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): August 19, 2020 (August 18, 2020)

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 August 18, 2020, Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), F. Hoffman-La Roche Ltd ("Roche Basel"), and Genentech, Inc. ("Genentech" and, together with Roche Basel, "Roche") entered into a global strategic collaboration to develop, manufacture, and commercialize the Company's novel investigational two-antibody "cocktail" treatment, consisting of the antibodies REGN10987 and REGN10933 (also known as REGN-COV2) (the "Antibody Product"), designed to prevent and treat infection from the SARS-CoV-2 virus (the "Collaboration"). The Collaboration is governed by a collaboration and license agreement (the "License Agreement"), dated August 18, 2020, by and among the Company, Roche Basel, and Genentech. Previously, to expedite the Collaboration, on July 22, 2020 the Company and Roche Basel entered into a technology transfer agreement to govern the transfer by the Company to Roche Basel of the process required for the manufacture of the Antibody Product.

Pursuant to the License Agreement, the Company has granted to Roche Basel (i) a non-exclusive license to make, import, and export the Antibody Product worldwide, (ii) a non-exclusive license to develop the Antibody Product worldwide, (iii) a co-exclusive license to obtain regulatory approval for the Antibody Product throughout the world outside the United States (the "Roche Territory"), and (iv) an exclusive license to market, commercially distribute, sell, and offer for sale the Antibody Product in the Roche Territory. Under the License Agreement, Roche Basel has granted to the Company (i) a non-exclusive license to make, import, and export the Antibody Product worldwide, (ii) a non-exclusive license to develop the Antibody Product worldwide, (iii) an exclusive license to obtain regulatory approval for the Antibody Product in the United States, and (iv) an exclusive license to market, commercially distribute, sell, and offer for sale the Antibody Product in the United States.

Pursuant to the License Agreement, Roche and the Company are obligated to dedicate and utilize the equivalent of at least 100,000 liters and at least 40,000 liters, respectively, of annualized bioreactor capacity on a full-time campaign basis for the manufacture of the Antibody Product, unless otherwise mutually agreed by the parties or determined by the joint manufacturing committee to be established for the Collaboration. Any worldwide gross profits from the Antibody Product will be aggregated and shared based on a pre-specified formula, which is estimated to result in Regeneron receiving approximately 50% - 60% of the worldwide gross profits, depending on the amount of manufactured Antibody Product delivered by each party. Any profit sharing will commence after the Antibody Product manufactured by Roche receives regulatory approval and is supplied to the market. Each party will bear its own commercial expenses in its designated territory. In addition, the parties will be obligated to jointly fund the ongoing Antibody Product Phase 3 COVID-19 prevention study and Phase 1 multi-dose safety study, as well as any additional new global studies to evaluate further the potential of the Antibody Product in treating or preventing COVID-19.

The term of the License Agreement will expire seven years after the first commercial sale of an Antibody Product in the European Union unless the parties mutually agree to extend the term. Either party may terminate the License Agreement in the event of bankruptcy or a material breach of the License Agreement by the other party that remains uncured for a period of 90 days. In addition, Roche may terminate the License Agreement upon 30 days' written notice to the Company if: (i) both of the two specified Antibody Product COVID-19 treatment studies are placed on clinical hold by the U.S. Food and Drug Administration (the "FDA") or the European Medicines Agency that continues for 30 days unless the Company is undertaking reasonable actions to have either such clinical hold removed, in which case if such clinical hold continues for 90 days; (ii) the Antibody Product has not received an emergency use authorization by the FDA prior to May 31, 2021; (iii) the Company has not filed for full regulatory approval of the Antibody Product in the United States prior to May 31, 2021; or (iv) the Company terminates further development of the Antibody Product. Further, if a third party's antibody product for SARS-CoV-2 virus has a safety and efficacy profile that provides a substantial public health benefit compared to the Antibody Product that is approved, Roche may terminate the License Agreement upon 60 days' written notice before the first commercial sale of the Antibody Product and six months' notice after the first commercial sale of the Antibody Product. Upon termination of the License Agreement in its entirety, generally all related rights and licenses granted by each party to the other will terminate on the effective date of the expiration or termination, subject to certain exceptions.

The foregoing description of the Collaboration is qualified in its entirety by reference to the full text of the License Agreement, a copy of which will be filed with the U.S. Securities and Exchange Commission as an exhibit to the Quarterly Report on Form 10-Q to be filed by the Company for the quarterly period ending September 30, 2020.

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: August 19, 2020