

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 12, 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 March 12, 2020, ADMA Biologics, Inc. issued a press release announcing its financial results for the three months and year ended December 31, 2019 and provided an update on its recent achievements and upcoming milestones. 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 March 12, 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.

March 12, 2020

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer



ADMA Biologics Reports Fourth Quarter and Full Year 2019 Financial Results and Highlights Recent Company Progress

Achieved Fourth Quarter 2019 Total Revenues of \$12.0 Million, a 197% Increase Over Fourth Quarter 2018

Achieved Full Year 2019 Total Revenues of \$29.3 Million, a 73% Increase Over Full Year 2018

Strengthened Balance Sheet Through Successful Completion of Underwritten Public Offering Resulting in Gross Proceeds of \$94.6 Million

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

RAMSEY, NJ and BOCA RATON, FL -- March 12, 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 fourth quarter and full year ended December 31, 2019 and provided an overview of recent progress and accomplishments.

"In 2019, ADMA embarked on the commercial rollout of BIVIGAM[®] and ASCENIV[™], our two lead intravenous immune globulin (IVIG) products for the treatment of patients with primary humoral immunodeficiency," said Adam Grossman, ADMA's President and Chief Executive Officer. "We are pleased with the commercial launch thus far and we look forward to continuing an upward production ramp throughout 2020. On the financial front, we recently strengthened our balance sheet and enhanced our working capital position by securing gross proceeds of \$94.6 million in an underwritten public offering of our common stock. Collectively, we believe all of these achievements leave us well positioned for continued growth in 2020 and beyond."

2019 and Recent Highlights

- Achieved fourth quarter 2019 total revenues of \$12.0 million, compared to \$4.1 million for the fourth quarter of 2018, representing a 197% increase. Achieved full year 2019 total revenues of \$29.3 million, compared to \$17.0 million for the full year 2018, representing a 73% increase.
 - Commercial launches for BIVIGAM and ASCENIV are progressing in line with management's expectations. ADMA continues to ramp commercial production of these two products and build inventory to support continued growth and market supply.
 - Strengthened the balance sheet through the successful completion of an underwritten public offering of ADMA's common stock resulting in gross proceeds of \$94.6 million to the Company, before deducting underwriting discounts and commissions and other offering expenses.
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- Added to the NASDAQ Biotechnology Index in December 2019.
- 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 immune globulin (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.

Fourth Quarter 2019 Financial Results

Total revenues for the quarter ended December 31, 2019 were \$12.0 million, compared to \$4.1 million for the quarter ended December 31, 2018, representing an increase of approximately \$7.9 million, or 197%. The increase in revenues was primarily due to the first commercial sales of ASCENIV in October 2019, the commercial relaunch of BIVIGAM in August 2019, intermediate fraction sales as well as contract manufacturing revenue, all generated by our Boca Raton, FL manufacturing operations, partially offset by a decrease in plasma center revenues due to the transfer of two of our plasma centers on January 1, 2019 as part of the purchase price for the Florida operations.

Consolidated net loss for the fourth quarter 2019 was \$10.6 million, or \$(0.18) per basic and diluted share, compared to a consolidated net loss of \$18.0 million, or \$(0.39) per basic and diluted share, for the fourth quarter 2018. The decrease in net loss of \$7.4 million was primarily due to the increase in higher revenues of approximately \$7.9 million and a reduction in total operating expenses of \$0.7 million during the fourth quarter 2019 compared to the fourth quarter 2018, partially offset by increased interest expense. Included in the net loss for the fourth quarter 2019 were non-cash expenses of approximately \$1.9 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

Full Year 2019 Financial Results

Total revenues for the full year 2019 were \$29.3 million, compared to \$17.0 million for the full year 2018, representing an increase of approximately \$12.3 million, or 73%. The increase in revenues was primarily due to the first commercial sales of ASCENIV and commercial relaunch of BIVIGAM, as well as intermediate fraction sales and contract manufacturing revenue, none of which were present in 2018, partially offset by a decrease in plasma center revenues.

Consolidated net loss for the full year 2019 was \$48.3 million, or \$(0.89) per basic and diluted share, compared to a consolidated net loss of \$65.7 million, or \$(1.45) per basic and diluted share, for the full year 2018. The decrease in net loss of \$17.4 million was primarily due to the increased revenues of \$12.3 million as well as lower total operating expenses of \$6.5 million for the year ended 2019 compared to 2018, partially offset by increased interest expense. Included in the net loss for the full year 2019 were non-cash expenses of approximately \$7.1 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

At December 31, 2019, ADMA had cash and cash equivalents of \$26.8 million and accounts receivable of \$3.5 million, compared to cash and cash equivalents and accounts receivable of \$22.8 million and \$1.4 million, respectively, at December 31, 2018. ADMA's net working capital as of December 31, 2019 was \$71.8 million, compared to \$34.9 million as of December 31, 2018.

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 gross proceeds of \$94.6 million. Net proceeds to ADMA, after deducting underwriting discounts and commissions and other offering expenses, were approximately \$88.5 million.

Conference Call Information

ADMA will host a conference call today, Thursday, March 12, 2020, at 4:30 p.m. Eastern Time, to discuss the fourth quarter and full year 2019 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 9365775. 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™ (Formerly RI-002)

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 United States Food and Drug Administration (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'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 expected revenues in the future and ADMA’s future results of operations; statements about increasing demand for our therapeutic products; statements about ADMA’s fractionation plant turnaround; expansion of ADMA’s plasma collection center network; statements about ADMA’s research and development activities and management’s belief regarding implementation of manufacturing strategies and improvements with the ultimate goal of efficiently bringing plasma-derived products to market. 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

	<u>Three Months Ended December 31,</u>		<u>Year ended December 31,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
REVENUES:				
Product revenue	\$ 12,001,340	\$ 4,020,715	\$ 29,206,249	\$ 16,842,456
License revenue	35,709	35,709	142,834	142,834
Total Revenues	<u>12,037,049</u>	<u>4,056,424</u>	<u>29,349,083</u>	<u>16,985,290</u>
OPERATING EXPENSES:				
Cost of product revenue	11,691,603	11,142,116	39,504,238	42,194,635
Research and development	464,823	917,304	2,343,848	3,926,120
Plasma center operating expenses	464,131	2,260,379	2,169,629	7,805,619
Amortization of intangible assets	211,234	211,234	844,938	844,938
Selling, general and administrative	7,032,067	6,073,051	25,910,757	22,502,922
Total operating expenses	<u>19,863,858</u>	<u>20,604,084</u>	<u>70,773,410</u>	<u>77,274,234</u>
LOSS FROM OPERATIONS	<u>(7,826,809)</u>	<u>(16,547,660)</u>	<u>(41,424,327)</u>	<u>(60,288,944)</u>
OTHER INCOME (EXPENSE):				
Interest and other income	181,682	60,206	800,785	195,403
Interest expense	(2,730,890)	(1,437,968)	(8,993,379)	(5,522,783)
Loss on extinguishment of debt	—	—	(9,962,495)	—
Gain on transfer of plasma center assets	—	—	11,527,421	—
Other (expense) income	(185,014)	(112,565)	(227,322)	(127,121)
Other expense, net	<u>(2,734,222)</u>	<u>(1,490,327)</u>	<u>(6,854,990)</u>	<u>(5,454,501)</u>
NET LOSS	<u>\$ (10,561,031)</u>	<u>\$ (18,037,987)</u>	<u>\$ (48,279,317)</u>	<u>\$ (65,743,445)</u>
BASIC AND DILUTED LOSS PER COMMON SHARE	<u>\$ (0.18)</u>	<u>\$ (0.39)</u>	<u>\$ (0.89)</u>	<u>\$ (1.45)</u>
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic and Diluted	<u>59,318,355</u>	<u>46,351,860</u>	<u>54,348,136</u>	<u>45,188,899</u>

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 26,752,135	\$ 22,754,852
Accounts receivable, net	3,469,919	1,392,441
Inventories	53,064,734	18,616,169
Prepaid expenses and other current assets	2,533,593	1,766,163
Total current assets	85,820,381	44,529,625
Property and equipment, net	31,741,317	30,115,730
Intangible assets, net	3,159,474	4,004,412
Goodwill	3,529,509	3,529,509
Assets to be transferred under purchase agreement	—	1,153,508
Restricted cash	—	4,000,000
Deposits and other assets	2,840,044	1,543,737
TOTAL ASSETS	\$ 127,090,725	\$ 88,876,521
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 9,174,591	\$ 5,900,394
Accrued expenses and other current liabilities	4,481,395	3,551,835
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	229,073	29,983
Total current liabilities	14,027,893	9,625,046
Senior notes payable, net of discount	68,291,163	26,440,830
End of term liability, notes payable	—	2,760,000
Deferred revenue, net of current portion	2,261,532	2,404,365
Subordinated note payable, net of discount	14,908,053	14,874,184
Obligation to transfer assets under purchase agreement	—	12,621,844
Lease obligations, net of current portion	1,302,361	119,080
Other non-current liabilities	106,574	260,734
TOTAL LIABILITIES	100,897,576	69,106,083
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 and 75,000,000 shares authorized, 59,318,355 and 46,353,068 shares issued and outstanding	5,932	4,635
Additional paid-in capital	290,903,772	236,203,041
Accumulated deficit	(264,716,555)	(216,437,238)
TOTAL STOCKHOLDERS' EQUITY	26,193,149	19,770,438
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 127,090,725	\$ 88,876,521