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): October 17, 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 Capital 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 8.01 Other Events.

On October 17, 2019, ADMA Biologics, Inc. issued a press release entitled "ADMA Biologics Announces Publication of an Article Describing the Manufacturing Process Optimization for its Commercial Products BIVIGAM® and ASCENIV™ in the Peer Reviewed Journal *Immunotherapy*." The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release dated October 17, 2019, entitled "ADMA Biologics Announces Publication of an Article Describing the Manufacturing Process Optimization for its Commercial Products BIVIGAM® and ASCENIV™ in the Peer Reviewed Journal *Immunotherapy*."

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.

October 17, 2019

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

Exhibit 99.1

ADMA Biologics Announces Publication of an
Article Describing the Manufacturing Process Optimization for its Commercial Products BIVIGAM® and ASCENIV™
in the Peer Reviewed Journal *Immunotherapy*

RAMSEY, N.J. and BOCA RATON, FL., – October 17, 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 the publication of an article describing the manufacturing process optimization of ADMA's Intravenous Immunoglobulin ("IVIG") products, BIVIGAM® and ASCENIV™ in the peer reviewed journal *Immunotherapy*.

The article, as published in the October 2019 online-edition and the soon to be available November 2019 print-edition of *Immunotherapy*, describes the manufacturing process changes and improvements instituted by ADMA for both BIVIGAM® and ASCENIV™ following its acquisition of the Boca Raton, FL manufacturing facility. These improvements to ADMA's manufacturing process resulted in engineering modifications and enhancements to procedural controls, and reductions in thermal, physical and chemical product stressors. The optimized manufacturing process demonstrates increased control of unit operations, process consistency and robustness, decrease in product variability and enhanced removal of impurities all of which lead to enhanced product quality.

"We are very proud of the achievements made by the ADMA Biologics team and are pleased that BIVIGAM and ASCENIV are now commercially available. The diligent work of ADMA's in-house development teams, including process development, analytical development, manufacturing, quality assurance and quality control, is evident from all the improvements to the manufacturing process described in this peer-reviewed publication," stated Adam Grossman, President and Chief Executive Officer. "We hope that the improvements and manufacturing enhancements described in this peer-reviewed publication provide confidence to ADMA's stakeholders."

About ASCENIV™ (Formerly RI-002)

ASCENIV, immune globulin intravenous, human – slra 10% liquid, is a plasma-derived, polyclonal, intravenous immune globulin ("IVIG"). ASCENIV, which is indicated for the treatment of Primary Humoral Immunodeficiency or Primary Immune Deficiency Disease ("PI") in adults and adolescents (12 to 17 years of age), was approved by the FDA on April 1, 2019 and anticipates commencing commercial sales in October 2019. 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 our 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 prevented serious bacterial infection among 59 patients treated for twelve months during the pivotal investigation. ASCENIV is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886.

About BIVIGAM®

BIVIGAM® is an immune globulin intravenous, human - 10% liquid, indicated for the treatment of primary humoral immunodeficiency. This includes, but is not limited to, X-linked and congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. These PIs are a group of genetic disorders. Initially thought to be very rare, it is now believed that as many as 250,000 people in the U.S. have some form of Primary Humoral Immunodeficiency ("PI"). 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. Antibodies are proteins in the human immune system that work to defend against infections and disease. BIVIGAM® was approved for marketing by the FDA in May 2019 and reintroduced to the U.S. market in August 2019.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is a commercial biopharmaceutical company dedicated to marketing and developing plasma-derived, human immune globulin products for immunodeficient patients at risk for infection. 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 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 ability to operate in accordance with FDA quality and compliance, regulations and expectations; our ability to provide a continuous supply of BIVIGAM® to PI patients; our ability to successfully pursue commercialization and prelaunch activities for our products; and the potential of our specialty plasma-based biologics products and product candidates to provide meaningful clinical improvement for patients living with Primary Immune Deficiency Disease or other indications. 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:
Jeremy Feffer
Managing Director, LifeSci Advisors, LLC | 212-915-2568 |