SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number: 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York	**13-3444607**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

777 Old Saw Mill River Road Tarrytown, New York 10591-6707
(Address of principal executive offices, including zip code)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Trading Symbol*	*Name of each exchange on which registered*
Common Stock - par value $.001 per share	**REGN**	**NASDAQ Global Select Market**

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ 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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant was approximately $63,344,000,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2020, the last trading day of the registrant's most recently completed second fiscal quarter. For purposes of this calculation only, the registrant has assumed that all of its directors and executive officers, and no other persons, are its affiliates. This determination of affiliate status is not necessarily a determination for other purposes.

The number of shares outstanding of each of the registrant's classes of common stock as of January 29, 2021:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,848,970
Common Stock, $.001 par value	105,282,929

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2021 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 92 to 97 of this filing.

REGENERON PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
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PART I

ITEM 1. BUSINESS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. (where applicable, together with its subsidiaries, "Regeneron," "Company," "we," "us," and "our"), 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 impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates being developed by Regeneron and/or its collaborators (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept) Injection, Dupixent® (dupilumab) Injection, Libtayo® (cemiplimab) Injection, Praluent® (alirocumab) Injection, Kevzara® (sarilumab) Injection, Inmazeb™ (atoltivimab, maftivimab, and odesivimab-ebgn), REGEN-COV™ (casirivimab and imdevimab), fasinumab, Evkeeza™ (evinacumab), garetosmab, pozelimab, odronextamab, itepekimab, REGN5458, REGN5713-5714-5715, Regeneron's other oncology programs (including its costimulatory bispecific portfolio), Regeneron's and its collaborators' earlier-stage programs, and the use of human genetics in Regeneron's research programs; the likelihood and timing of achieving any of our anticipated development milestones referenced in this report; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; the likelihood, timing, and scope of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for Regeneron's Products, including without limitation EYLEA, Dupixent, Libtayo, Praluent, Kevzara, REGEN-COV, fasinumab, Evkeeza, garetosmab, pozelimab, odronextamab, itepekimab, REGN5458, and REGN5713-5714-5715; the extent to which the results from the research and development programs conducted by us and/or our collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; ongoing regulatory obligations and oversight impacting Regeneron's Products (such as EYLEA, Dupixent, Libtayo, Praluent, and Kevzara), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; uncertainty of market acceptance and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's Products and Regeneron's Product Candidates; our ability to manufacture and manage supply chains for multiple products and product candidates; the ability of our 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 Regeneron's Product Candidates; the availability and extent of reimbursement of Regeneron's Products from third-party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid (including the impact of the recently issued "most-favored-nation" interim final rule); coverage and reimbursement determinations by such payors and new policies and procedures adopted by such payors; unanticipated expenses; the costs of developing, producing, and selling products; our ability to meet any of our financial projections or guidance, including without limitation capital expenditures, and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including our agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as Regeneron's agreement with Roche relating to REGEN-COV, to be cancelled or terminated; and risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings relating to EYLEA, Dupixent, Praluent, and REGEN-COV described further in Note 15 to our Consolidated Financial Statements included in this report), other litigation and other proceedings and government investigations relating to the Company and/or its operations (including without limitation those described in Note 15 to our Consolidated Financial Statements included in this report), the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on our business, prospects, operating results, and financial condition. These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under Part I, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events, or otherwise.

General

Regeneron Pharmaceuticals, Inc. is a fully integrated biotechnology company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious diseases. Our commercialized medicines and product candidates in development are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, infectious diseases, and rare diseases.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, and to build on that foundation with our clinical development, manufacturing, and commercial capabilities. Our objective is to continue to be an integrated, multi-product biotechnology company that provides patients and medical professionals with important options for preventing and treating human diseases.

Selected financial information is summarized as follows:

	Year Ended December 31,		
(In millions, except per share data)	**2020**	**2019***	**2018***
Revenues	$ 8,497.1	$ 6,557.6	$ 5,145.6
Net income	$ 3,513.2	$ 2,115.8	$ 2,444.4
Net income per share - diluted	$ 30.52	$ 18.46	$ 21.29

* Certain revisions have been made to the previously reported revenues for the years ended December 31, 2019 and 2018. See Note 1 to our Consolidated Financial Statements for further details.

For purposes of this report, references to our products encompass products marketed or otherwise commercialized by us and/or our collaborators and references to our product candidates encompass product candidates in development by us and/or our collaborators (in the case of collaborated products or product candidates under the terms of the applicable collaboration agreements), unless otherwise stated or required by the context.

Products

Products that have received marketing approval are summarized in the table below.

		Territory			
Product	**Disease Area**	**U.S.**	**EU**	**Japan**	**ROW[4]**
EYLEA (aflibercept) Injection[1]	- Neovascular age-related macular degeneration ("wet AMD")	a	a	a	a
	- Diabetic macular edema ("DME")	a	a	a	a
	- Macular edema following retinal vein occlusion ("RVO"), which includes macular edema following central retinal vein occlusion ("CRVO") and macular edema following branch retinal vein occlusion ("BRVO")	a	a	a	a
	- Myopic choroidal neovascularization ("mCNV")		a	a	a
	- Diabetic retinopathy	a			
	- Neovascular glaucoma ("NVG")			a	
Dupixent (dupilumab) Injection[2]	- Atopic dermatitis (in adults and adolescents)[5]	a	a	a	a
	- Atopic dermatitis (in pediatrics 6–11 years of age)	a	a		a
	Asthma (in adults and adolescents)	a	a	a	a
	- Chronic rhinosinusitis with nasal polyposis ("CRSwNP")	a	a	a	a
Libtayo (cemiplimab) Injection[2]	- Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	a	a		a

Product *(continued)*	Disease Area	Territory			
		U.S.	EU	Japan	ROW[4]
Praluent (alirocumab) Injection[3]	LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD") (in adults)	a	a	[7]	a
	- Cardiovascular risk reduction in patients with established cardiovascular disease	a	a		a
Kevzara (sarilumab) Solution for Subcutaneous Injection[2]	- Rheumatoid arthritis ("RA") (in adults)	a	a	a	a
Inmazeb (atoltivimab, maftivimab, and odesivimab-ebgn) Injection	- Infection caused by *Zaire ebolavirus*	a			
ARCALYST® (rilonacept) Injection for Subcutaneous Use[8]	- Cryopyrin-Associated Periodic Syndromes ("CAPS"), including Familial Cold Auto inflammatory Syndrome ("FCAS") and Muckle-Wells Syndrome ("MWS")	a			
	- Deficiency of Interleukin-1 Receptor Antagonist ("DIRA") (in adults and pediatrics)	a			
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[6]	- Metastatic colorectal cancer ("mCRC")	a	a	a	a

Note 1: Refer to "Net Product Sales of Regeneron-Discovered Products" section below for information regarding whether net product sales for a particular product are recorded by us, Bayer, or Sanofi

Note 2: Refer to product label in each territory for specific information

[1] In collaboration with Bayer (outside the United States)

[2] In collaboration with Sanofi

[3] In collaboration with Sanofi prior to April 2020. Effective April 2020, the Company is solely responsible for the development and commercialization of Praluent in the United States, and Sanofi is solely responsible for the development and commercialization of Praluent outside of the United States. Pursuant to the April 2020 agreement, Sanofi pays us a royalty on net product sales of Praluent outside the United States. Refer to "Collaboration, License, and Other Agreements - Sanofi" section below for further details.

[4] Rest of world. Checkmark in this column indicates that the product has received marketing approval in at least one country outside of the United States, European Union ("EU"), or Japan.

[5] Approval in Japan is for adults and adolescents 15 years of age and older

[6] Pursuant to a 2015 amended and restated ZALTRAP agreement, Sanofi is solely responsible for the development and commercialization of ZALTRAP, and Sanofi pays us a percentage of aggregate net product sales of ZALTRAP

[7] No longer marketed by Sanofi in Japan due to injunction (see Note 15 to our Consolidated Financial Statements for further details)

[8] Pursuant to a 2017 license agreement with Kiniksa Pharmaceuticals, Ltd., we granted Kiniksa the right to develop and commercialize certain new indications for ARCALYST. We currently maintain exclusive rights to ARCALYST in the United States for existing indications. Commencing with the receipt of marketing approval by Kiniksa for the first new indication of ARCALYST in the United States, we will grant U.S. commercial rights to ARCALYST for all approved indications and Kiniksa will pay us a share of ARCALYST profits. Refer to "Collaboration, License, and Other Agreements - Kiniksa" section below for further details.

Additional Information - Product Updates

Inmazeb

Inmazeb is a cocktail of three fully human monoclonal antibodies that each bind to the Ebola virus at different points, which may serve to increase efficacy, reduce the development of viral sequences that lead to resistance, and potentially enable utility in future outbreaks as viruses continue to evolve. In October 2020, the U.S. Food and Drug Administration ("FDA") approved Inmazeb for the treatment of infection caused by *Zaire ebolavirus* in adult and pediatric patients, including newborns of mothers who have tested positive for the infection. In connection with this approval, we were also granted a material threat medical countermeasure priority review voucher by the FDA.

REGEN-COV - Emergency Use Authorization

In November 2020, REGEN-COV (antibody cocktail casirivimab and imdevimab administered together) received Emergency Use Authorization ("EUA") from the FDA for the treatment of mild to moderate COVID-19 in adults, as well as in pediatric patients at least 12 years of age and weighing at least 40 kg, who have received positive results of direct SARS-CoV-2 viral testing and are

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