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): September 3, 2020

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, 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 8.01 Other Events

On September 3, 2020, ADMA Biologics, Inc. (the "Company") issued a press release announcing the launch of COVID-19 ImmunoRank Neutralization MICRO-ELISA, a proprietary, fully-validated ELISA assay for the detection of SARS-CoV-2 neutralizing antibodies in plasma, which was developed in collaboration with Leinco Technologies, Inc. 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 September 3, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

September 3, 2020

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

ADMA Biologics Highlights Launch of COVID-19 ImmunoRank™ Neutralization MICRO-ELISA Assay to Detect SARS-CoV-2 Neutralizing Antibodies in Plasma

ImmunoRank Offers a Faster, Simpler, More Cost Effective Way to Identify High Titer Convalescent Plasma for Use in Both Treating COVID-19 Patients and for Creating COVID-19 Hyperimmune Globulins

Proprietary Assay Developed in Collaboration with Leinco Technologies

RAMSEY, N.J. and BOCA RATON, Fla. – September 3, 2020 – ADMA Biologics, Inc. (Nasdaq: ADMA) ("ADMA"), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics, today announced the launch of COVID-19 ImmunoRank Neutralization MICRO-ELISA, a proprietary, fully-validated ELISA assay for the detection of SARS-CoV-2 neutralizing antibodies in plasma. ImmunoRank™ was developed in collaboration with Leinco Technologies, Inc. ("Leinco"). ImmunoRank is intended for use as an aid to identify individuals who produce an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, and specifically for the detection of circulating SARS-CoV-2 neutralizing antibodies in human plasma of all immune globulin classes.

ImmunoRank is designed to test up to 90 samples per test kit with 99.8% specificity. The assay procedure takes approximately 80 minutes. An Emergency Use Authorization (EUA) submission is currently being prepared for review and potential approval by the U.S. Food and Drug Administration. We will report on material regulatory and commercial developments as we progress. ADMA has submitted patents for ImmunoRank in the U.S. and certain foreign markets. Both ADMA and Leinco are named as co-inventors on the patents.

"We are confident the ImmunoRank assay will be an efficient and effective tool for selecting high titer convalescent plasma units containing neutralizing antibodies to SARS-CoV-2 both for the treatment of COVID-19 patients as well as identifying plasma that can be used for development and production of hyperimmune globulins to treat COVID-19," said Adam Grossman, President and Chief Executive Officer of ADMA. "Current screening methods to identify circulating SARS-CoV-2 neutralizing antibodies are labor and cost intensive and take multiple days to complete. This assay can be run in approximately 80 minutes, resulting in numerous tests per day, and can be performed at a fraction of the cost of other, more laborious assays. We believe this proprietary assay will result in important potential product and business development opportunities as we continue to seek out meaningful ways to help patients battling COVID-19."

Under the terms of the collaboration agreement between ADMA and Leinco, ADMA has the right to use, market and commercialize ImmunoRank for the screening and selection of human plasma units or plasma pools containing SARS-CoV-2 neutralizing antibodies, for manufacturing products such as plasma proteins for therapeutic use, including but not limited to producing intravenous immunoglobulins ("IVIG") or hyperimmune globulin products, for the screening of convalescent plasma or vaccinated plasma donors, as well as combining these products with SARS-CoV-2 neutralizing monoclonal antibodies. ADMA also has the rights for commercializing ImmunoRank test kits for use by plasma donation centers to screen donors for neutralizing antibodies to SARS-CoV-2. Leinco will be responsible for manufacturing ImmunoRank and has the right to market and sell the assay for all other potential markets, other than those reserved exclusively to ADMA.

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 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.

About Leinco Technologies Inc. (Leinco)

Leinco Technologies, Inc. is a biotechnology company founded in 1992 as a specialty manufacturer of early discovery research products including antibodies, recombinant proteins, ELISA kits, second step reagents and other life sciences products. Shortly thereafter, we also established ourselves as a premier provider of custom R&D and manufacturing services focusing on monoclonal antibodies and recombinant proteins. Our innovative products and services are used to augment the early discovery process in life science research, diagnostics and ground\breaking development of protein therapeutics. To order the ImmunoRank Neutralization MICRO-ELISA Assay to Detect SARS-CoV-2 Neutralizing Antibodies in Plasma for academic use or for more information visit www.leincotechnologies.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 opportunities relating to the use, sale, and marketing of ImmunoRank™, the potential approval of Emergency Use Authorization for the use of ImmunoRank™, and the opportunities presented by the collaboration between ADMA and Leinco. 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:

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