revenues. Included in the net loss for the first quarter of 2020 were non-cash expenses of approximately \$1.9 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

At March 31, 2020, ADMA had cash and cash equivalents of \$101.2 million and accounts receivable of \$7.1 million, compared to cash and cash equivalents and accounts receivable of \$26.8 million and \$3.5 million, respectively, at December 31, 2019. ADMA's net working capital as of March 31, 2020 was \$151.6 million, compared to \$71.8 million as of December 31, 2019.

In February 2020, ADMA completed an underwritten public offering of 27,025,000 shares of its common stock at a public offering price of \$3.50 per share, resulting in net proceeds of \$88.7 million.

Conference Call Information

ADMA will host a conference call today, Wednesday, May 6, 2020, at 4:30 p.m. Eastern Time, to discuss the first quarter 2020 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 5339498. 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 Primary Humoral Immunodeficiency

Primary humoral immunodeficiency (PI), also known as primary immune deficiency disease (PIDD), is a class of inherited genetic disorders that causes an individual to have a deficient or absent immune system. According to the World Health Organization, there are approximately 350 different genetic mutations encompassing PI. Some disorders are present at birth or in early childhood and the disorders can affect anyone regardless of age or gender. Some affect a single part of the immune system, others may affect one or more components of the system. PI patients are vulnerable to infections and are more likely to suffer complications from these infections compared to individuals with a normal functioning immune system. Because patients suffering from PI lack a properly functioning immune system, they typically receive monthly treatment with polyclonal immune globulin products. Without this exogenous antibody replacement, these patients would remain vulnerable to persistent and chronic infections. Initially thought to be very rare, it is now estimated that the prevalence of PI in the U.S. is 1 in 1,200, which translates to approximately 250,000 people.

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 (IgG) antibodies.

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 on April 1, 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 plasma 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.

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 FDA approved plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases: ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) for the treatment of primary humoral immunodeficiency (PI); BIVIGAM® (immune globulin intravenous, human) 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 Bio Centers 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,” “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 also include, but are not limited to, statements about ADMA’s future results of operations; being well-positioned to weather current macromarket challenges while continuing to execute on future growth plans; continuing progress regarding the commercial launches for BIVIGAM and ASCENIV; ramping production throughput for commercial products and building inventory; continued sales growth and market penetration; potential plasma product supply constraints; increasing ADMA’s production throughput; expansion of manufacturing capacity, investments related thereto, and the timing of such investments; and expected annual revenues from ADMA’s manufacturing and supply agreement to produce and sell plasma-derived intermediate fractions. 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.

COMPANY CONTACT:

Brian Lenz

Executive Vice President and Chief Financial Officer | 201-478-5552 | www.admabiologics.com

INVESTOR RELATIONS CONTACT:

Sam Martin

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

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2020	2019
REVENUES:		
Product revenue	\$ 10,164,036	\$ 3,492,881
License revenue	35,708	35,708
Total Revenues	10,199,744	3,528,589
OPERATING EXPENSES:		
Cost of product revenue (exclusive of amortization expense shown below)	16,829,226	9,405,179
Research and development	1,528,738	870,635
Plasma center operating expenses	500,644	654,486
Amortization of intangible assets	178,838	211,235
Selling, general and administrative	7,932,084	5,595,470
Total operating expenses	26,969,530	16,737,005
LOSS FROM OPERATIONS	(16,769,786)	(13,208,416)
OTHER INCOME (EXPENSE):		
Interest and other income	248,068	127,399
Interest expense	(2,717,091)	(1,540,507)
Loss on extinguishment of debt	—	(9,962,495)
Gain on transfer of plasma center assets	—	11,527,421
Other expense, net	(6,421)	(11,357)
Other (expense) income, net	(2,475,444)	140,461
NET LOSS	\$ (19,245,230)	\$ (13,067,955)
BASIC AND DILUTED LOSS PER COMMON SHARE	\$ (0.26)	\$ (0.28)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:		
Basic and Diluted	73,781,507	46,353,068

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2020	December 31, 2019
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$ 101,235,699	\$ 26,752,135
Accounts receivable, net	7,107,834	3,469,919
Inventories	52,288,803	53,064,734
Prepaid expenses and other current assets	4,855,344	2,533,593
Total current assets	165,487,680	85,820,381
Property and equipment, net	35,060,795	31,741,317
Intangible assets, net	2,980,636	3,159,474
Goodwill	3,529,509	3,529,509
Deposits and other assets	3,465,207	2,840,044
TOTAL ASSETS	\$ 210,523,827	\$ 127,090,725
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 9,152,239	\$ 9,174,591
Accrued expenses and other current liabilities	4,419,043	4,481,395
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	193,987	229,073
Total current liabilities	13,908,103	14,027,893
Senior notes payable, net of discount	81,212,090	68,291,163
Deferred revenue, net of current portion	2,225,823	2,261,532
Subordinated note payable, net of discount	14,916,837	14,908,053
Lease obligations, net of current portion	1,831,639	1,302,361
Other non-current liabilities	93,652	106,574
TOTAL LIABILITIES	114,188,144	100,897,576
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, 150,000,000 shares authorized, 86,345,313 and 59,318,355 shares issued and outstanding	8,635	5,932
Additional paid-in capital	380,288,833	290,903,772
Accumulated deficit	(283,961,785)	(264,716,555)
TOTAL STOCKHOLDERS' EQUITY	96,335,683	26,193,149
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 210,523,827	\$ 127,090,725