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 16, 2021 (September 14, 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 September 14, 2021, Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") entered into a modified Statement of Work (the "Amendment") under the supply agreement (the "Supply Agreement" (previously filed as Exhibit 10.1 to Regeneron's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021)) 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 supply to the U.S. Government an additional 1.4 million doses of REGEN-COV™ (casirivimab and imdevimab), the Company's cocktail of two monoclonal antibodies that has received an Emergency Use Authorization from the U.S. Food and Drug Administration (the "FDA") for use in certain individuals in the United States. Pursuant to the Supply Agreement, as amended by the Amendment (the "Amended Supply Agreement"), the U.S. Government is obligated to purchase all such filled and finished doses of drug product delivered to vendor-managed inventory by January 31, 2022. Regeneron is required to deliver at least 100,000 doses by the end of each of September, October, November, and December 2021, with the remaining doses to be delivered by January 31, 2022, and to use commercially reasonable efforts to deliver doses early. In addition, the Amendment sets forth a good faith obligation to deliver filled and finished doses of drug product based on a non-binding monthly schedule that, if met, would result in the delivery of all doses by the end of 2021. The U.S. Government will acquire doses at the lowest therapeutic dose (other than a pediatric dose) authorized or approved by the FDA prior to or on the date of delivery for a price of $2,100 per dose, resulting in payments to Regeneron of $2.940 billion in the aggregate based on the delivery of 1.4 million doses, and will be obligated to pay for partial deliveries. A number of factors may impact available filled and finished supply, including manufacturing considerations. 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 Amended 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 Amended Supply Agreement for convenience. If the Amended 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 foregoing description of the Amended Supply Agreement is qualified in its entirety by reference to the full text of (i) the Amendment, a copy of which will be filed with the U.S. Securities and Exchange Commission (the "SEC") as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarterly period ending September 30, 2021; and (ii) the Supply Agreement, a copy of which has been filed with the SEC as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended 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 and/or its 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 REGEN-COV™ (casirivimab and imdevimab)) and the impact of the foregoing on Regeneron's ability to supply its products and product candidates, including its ability to supply doses of REGEN-COV under the terms of the amended supply agreement with the U.S. government discussed in this Report (the "Amended Supply Agreement"); whether and to what extent Regeneron will be able to supply doses of REGEN-COV under the Amended Supply Agreement; the amount of payments (if any) Regeneron may receive pursuant to the Amended Supply Agreement; what the lowest therapeutic dose (other than a pediatric dose) authorized or approved by the FDA will be at the time of delivery to the U.S. government under the Amended Supply Agreement; and whether the Amended 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, 2020 and its Form 10-Q for the quarterly period ended June 30, 2021. 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: September 16, 2021
