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): January 15, 2021 (January 12, 2021)

REGENERON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

New York		
(State or other jurisdiction of incorporation)		
000-19034		**13-3444607**
(Commission File Number)		(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road, Tarrytown, New York		**10591-6707**
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code: (914) 847-7000

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):

☐ 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 $0.001 per share	REGN	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company 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 1.01. Entry into a Material Definitive Agreement.

On January 12, 2021, Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") entered into a supply agreement (the "Supply Agreement") with the Army Contracting Command, New Jersey, an entity acting on behalf of the U.S. Department of Defense and the U.S. Department of Health and Human Services (collectively, the "U.S. Government"), to manufacture and supply to the U.S. Government casirivimab and imdevimab, the Company's novel investigational dual antibody therapy that has received an Emergency Use Authorization ("EUA") from the U.S. Food and Drug Administration (the "FDA") for the treatment of mild to moderate COVID-19 in high-risk non-hospitalized patients (the "EUA Indication"). Pursuant to the Supply Agreement, the U.S. Government is obligated to purchase all filled and finished doses of drug product delivered by June 30, 2021, up to 1.25 million doses total, and may accept doses during the period from July 1, 2021 through September 30, 2021 at its discretion. The U.S. Government will acquire doses at the lowest dose authorized or approved by the FDA for the EUA Indication prior to or on the date of delivery for a price of $2,100 per dose, resulting in payments to Regeneron of up to $2.625 billion in the aggregate. Under the EUA, the current authorized dose for the EUA Indication is 2,400 mg; and Regeneron is evaluating the safety and efficacy of a lower 1,200 mg dose. A number of factors may impact available filled and finished supply by June 30, 2021, including manufacturing considerations and authorized dose levels. The Company is also obligated to distribute the filled and finished drug product to patient care sites as directed by the U.S. Government.

The Supply Agreement contains terms and conditions that are customary for U.S. Government agreements of this nature, including provisions giving the U.S. Government the right to terminate the Supply Agreement for convenience. If the Supply Agreement is terminated for convenience prior to completion, Regeneron is entitled to be paid certain termination costs, including the percentage of the contract price reflecting the percentage of work performed plus certain reasonable charges resulting from termination. The performance period under the Supply Agreement extends from January 12, 2021 through January 12, 2022, except as noted above with respect to the delivery of filled and finished doses.

The foregoing description of the Supply Agreement is qualified in its entirety by reference to the full text of the Supply Agreement, a copy of which will be filed with the U.S. Securities and Exchange Commission as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarterly period ending March 31, 2021.

Note Regarding Forward-Looking Statements

This Current Report on Form 8-K (this "Report") includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's products and product candidates (including the casirivimab and imdevimab antibody cocktail) and the impact of the foregoing on Regeneron's ability to supply its products and product candidates, including its ability to supply doses of the casirivimab and imdevimab antibody cocktail under the terms of the supply agreement with the U.S. government discussed in this Report (the "Supply Agreement"); whether and to what extent Regeneron will be able to supply doses of the casirivimab and imdevimab antibody cocktail under the Supply Agreement; the amount of payments (if any) Regeneron may receive pursuant to the Supply Agreement; what the lowest authorized dose of the casirivimab and imdevimab antibody cocktail will be at the time of delivery to the U.S. government under the Supply Agreement; and whether the Supply Agreement is terminated by the U.S. government or otherwise prior to completion. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2019 and its Form 10-Q for the quarterly period ended September 30, 2020. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

SIGNATURES

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 thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

/s/ Joseph J. LaRosa
Joseph J. LaRosa
Executive Vice President, General Counsel and Secretary

Date: January 15, 2021