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 6, 2019

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):

o 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 November 6, 2019, ADMA Biologics, Inc. issued a press release announcing its financial results for the three and nine months ended September 30, 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

Exhibit No.	**Description**
99.1	ADMA Biologics, Inc. Press Release, dated November 6, 2019.

* 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 6, 2019

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

Exhibit 99.1

ADMA Biologics Reports Third Quarter 2019 Financial Results and Highlights Recent Company Progress

Third Quarter Total Revenues of $7.2 Million, a 71% Increase Year Over Year

Commercial Rollouts for Immunoglobulins (IVIG) Off to an Encouraging Start

RAMSEY, N.J. and BOCA RATON, FL., – November 6, 2019 – ADMA Biologics, Inc. (NASDAQ: ADMA) (ADMA or the Company), a commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and the prevention of certain infectious diseases, today announced financial results for the third quarter and nine months ended September 30, 2019, and provided an overview of its recent corporate achievements.

“To date, 2019 has been a transformational year for ADMA, marked most importantly by the recent re-launch and launch, respectively, and first commercial sales of our lead assets BIVIGAM and ASCENIV, both indicated for the treatment of patients with primary humoral immunodeficiency (PI),” said Adam Grossman, ADMA’s President and Chief Executive Officer. “Our commercial rollouts are off to an encouraging early start for our IVIG brands. As we look ahead to the remainder of 2019 and into 2020, we remain focused on maximizing these initial product launches and executing on several strategic corporate initiatives aimed at growing our overall revenues, including potentially expanding the capacity at our manufacturing facility, opening new plasma collection centers, as well as growing our commercial team and hiring additional staff to support the anticipated production ramp up for 2020 and beyond.”

Third Quarter 2019 and Recent Highlights

- ***BIVIGAM and ASCENIV Now Commercially Available in the U.S.*** – Following FDA approval of both products, ADMA commercially launched its lead intravenous immunoglobulin (IVIG) products BIVIGAM and ASCENIV and recorded its first commercial sales for both products.

- ***Presented key ASCENIV data at IDWeek 2019*** – Key supportive data highlighting the encouraging results of ASCENIV for the treatment of Respiratory Syncytial Virus (RSV) in immunocompromised children were presented at IDWeek 2019. The data described how ASCENIV demonstrated positive outcomes when used under the Company’s compassionate use program to treat documented RSV lower respiratory tract infections in two immunocompromised children at the Mayo Clinic.

- ***Named "Company of the Year" by BioFlorida*** – ADMA was recently named "Company of the Year" by BioFlorida, in recognition of the Company's significant achievements over the past year.

- ***Published Manufacturing Process Optimization Article in* Immunotherapy** – A manuscript highlighting ADMA's manufacturing process optimization for BIVIGAM and ASCENIV was published in the peer-reviewed journal *Immunotherapy*. The article describes certain manufacturing process changes and improvements instituted by ADMA following the acquisition of its Boca Raton, FL manufacturing facility (the "Boca Facility") in 2017.

- ***Received FDA Issuance for a New Plant License for the Boca Raton, FL Manufacturing Facility and FDA BLA License Transfers for BIVIGAM and Nabi-HB®*** – ADMA received notification from the FDA that the licenses for both BIVIGAM and Nabi-HB were transferred and issued to ADMA's new manufacturing facility U.S. License No. 2019.

Third Quarter 2019 Financial Results

Total revenues for the quarter ended September 30, 2019 were $7.2 million, compared to $4.2 million for the quarter ended September 30, 2018, representing an increase of $3.0 million, or approximately 71%. The increase in revenues was primarily due to increased production and sales of IVIG and related products manufactured at the Boca Facility.

Consolidated net loss for the quarter ended September 30, 2019 was $11.4 million, or $(0.19) per basic and diluted share, compared to a consolidated net loss of $15.1 million, or $(0.33) per basic and diluted share, for the quarter ended September 30, 2018. The decrease in net loss of $3.7 million was primarily due to the $3.0 million of higher revenues and a $1.7 million reduction in total operating expenses, partially offset by higher interest expense of $1.2 million. The reduction in operating expenses was comprised of (i) lower product revenue costs of $1.2 million attributable to a reduction in underabsorbed manufacturing expenses, (ii) lower research and development expenses of $0.5 million related to the FDA approval of ASCENIV earlier in 2019, (iii) lower plasma center expenses of $1.5 million resulting from the transfer of two of our plasma centers on January 1, 2019 in connection with the acquisition of the Boca Facility; partially offset by (iv) higher selling, general and administrative expenses of $1.5 million attributable to expenses associated with the BIVIGAM and ASCENIV product launches and enhancements to our information technology and customer support infrastructure necessary to support our commercialization activities. Included in the net loss for the third quarter 2019 were non-cash expenses of approximately $1.8 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

Financial Results for the Nine Months Ended September 30, 2019

Total revenues for the nine months ended September 30, 2019 were $17.3 million, compared to $12.9 million for the nine months ended September 30, 2018, representing an increase of $4.4 million, or approximately 34%. The increase in revenues was primarily due to increased production and sales of IVIG and related products manufactured at the Boca Facility.

Consolidated net loss for the nine months ended September 30, 2019 was $37.7 million, or $(0.72) per basic and diluted share, compared to a consolidated net loss of $47.7 million, or $(1.06) per basic and diluted share, for the nine months ended September 30, 2018. The decrease in net loss of $10.0 million was primarily due to the $4.4 million of higher revenues and lower total operating expenses of $5.8 million, which reflects reductions in product revenue costs of $3.2 million, research and development costs of $1.1 million and plasma center operating expenses of $3.8 million, partially offset by higher selling, general and administrative expenses of $2.4 million. Included in the net loss for the nine months ended September 30, 2019 were non-cash expenses of approximately $5.2 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

At September 30, 2019, ADMA had cash and cash equivalents of $48.0 million and accounts receivable of $7.3 million, as 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 September 30, 2019 was $82.2 million, as compared to $34.9 million as of December 31, 2018.

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 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 Biologics is a commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatments of immunodeficient patients at risk for infection. ADMA currently manufactures and markets three United States Food and Drug Administration 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 hepatitis B. 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 disease, 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 concerning our expectations regarding recent commercial launches of BIVIGAM and ASCENIV and the expected benefits related thereto; our focus on maximizing the launch of those products and expanding the capacity at our manufacturing facility; our intent to open new plasma collection centers; and our expectations for future capital expenditures and requirements. 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.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
REVENUES:				
Product revenue	$ 7,186,795	$ 4,194,602	$ 17,204,909	$ 12,821,741
License revenue	35,708	35,708	107,125	107,125
Total revenues	7,222,503	4,230,310	17,312,034	12,928,866
OPERATING EXPENSES:				
Cost of product revenue	7,916,220	9,164,109	27,812,635	31,052,519
Research and development	491,404	1,002,818	1,879,025	3,008,816
Plasma center operating expenses	456,899	1,973,338	1,705,498	5,545,240
Amortization of intangible assets	211,235	211,235	633,704	633,704
Selling, general and administrative	7,197,173	5,670,210	18,878,690	16,429,871
Total operating expenses	16,272,931	18,021,710	50,909,552	56,670,150
LOSS FROM OPERATIONS	(9,050,428)	(13,791,400)	(33,597,518)	(43,741,284)
OTHER INCOME (EXPENSE):				
Interest and other income	281,896	75,581	619,103	135,197
Interest expense	(2,649,404)	(1,402,475)	(6,262,489)	(4,084,815)
Loss on extinguishment of debt	—	—	(9,962,495)	—
Gain on transfer of plasma center assets	—	—	11,527,421	—
Other expense	(20,523)	(17,191)	(42,308)	(14,556)
Other expense, net	(2,388,031)	(1,344,085)	(4,120,768)	(3,964,174)
NET LOSS	$ (11,438,459)	$ (15,135,485)	$ (37,718,286)	$ (47,705,458)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.19)	$ (0.33)	$ (0.72)	$ (1.06)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic and Diluted	59,317,830	46,350,392	52,673,190	44,796,986

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2019	December 31, 2018
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	$ 48,006,152	$ 22,754,852
Accounts receivable, net	7,315,481	1,392,441
Inventories	40,285,339	18,616,169
Prepaid expenses and other current assets	1,716,337	1,766,163
Total current assets	97,323,309	44,529,625
Property and equipment, net	30,712,915	30,115,730
Intangible assets, net	3,370,708	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	2,843,332	1,543,737
TOTAL ASSETS	$ 137,779,773	$ 88,876,521
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,959,903	$ 5,900,394
Accrued expenses and other current liabilities	4,762,771	3,551,835
Current portion of deferred revenue	1,197,910	142,834
Current portion of lease obligations	229,516	29,983
Total current liabilities	15,150,100	9,625,046
Senior notes payable, net of discount	67,839,162	26,440,830
End of term liability, notes payable	—	2,760,000
Deferred revenue, net of current portion	2,297,240	2,404,365
Subordinated note payable, net of discount	14,899,313	14,874,184
Obligation to transfer assets under purchase agreement	—	12,621,844
Lease obligations, net of current portion	1,356,390	119,080
Other non-current liabilities	119,496	260,734
TOTAL LIABILITIES	101,661,701	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	290,267,664	236,203,041
Accumulated deficit	(254,155,524)	(216,437,238)
TOTAL STOCKHOLDERS' EQUITY	36,118,072	19,770,438
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 137,779,773	$ 88,876,521