UNITED STATES
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, 2022
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: 000-19034

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 $62.0 billion, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2022, 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 26, 2023:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,818,146
Common Stock, $.001 par value	107,507,386

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2023 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 96 to 101 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 or licensees (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 or licensees (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, Evkeeza® (evinacumab), aflibercept 8 mg, pozelimab, odronextamab, itepekimab, fianlimab, garetosmab, linvoseltamab, 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 those listed above; 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, 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 the utilization, 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) or recommendations and guidelines from governmental authorities and other third parties 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; 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 and Bayer (or their respective affiliated companies, as applicable), 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 described further in Note 16 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 16 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 invents, develops, manufactures, and commercializes medicines for people with serious diseases. Our products and product candidates in development are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, hematologic conditions, 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 medicines for preventing and treating human diseases.

Selected financial information is summarized as follows:

	Year Ended December 31,		
(In millions, except per share data)	**2022**	**2021**	**2020**
Revenues	$ 12,172.9	$ 16,071.7	$ 8,497.1
Net income	$ 4,338.4	$ 8,075.3	$ 3,513.2
Net income per share - diluted	$ 38.22	$ 71.97	$ 30.52

For purposes of this report, references to our products encompass products marketed or otherwise commercialized by us and/or our collaborators or licensees and references to our product candidates encompass product candidates in development by us and/or our collaborators or licensees (in the case of collaborated or licensed products or product candidates under the terms of the applicable collaboration or license 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**	**U.S.**	**EU**	**Japan**	**ROW[e]**
EYLEA (aflibercept) Injection[a]	Neovascular age-related macular degeneration ("wet AMD")	✔	✔	✔	✔
	Diabetic macular edema ("DME")	✔	✔	✔	✔
	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")	✔	✔	✔	✔
	Myopic choroidal neovascularization ("mCNV")		✔	✔	✔
	Diabetic retinopathy ("DR")	✔			
	Neovascular glaucoma ("NVG")			✔	
	Retinopathy of prematurity ("ROP")		✔	✔	
Dupixent (dupilumab) Injection[b]	Atopic dermatitis (in adults and adolescents)	✔	✔	✔	✔
	Atopic dermatitis (in pediatrics 6–11 years of age)	✔	✔		✔
	Atopic dermatitis (in pediatrics 6 months–5 years of age)	✔			✔
	Asthma (in adults and adolescents)	✔	✔	✔	✔
	Asthma (in pediatrics 6–11 years of age)	✔	✔		✔
	Chronic rhinosinusitis with nasal polyposis ("CRSwNP")	✔	✔	✔	✔

Product *(continued)*	Disease	Territory			
		U.S.	EU	Japan	ROW[e]
Dupixent (dupilumab) Injection[b] *(continued)*	Eosinophilic esophagitis ("EoE") (in adults and adolescents)	✔	✔		✔
	Prurigo nodularis	✔	✔		✔
Libtayo (cemiplimab) Injection[c]	Metastatic or locally advanced first-line non-small cell lung cancer ("NSCLC")	✔	✔		✔
	Metastatic or locally advanced first-line NSCLC (in combination with chemotherapy)	✔			
	Metastatic or locally advanced basal cell carcinoma ("BCC")	✔	✔		✔
	Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	✔	✔		✔
	Metastatic or recurrent second-line cervical cancer		✔	✔	✔
Praluent (alirocumab) Injection[d]	LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD")	✔	✔		✔
	Cardiovascular risk reduction in patients with established cardiovascular disease	✔	✔		✔
	Homozygous familial hypercholesterolemia ("HoFH")	✔			
REGEN-COV®[f]	COVID-19		✔	✔	✔
Kevzara (sarilumab) Solution for Subcutaneous Injection[b]	Rheumatoid arthritis ("RA")	✔	✔	✔	✔
Evkeeza (evinacumab) Injection[g]	HoFH (in adults and adolescents)	✔	✔		✔
Inmazeb® (atoltivimab, maftivimab, and odesivimab-ebgn) Injection	Infection caused by *Zaire ebolavirus*	✔			
ARCALYST® (rilonacept) Injection for Subcutaneous Use[h]	Cryopyrin-associated periodic syndromes ("CAPS"), including familial cold auto-inflammatory syndrome ("FCAS") and Muckle-Wells syndrome ("MWS") (in adults and adolescents)	✔			
	Deficiency of interleukin-1 receptor antagonist ("DIRA") (in adults and pediatrics)	✔			
	Recurrent pericarditis (in adults and adolescents)	✔			
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[i]	Metastatic colorectal cancer ("mCRC")	✔	✔	✔	✔

Note: Refer to table below (net product sales of Regeneron-discovered products) for information regarding whether net product sales for a particular product are recorded by us or others. In addition, unless otherwise noted, products in the table above are generally approved for use in adults in the above-referenced diseases.

[a] In collaboration with Bayer outside the United States

[b] In collaboration with Sanofi

[c] In collaboration with Sanofi prior to July 2022. Effective July 2022, the Company is solely responsible for the development, commercialization, and manufacturing of Libtayo. Refer to "Collaboration, License, and Other Agreements" section below for further details.

[d] 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.

(e) Rest of world ("ROW"). A 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.

(f) Known as REGEN-COV in the United States and Ronapreve™ in other countries.

(g) The Company is solely responsible for the development and commercialization of Evkeeza in the United States. In January 2022, the Company entered into a license and collaboration agreement for Ultragenyx to develop and commercialize Evkeeza outside of the United States.

(h) Kiniksa is solely responsible for the development and commercialization of ARCALYST.

(i) Sanofi is solely responsible for the development and commercialization of ZALTRAP.

Net product sales of Regeneron-discovered products consist of the following:

	Year Ended December 31,								
	2022			2021			2020		
(In millions)	U.S.	ROW	Total	U.S.	ROW	Total	U.S.	ROW	Total
EYLEA[a]	$ 6,264.6	$ 3,382.8	$ 9,647.4	$ 5,792.3	$ 3,450.9 *	$ 9,243.2	$ 4,947.2	$ 2,820.7 *	$ 7,767.9
Dupixent[b]	$ 6,668.0	$ 2,013.2	$ 8,681.2	$ 4,713.0	$ 1,485.3	$ 6,198.3	$ 3,226.2	$ 818.6	$ 4,044.8
Libtayo[c]	$ 374.5	$ 203.5	$ 578.0	$ 306.3	$ 151.9	$ 458.2	$ 270.7	$ 77.5	$ 348.2
Praluent[d]	$ 130.0	$ 337.4	$ 467.4	$ 170.0	$ 251.1	$ 421.1	$ 186.0	$ 172.8	$ 358.8
REGEN-COV[e]	$ —	$ 1,769.6	$ 1,769.6	$ 5,828.0	$ 1,745.9	$ 7,573.9	$ 185.7	$ —	$ 185.7
Kevzara[b]	$ 199.7	$ 158.3	$ 358.0	$ 161.9	$ 176.1	$ 338.0	$ 141.6	$ 128.3	$ 269.9
Other products[f]	$ 56.1	$ 69.1	$ 125.2	$ 25.9	$ 86.4	$ 112.3	$ 18.9	$ 97.9	$ 116.8

* Effective January 1, 2022, the Company and Bayer commenced sharing equally in profits and losses based on sales from Bayer to its distributor in Japan. Previously, the Company received from Bayer a tiered percentage of sales based on sales by Bayer's distributor in Japan. Consequently, the prior year net product sales amount has been revised for comparability purposes.

(a) Regeneron records net product sales of EYLEA in the United States. Bayer records net product sales of EYLEA outside the United States. The Company records its share of profits/losses in connection with sales of EYLEA outside the United States.

(b) Sanofi records global net product sales of Dupixent and Kevzara. The Company records its share of profits/losses in connection with global sales of Dupixent and Kevzara.

(c) Prior to July 1, 2022, Regeneron recorded net product sales of Libtayo in the United States and Sanofi recorded net product sales of Libtayo outside the United States. The parties equally shared profits/losses in connection with global sales of Libtayo. Effective July 1, 2022, the Company began recording net product sales of Libtayo outside the United States and pays Sanofi a royalty on global sales. Refer to "Collaboration, License, and Other Agreements" section below for further details. Included in this line item is approximately $34 million of net product sales recorded by Sanofi in the second half of 2022 in connection with sales in certain markets (Sanofi will record net product sales in such markets during a transition period until inventory on hand as of July 1, 2022 is sold through to the end customers).

(d) Effective April 1, 2020, Regeneron records net product sales of Praluent in the United States. Also effective April 1, 2020, Sanofi records net product sales of Praluent outside the United States and pays the Company a royalty on such sales. Previously, Sanofi recorded global net product sales of Praluent and the Company recorded its share of profits/losses in connection with such sales.

(e) Regeneron records net product sales of REGEN-COV in the United States and Roche records net product sales of Ronapreve outside the United States. The parties share gross profits from global sales of REGEN-COV and Ronapreve based on a pre-specified formula.

(f) Included in this line item are products which are sold by the Company and others. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Revenues" for a complete listing of net product sales recorded by the Company. Not included in this line item are net product sales of ARCALYST subsequent to the first quarter of 2021, which are recorded by Kiniksa.

Programs in Clinical Development

Product candidates in clinical development, which are being developed by us and/or our collaborators, are summarized in the table below.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development (including any post-approval studies), uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes to drug pricing and reimbursement regulations and requirements, and changes in the competitive landscape affecting a product candidate. The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results.

Refer to Part I, Item 1A. "Risk Factors" for a description of risks and uncertainties that may affect our clinical programs. Any of such risks and uncertainties may, among other matters, negatively impact the development timelines set forth in the table below.

Clinical Program	Phase 1	Phase 2	Phase 3	Regulatory Review[(h)]	2022 and 2023 Events to Date	Select Upcoming Milestones
Ophthalmology						
EYLEA (aflibercept)[(a)]			–ROP[(c)]	–ROP (U.S.)	–Granted pediatric exclusivity by U.S. Food and Drug Administration ("FDA") in connection with ROP study, extending period of EYLEA U.S. market exclusivity by six months through May 17, 2024 –Approved by European Commission ("EC") for ROP –Approved by Ministry of Health, Labour and Welfare ("MHLW") for ROP in Japan –Withdrew supplemental Biologics License Application ("sBLA") for every-16-weeks dosing regimen in patients with DR	–FDA decision on sBLA for ROP (target action date of February 11, 2023)
Aflibercept 8 mg[(a)]			–Wet AMD –DME	–Wet AMD and DME (U.S.)	–Reported that Phase 3 trials in wet AMD and DME met their primary endpoints	–FDA decision on BLA for wet AMD and DME (third quarter 2023) –Submit regulatory application in the EU for wet AMD and DME (first quarter 2023) –Report two-year data from Phase 3 studies in wet AMD and DME (third quarter 2023)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[(h)]	2022 and 2023 Events to Date	Select Upcoming Milestones
Immunology & Inflammation						
Dupixent (dupilumab)[(b)] *Antibody to IL-4R alpha subunit*			–EoE in pediatrics[(c)] –Chronic obstructive pulmonary disease ("COPD") –Bullous pemphigoid (Phase 2/3)[(c)] –Chronic spontaneous urticaria ("CSU") –Chronic inducible urticaria - cold –Chronic rhinosinusitis without nasal polyposis –Allergic fungal rhinosinusitis –Chronic pruritus of unknown origin	–Atopic dermatitis in pediatrics (6 months–5 years of age) (EU) and in pediatrics and adolescents (6 months–14 years of age (Japan) –Prurigo nodularis (Japan) –CSU in adults and adolescents (U.S.)	–Approved by FDA for atopic dermatitis in pediatrics (6 months–5 years of age) –European Medicines Agency's ("EMA") Committee for Medicinal Products for Human Use ("CHMP") adopted positive opinion for atopic dermatitis in pediatrics (6 months–5 years of age) –Approved by EC for severe asthma in pediatrics (6–11 years of age) –Approved by FDA and EC for EoE in adults and adolescents –Reported that Phase 3 trial in EoE in pediatrics (1–11 years of age) met its primary endpoint –Approved by FDA and EC for prurigo nodularis –Stopped one of the Phase 3 trials in CSU (in patients refractory to omalizumab) due to futility, based on pre-specified interim analysis –Initiated additional Phase 3 trial in CSU (in biologic-naïve patients) –Discontinued further clinical development in peanut allergy	–EC decision on regulatory submission for atopic dermatitis in pediatrics (6 months–5 years of age) (first half 2023) –MHLW decision on regulatory submission for atopic dermatitis in pediatrics and adolescents (6 months–14 years of age) in Japan (second half 2023) –Submit sBLA for EoE in pediatrics (mid-2023) –Report results from first Phase 3 study in COPD (first half 2023) –FDA decision on sBLA for CSU in adults and adolescents (second half 2023) –Report results from Phase 3 study in chronic inducible urticaria - cold (first half 2023)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2022 and 2023 Events to Date	Select Upcoming Milestones
Kevzara (sarilumab)[b] *Antibody to IL-6R*		–Polyarticular-course juvenile idiopathic arthritis ("pcJIA") –Systemic juvenile idiopathic arthritis ("sJIA")		–Polymyalgia rheumatica ("PMR") (U.S.)		–FDA decision on sBLA for PMR (target action date of February 28, 2023)
Itepekimab[b] (REGN3500) *Antibody to IL-33*			–COPD			–Report results from Phase 3 study in COPD (2024)
REGN5713-5714-5715 *Multi-antibody therapy to Bet v 1*			–Birch allergy			
Solid Organ Oncology						
Libtayo (cemiplimab)[n][g] *Antibody to PD-1*		–Neoadjuvant CSCC –Second-line cervical cancer, ISA101b combination	–Adjuvant CSCC	–First-line NSCLC, chemotherapy combination (EU)	–Approved by FDA in combination with chemotherapy for NSCLC –Approved by EC and MHLW for cervical cancer –Voluntarily withdrew sBLA for cervical cancer due to inability to align with FDA on certain post-marketing studies –Positive data from Phase 2 trial in neoadjuvant CSCC presented at European Society for Medical Oncology ("ESMO") Congress 2022 and published in *New England Journal of Medicine*	–EC decision on regulatory submission for NSCLC, chemotherapy combination (first half 2023)
Fianlimab[f] (REGN3767) *Antibody to LAG-3*	–Solid tumors and advanced hematologic malignancies		–First-line metastatic melanoma –First-line adjuvant melanoma		–Presented positive data from Phase 1 trial (in combination with Libtayo) in advanced melanoma at ESMO Congress 2022	–Initiate Phase 3 study (in combination with Libtayo) in perioperative melanoma (mid-2023)

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2022 and 2023 Events to Date	Select Upcoming Milestones
Fianlimab[f] *(continued)*					–Positive initial data from Phase 1 trial (in combination with Libtayo) in NSCLC presented at ESMO Immuno-Oncology Congress 2022	–Initiate Phase 2/3 studies (in combination with Libtayo) in first-line advanced NSCLC (first half 2023) –Initiate Phase 2 study (in combination with Libtayo) in perioperative NSCLC (second half 2023)
Vidutolimod *Immune activator targeting TLR9*		–Solid tumors				–Initiate Phase 2 study in melanoma
Ubamatamab[f] **(REGN4018)** *Bispecific antibody targeting MUC16 and CD3*		–Platinum-resistant ovarian cancer			–Presented positive initial data from monotherapy dose escalation portion of Phase 1/2 study in platinum-resistant ovarian cancer at ESMO Congress 2022	–Report results from Phase 1/2 study (in combination with Libtayo) in platinum-resistant ovarian cancer (2023)
REGN5668[o] *Bispecific antibody targeting MUC16 and CD28*	–Platinum-resistant ovarian cancer					
REGN5678 *Bispecific antibody targeting PSMA and CD28*	–Prostate cancer				–Reported preliminary data from dose escalation portion of Phase 1/2 study (in combination with Libtayo) in prostate cancer	–Report additional results from Phase 1/2 study (in combination with Libtayo) in prostate cancer (2023)
REGN4336 *Bispecific antibody targeting PSMA and CD3*	–Prostate cancer					
REGN5093 *Bispecific antibody targeting two distinct MET epitopes*	–MET-altered advanced NSCLC				–Presented positive initial data from dose escalation portion of Phase 1/2 study in MET-altered advanced NSCLC at ESMO Congress 2022	
REGN5093-M114 *Bispecific antibody-drug conjugate targeting two distinct MET epitopes*	–MET overexpressing advanced cancer					
REGN6569 *Antibody to GITR*	–Solid tumors					

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2022 and 2023 Events to Date	Select Upcoming Milestones
REGN7075 *Bispecific antibody targeting EGFR and CD28*	–Solid tumors					
Hematology						
Odronextamab[i] (REGN1979) *Bispecific antibody targeting CD20 and CD3*	–Certain B-cell malignancies[c][m]	–B-cell non-Hodgkin lymphoma ("B-NHL")[m] (pivotal study)			–Presented positive data from two cohorts of pivotal Phase 2 study in patients with diffuse large B-cell lymphoma ("DLBCL") and follicular lymphoma ("FL") at American Society of Hematology ("ASH") Annual Meeting	–Initiate Phase 3 studies in FL and DLBCL, including earlier lines of therapy (first half 2023) –Submit BLA for relapsed/refractory FL and DLBCL (second half 2023)
Linvoseltamab[f] (REGN5458) *Bispecific antibody targeting BCMA and CD3*	–Multiple myeloma[c]	–Multiple myeloma (pivotal study)[c]			–Completed enrollment in pivotal Phase 2 study in multiple myeloma –Presented positive data from pivotal Phase 2 study in multiple myeloma at ASH Annual Meeting	–Initiate Phase 3 study in multiple myeloma, including earlier lines of therapy (first half 2023) –Submit BLA for relapsed/refractory multiple myeloma (second half 2023)
REGN5459[f] *Bispecific antibody targeting BCMA and CD3*	–Transplant desensitization in patients with chronic kidney disease					
Pozelimab[f] (REGN3918) *Antibody to C5; studied as monotherapy and in combination with cemdisiran*		–CD55-deficient protein-losing enteropathy ("CHAPLE"), monotherapy[c][e] (potentially pivotal study)	–Myasthenia gravis, cemdisiran combination[k] –Paroxysmal nocturnal hemoglobinuria ("PNH"), cemdisiran combination[c][k]	–CHAPLE, monotherapy (U.S.)		–FDA decision on BLA for CHAPLE, monotherapy (second half 2023)
REGN7257 *Antibody to IL2Rg*	–Aplastic anemia					
NTLA-2001[j] *TTR gene knockout using CRISPR/Cas9*	–Transthyretin ("ATTR") amyloidosis[c]				–Reported positive interim data from Phase 1 trial in ATTR	
REGN9933 *Antibody to Factor XI*	–Thrombosis					

Clinical Program *(continued)*	Phase 1	Phase 2	Phase 3	Regulatory Review[h]	2022 and 2023 Events to Date	Select Upcoming Milestones
REGN7508 *Antibody to Factor XI*	–Thrombosis					
REGN7999 *Antibody to TMPRSS6*	–Transfusion dependent iron overload					
General Medicine						
"Next Generation" Covid Antibodies *Antibodies to SARS-CoV-2 variants*						–Initiate clinical development of "next generation" antibody
Praluent (alirocumab) *Antibody to PCSK9*			–HeFH in pediatrics			–Submit sBLA for HeFH in pediatrics (mid-2023)
Evkeeza (evinacumab)[f][l] *Antibody to ANGPTL3*				–HoFH in pediatrics (5–11 years of age) (U.S.)	–Reported that Phase 3 trial for HoFH in pediatrics (5–11 years of age) met its primary endpoint	–FDA decision on sBLA for HoFH in pediatrics (5–11 years of age) (target action date of March 30, 2023)
Garetosmab[f] (REGN2477) *Antibody to Activin A*			–Fibrodysplasia ossificans progressiva ("FOP")[c][d][e]			
Mibavademab[f] (REGN4461) *Agonist antibody to leptin receptor ("LEPR")*		–Generalized lipodystrophy[e] –Partial lipodystrophy				
REGN5381/REGN9035 *Agonist antibody to NPR1/reversal agent to REGN5381*	–Reversal agent in healthy volunteers	–Heart failure				–Report initial data in healthy volunteers (2023)
ALN-HSD[p] *RNAi therapeutic targeting HSD17B13*	–Nonalcoholic steatohepatitis ("NASH")				–Reported preliminary data from Phase 1 study in NASH	–Initiate Phase 2 study in NASH (first quarter 2023)
ALN-PNP[k] *RNAi therapeutic targeting PNPLA3*	–NASH					
ALN-APP[k] *RNAi therapeutic targeting APP*	–Early-onset Alzheimer's disease					–Report results from Phase 1 study in early-onset Alzheimer's disease (mid-2023)

Note 1: For purposes of the table above, a program is classified in Phase 1, 2, or 3 clinical development after recruitment for the corresponding study or studies has commenced.

Note 2: We have discontinued further clinical development of fasinumab (REGN475), an antibody to NGF, which was previously being studied in osteoarthritis pain of the knee or hip in collaboration with Teva and Mitsubishi Tanabe Pharma Corporation ("MTPC"); REGN6490, an antibody to IL-36R, which was previously being studied in palmo-plantar pustulosis; and the Phase 3 study of REGN1908-1909, a multi-antibody therapy to Fel d 1, in cat allergy, due to futility.

[a] In collaboration with Bayer outside the United States

[b] In collaboration with Sanofi

[c] FDA granted orphan drug designation

[d] FDA granted Breakthrough Therapy designation

[e] FDA granted Fast Track designation

[f] Sanofi did not opt-in to or elected not to continue to co-develop the product candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on sales of the product, if any.

[g] Studied as monotherapy and in combination with other antibodies and treatments

[h] Information in this column relates to U.S., EU, and Japan regulatory submissions only

[i] In collaboration with Zai Lab in mainland China, Hong Kong, Taiwan, and Macau

[j] In collaboration with Intellia

[k] In collaboration with Alnylam

[l] In collaboration with Ultragenyx outside the United States

[m] FDA granted Fast Track designation for follicular lymphoma and diffuse large B-cell lymphoma

[n] In collaboration with Sanofi prior to July 2022. Effective July 2022, the Company is solely responsible for the research, development, and commercialization of Libtayo. Refer to "Collaboration, License, and Other Agreements" section below for further details.

[o] Studied in combination with ubamatamab

[p] Alnylam elected to opt-out of the product candidate. Under the terms of our agreement, Alnylam is entitled to receive royalties on sales of the product, if any.

Additional Information - Clinical Development Programs

Aflibercept 8 mg

In September 2022, the Company announced that the primary endpoints were met in two pivotal trials investigating aflibercept 8 mg with 12- and 16-week dosing regimens in patients with DME and wet AMD. The PHOTON trial in DME and the PULSAR trial in wet AMD both demonstrated that aflibercept 8 mg 12- and 16-week dosing regimens achieved non-inferiority in vision gains compared to the EYLEA 8-week dosing regimen. Furthermore, of the patients randomized to 12- and 16-week dosing intervals, 91% and 89% of DME patients, respectively, and 79% and 77% of wet AMD patients, respectively, maintained those intervals through 48 weeks. The safety of aflibercept 8 mg was similar to EYLEA in both trials, and consistent with the known safety profile of EYLEA from previous clinical trials. The Company is utilizing a priority review voucher in connection with the December 2022 submission of the BLA for DME and wet AMD.

REGEN-COV (casirivimab and imdevimab)

REGEN-COV, a multi-antibody therapy to SARS-CoV-2 virus, previously received an EUA for use in certainpost-exposure prophylaxissettings and as a treatment for people with mild to moderate COVID-19 who are at high risk of serious consequences from COVID-19. Based on laboratory data, in January 2022, the FDA revised the EUA for REGEN-COV to exclude its use in geographic regions where, based on available information including variant susceptibility and regional variant frequency, infection or exposure is likely due to a variant such as an Omicron-lineage variant that is not susceptible to the treatment. With this EUA revision, REGEN-COV is not currently authorized for use in any U.S. states, territories, or jurisdictions, since Omicron-lineage variants are currently dominant across the United States. In December 2022, the FDA issued a complete response letter ("CRL") on the BLA for REGEN-COV to treat COVID-19 in non-hospitalized patients and as prophylaxis in certain individuals.

Descriptions of Marketed Products Studied in Additional Indications and Product Candidates in Late-Stage Clinical Development

EYLEA (aflibercept)

EYLEA is a soluble fusion protein that acts as a vascular endothelial growth factor ("VEGF") inhibitor, formulated as a 2 mg intravitreal injection for the eye. It is designed to block the growth of new blood vessels and decrease the ability of fluid to pass through blood vessels (vascular permeability) in the eye by blocking VEGF-A and PLGF, two growth factors involved in angiogenesis.

Aflibercept 8 mg

Aflibercept 8 mg is an investigational soluble fusion protein that acts as a VEGF inhibitor. Through a novel formulation, it is designed to deliver a concentrated dose of aflibercept to block VEGF-A and PLGF and inhibit the growth of new blood vessels and decrease vascular permeability. Aflibercept 8 mg is being studied in wet AMD and DME using extended dosing intervals of every 12 weeks and every 16 weeks.

Dupixent (dupilumab)

Dupixent is a fully human monoclonal antibody that inhibits signaling of the IL-4 and IL-13 pathways, and is not an immunosuppressant. IL-4 and IL-13 are key and central drivers of the type 2 inflammation that plays a major role in atopic dermatitis, asthma, CRSwNP, EoE, prurigo nodularis, and potentially other chronic allergic and inflammatory diseases.

Kevzara (sarilumab)

Kevzara is a fully human monoclonal antibody that binds specifically to the IL-6 receptor and inhibits IL-6-mediated signaling. IL-6 is a signaling protein produced in increased quantities in patients with RA and has been associated with disease activity, joint destruction, and other systemic problems.

Itepekimab

Itepekimab is an investigational, fully human monoclonal antibody that inhibits IL-33, a protein that is believed to play a key role in lung inflammation in COPD.

REGN5713-5714-5715

REGN5713-5714-5715 is an investigational combination of three fully human monoclonal antibodies designed to treat allergic inflammatory conditions caused by the allergen Betv1, which is the main allergen responsible for birch pollen allergies. Birch pollen allergy is one of the most common causes of seasonal allergies that occur in the spring, and is also believed to trigger "oral allergy syndrome" food reactions to related allergens found in nuts and fruits such as apples, pears, and cherries.

Libtayo (cemiplimab)

Libtayo is a fully human monoclonal antibody targeting the immune checkpoint receptor PD-1 on T-cells. The PD-1/PD-L1 immune checkpoint pathway is a well-known mechanism by which cancers evade immune destruction. Regeneron is studying Libtayo as monotherapy and in combination with either conventional or novel therapeutic approaches in various solid tumors and blood cancers. It is also being studied in combination with proprietary anti-cancer assets of other companies.

Fianlimab

Fianlimab is an investigational, fully human monoclonal antibody targeting the immune checkpoint receptor LAG-3 on T-cells. In melanoma, LAG-3 expression in the tumor microenvironment may be associated with therapeutic resistance to PD-1 inhibitors. Fianlimab is being investigated in combination with Libtayo to determine whether concurrent blockade of LAG-3 and PD-1 can help overcome this resistance and release the brakes on T-cell activation.

Odronextamab

Odronextamab is an investigational bispecific monoclonal antibody designed to bind to a component of the T-cell receptor ("TCR") complex (CD3), while also binding and bridging T-cells to a protein expressed on B-cells (CD20). We are studying whether odronextamab may help to activate T-cells via their CD3 receptors and trigger targeted, T-cell mediated killing of cancerous cells in several types of B-cell non-Hodgkin lymphoma.

Linvoseltamab

Linvoseltamab is an investigational bispecific monoclonal antibody designed to bind to CD3 while also binding and bridging T-cells to the BCMA protein on multiple myeloma cells. We are studying whether linvoseltamab may help to activate T-cells via their CD3 receptors and trigger targeted, T-cell mediated killing of multiple myeloma.

Pozelimab

Pozelimab is an investigational, fully human monoclonal antibody designed to block complement factor C5 in order to treat diseases mediated by abnormal complement pathway activity, including PNH, CHAPLE, and myasthenia gravis. Pozelimab is being studied as monotherapy and also in combination with Alnylam's investigational small interfering RNA ("siRNA") therapy, cemdisiran.

Praluent (alirocumab)

Praluent is a fully human monoclonal antibody that inhibits the binding of PCSK9 to the LDL receptor. Through inhibiting PCSK9, Praluent increases the number of available LDL receptors on the surface of liver cells to clear LDL, which lowers LDL cholesterol levels in the blood.

Evkeeza (evinacumab)

Evkeeza is a fully human monoclonal antibody that specifically binds to and blocks ANGPTL3. ANGPTL3 plays a key role in regulating plasma lipid levels, including triglycerides, LDL cholesterol, and HDL cholesterol, through inhibition of lipase enzymes (lipoprotein lipase and endothelial lipase).

Garetosmab

Garetosmab is an investigational, fully-human monoclonal antibody that binds to and neutralizes Activin A, which drives the abnormal bone formation that is the main pathology of the ultra-rare genetic disorder FOP. This abnormal bone formation in soft tissue outside of the normal skeleton, a process known as heterotopic ossification, leads to loss of mobility and premature death in FOP patients. Garetosmab is being investigated to determine whether it can help reduce and/or prevent the formation of heterotopic bone lesions by neutralizing the Activin A protein.

Other Programs

Our preclinical research programs include the areas of oncology/immuno-oncology, angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain and neurobiology, auditory conditions, enzyme replacement therapy, cardiovascular diseases, infectious diseases, and diseases related to aging. These preclinical research programs include both rare diseases and those involving broader populations.

Research and Development Technologies

Many proteins that play an important role in biology and disease are secreted by cells or located on the cell surface. Moreover, cells communicate through secreted factors and surface molecules. Our scientists have developed two different technologies to make protein therapeutics that potently and specifically block, activate, or inhibit the action of specific cell surface or secreted molecules. The first technology fuses receptor components to the constant region of an antibody molecule to make a class of drugs we call "Traps". EYLEA, ZALTRAP, and ARCALYST are drugs generated using our Trap technology. *VelociSuite*® is our second technology platform, which is used for discovering, developing, and producing fully human antibodies that can address both secreted and cell-surface targets.

VelociSuite

VelociSuite consists of *VelocImmune*®, *VelociGene*®, *VelociMouse*®, *VelociMab*®, *Veloci-Bi*®, *VelociT*®, *VelociHum*®, and other related technologies. The *VelocImmune* mouse platform is utilized to produce fully human antibodies. *VelocImmune* was generated by leveraging our *VelociGene* technology (see below), in a process in which six megabases of mouse immunoglobulin gene loci were replaced, or "humanized," with corresponding human immunoglobulin gene loci. *VelocImmune* mice can be used efficiently to generate fully human antibodies to targets of therapeutic interest. *VelocImmune* and our entire *VelociSuite* offer the potential to increase the speed and efficiency through which human antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early-stage drug development activities. We are utilizing the *VelocImmune* technology to produce our next generation of therapeutic antibody drug candidates for preclinical and clinical development.

Our *VelociGene* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of preclinical development and pharmacology programs, *VelociGene* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog or variants thereof. Thus, *VelociGene* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells ("ES cells"), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, mice developed using our *VelociMouse* technology are suitable for direct phenotyping or other studies.

We have also developed our *VelociMab* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune* human antibodies.

We have utilized our *VelociSuite* technologies to develop a class of potential drug candidates, known as bispecific antibodies. *Veloci-Bi* allows for the generation of full-length bispecific antibodies similar to native antibodies that are amenable to production by standard antibody manufacturing techniques, and are likely to have favorable antibody-like pharmacokinetic properties. In the area of immunotherapies in oncology, we are exploring the use of bispecific antibodies that target tumor antigens and the CD3 receptor on T-cells to harness the oncolytic properties of T-cells. We are exploring additional indications and applications for our bispecific technologies, including a new class of CD28 and 4-1BB costimulatory bispecifics. We are also exploring a variety of alternative antibody formats (Altibodies™) that can bring binding partners together in restrained geometries.

The *VelociT* mouse extends our research and drug discovery capabilities into cell-mediated immunity and therapeutic TCRs for oncology and other indications. *VelociT* was developed by using our *VelociGene* technology to humanize genes encoding TCRα and TCRβ variable sequences, CD4 and CD8 co-receptors, β2m, and class-I and -II major histocompatibility complexes. As a result, *VelociT* mice generate fully human TCRs, providing for customized modeling of T-cell function in different diseases and a powerful platform for the discovery of unique TCR-based therapies. We are also able to produce antibodies that recognize intracellular peptides bound in the groove of human leukocyte antigen ("HLA"), enabling the targeting of intracellular proteins in cancer cells.

VelociHum is our immunodeficient mouse platform that can be used to accurately test human therapeutics against human immune cells and to study human tumor models. Through genetic humanizations, *VelociHum* mice have been optimized to allow for better development of human immune cells *in vivo*, as well as to allow for engraftment of primary patient-derived tumors that do not take in other commercially available mice.

Regeneron Genetics Center®

Regeneron Genetics Center LLC (RGC™), a wholly owned subsidiary of Regeneron Pharmaceuticals, Inc., leverages de-identified clinical, genomic, and other types of molecular data from properly consented human volunteers from around the world to identify medically relevant associations in a blinded fashion designed to preserve a patients' privacy while uncovering the unique characteristics of their health and wellness. The objective of RGC is to expand the use of human genetics for discovering and validating genetic factors that cause or influence a range of diseases where there are major unmet medical needs, with the prospect of improving the drug discovery and development process and to advance innovation in clinical care design. RGC is undertaking multiple collaborative approaches to study design and implementation, including large population-based efforts that engage study participants to more discrete disease specific and founder populations with data on strategic phenotypes of interest. RGC utilizes laboratory automation and innovative approaches to cloud computing to achieve high-quality throughput, attaining approximately 2 million samples sequenced to date.

Central to the work of RGC is the portfolio of collaborations with over 100 academic and clinical collaborators around the world, including the University of Colorado, Geisinger Health System, Mayo Clinic, University of Pennsylvania, UCLA Medical Center, UK Biobank, University of Oxford, University of Cambridge, and the University of Helsinki. These collaborations provide access to biological samples and associated phenotype data from properly consented patient volunteers for purposes of genomic research. RGC undertakes genetic sequencing of these samples to create a unique resource of de-identified genetic data and associated phenotype data for research. Furthermore, the RGC has deployed bulk RNA sequencing, whole genome sequencing, and an O-LINK proteomic assay to complement whole exome sequencing and genotyping. In addition, the RGC leverages organoid models, siRNA, and CRISPR knockout models to validate genetic associations that lead to new therapeutic targets. The RGC continues to publish results from its research efforts in journals and publications in partnership with its collaborators to advance the field of genomics.

These efforts at the RGC have led to the identification of more than 20 novel genetic targets. Through our Regeneron Genetics Medicines initiative, we are currently advancing these targets using either our *VelociSuite* technologies or other technologies, such as siRNA gene silencing, genome editing, and targeted viral-based gene delivery and expression. See the "Collaboration, License, and Other Agreements" section below for descriptions of our collaborations with Alnylam and Intellia.

Agreements Related to COVID-19

U.S. Government

In 2020, the Company expanded its Other Transaction Agreement with the Biomedical Advanced Research Development Authority ("BARDA"), pursuant to which the U.S. Department of Health and Human Services ("HHS") was obligated to fund certain of our costs incurred for research and development activities related to COVID-19 treatments. In 2020, the Company also entered into an agreement with entities acting at the direction of BARDA and the U.S. Department of Defense to manufacture and deliver filled and finished drug product of REGEN-COV to the U.S. government. The agreement, as subsequently amended, provided for payments to the Company of up to $465.9 million in the aggregate for bulk manufacturing of the drug substance, as well as fill/finish, storage, and other activities.

In January 2021, the Company entered into an agreement with the U.S. Department of Defense and HHS to manufacture and deliver additional filled and finished drug product of REGEN-COV to the U.S. government. Pursuant to the agreement, the U.S. government was obligated to purchase 1.25 million doses of drug product, resulting in payments to the Company of $2.625 billion.

In September 2021, the Company entered into an amendment to its January 2021 agreement to supply the U.S. government with an additional 1.4 million doses of REGEN-COV. Pursuant to the agreement, the U.S. government was obligated to purchase all filled and finished doses of such additional drug product delivered by January 31, 2022, resulting in payments to the Company of $2.940 billion in the aggregate. Additionally, Roche supplied a portion of the doses to Regeneron to fulfill our agreement with the U.S. government (see "Roche" section below for further details regarding our collaboration agreement with Roche).

As of December 31, 2021, the Company had completed its final deliveries of drug product under the agreements described above.

Roche

In 2020, we entered into a collaboration agreement with Roche to develop, manufacture, and distribute the casirivimab and imdevimab antibody cocktail (known as REGEN-COV in the United States and Ronapreve in other countries). We have the right to distribute the product in the United States and Roche has the right to distribute the product outside of the United States. The parties share gross profits from worldwide sales based on a pre-specified formula, depending on the amount of manufactured product supplied by each party to the market.

Collaboration, License, and Other Agreements

Sanofi

Antibody

We are collaborating with Sanofi on the global development and commercialization of Dupixent, Kevzara, and itepekimab (the "Antibody Collaboration"). Under the terms of the Antibody License and Collaboration Agreement (the "LCA"), Sanofi is generally responsible for funding 80% to 100% of agreed-upon development costs. We are obligated to reimburse Sanofi for 30% to 50% of worldwide development expenses that were funded by Sanofi based on our share of collaboration profits from commercialization of collaboration products. Under the terms of the LCA, we were required to apply 10% of our share of the profits from the Antibody Collaboration in any calendar quarter to reimburse Sanofi for these development costs. On July 1, 2022, an amendment to the LCA became effective, pursuant to which the percentage of Regeneron's share of profits used to reimburse Sanofi for such development costs increased from 10% to 20%.

Under our collaboration agreement, Sanofi records product sales for commercialized products, and Regeneron has the right to co-commercialize such products on a country-by-country basis. We co-commercialize Dupixent in the United States and in certain countries outside the United States. We supply certain commercial bulk product to Sanofi. We and Sanofi equally share profits and losses from sales within the United States. We and Sanofi share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us), and share losses outside the United States at 55% (Sanofi)/45% (us). In each of 2020 and 2021, we earned a $50.0 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding $1.0 billion and $1.5 billion, respectively, on a rolling twelve-month basis. In 2022, we earned two additional $50.0 million sales-based milestones, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding $2.0 billion and $2.5 billion, respectively, on a rolling twelve-month basis. We are entitled to receive the final sales milestone payment of $50.0 million when such sales outside the United States exceed $3.0 billion on a rolling twelve-month basis.

In April 2020, the Company and Sanofi entered into an amendment to the LCA in connection with, among other things, the removal of Praluent from the LCA such that (i) effective April 1, 2020, the LCA no longer governs the development, manufacture, or commercialization of Praluent and (ii) the quarterly period ended March 31, 2020 was the last quarter for which Sanofi and the Company shared profits and losses for Praluent under the LCA. The parties also entered into a Praluent Cross License & Commercialization Agreement (the "Praluent Agreement") pursuant to which, effective April 1, 2020, the Company, at its sole cost, became solely responsible for the development and commercialization of Praluent in the United States, and Sanofi, at its sole cost, is solely responsible for the development and commercialization of Praluent outside of the United States. Under the Praluent Agreement, Sanofi pays the Company a 5% royalty on Sanofi's net product sales of Praluent outside the United States until March 31, 2032. The Company does not owe Sanofi royalties on the Company's net product sales of Praluent in the United States. Although each party will be responsible for manufacturing Praluent for its respective territory, the parties have entered into definitive supply agreements under which, for a certain transitional period, the Company will continue to supply drug substance to Sanofi and Sanofi will continue to supply finished product to Regeneron. With respect to any intellectual property or product liability litigation relating to Praluent, the parties have agreed that, effective April 1, 2020, Regeneron and Sanofi each will be solely responsible for any such litigation (including damages and other costs and expenses thereof) in the United States and outside the United States, respectively, arising out of Praluent sales or other activities on or after April 1, 2020 (subject to Sanofi's right to set off a portion of any third-party royalty payments resulting from certain patent litigation proceedings against up to 50% of any Praluent royalty payment owed to Regeneron). The parties will each bear 50% of any damages arising out of Praluent sales or other activities prior to April 1, 2020.

Immuno-Oncology

We previously collaborated with Sanofi for antibody-based cancer treatments in the field of immuno-oncology (the "IO Collaboration"). Under the terms of the Immuno-oncology License and Collaboration Agreement, the parties were co-developing and co-commercializing Libtayo. The parties shared equally, on an ongoing basis, development and commercialization expenses for Libtayo. We had principal control over the development of Libtayo and led commercialization activities in the United States, while Sanofi led commercialization activities outside of the United States. The parties shared equally in profits and losses in connection with the commercialization of Libtayo.

Effective July 1, 2022, the Company obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide under an Amended and Restated Immuno-oncology License and Collaboration Agreement with Sanofi (the "A&R IO LCA"). In connection with the A&R IO LCA, in 2022, the Company made a $900.0 million up-front payment to Sanofi, as well as a $100.0 million regulatory milestone payment. In addition, Sanofi earned a $65.0 million sales-based milestone upon the achievement of a specified amount of worldwide net product sales of Libtayo in 2022, and is eligible to receive an additional $35.0 million sales-based milestone upon the achievement of a specified amount of worldwide net product sales of Libtayo in 2023. We also pay

Sanofi an 11% royalty on net product sales of Libtayo through March 31, 2034. The parties have also entered into a transition services agreement, a transitional distribution agreement, and a manufacturing services agreement, pursuant to which, during certain transitional periods, Sanofi will perform for Regeneron certain transition, distribution, and manufacturing services, respectively.

Under the Amended and Restated Immuno-oncology Discovery and Development Agreement, we were obligated to reimburse Sanofi for half of the development costs it funded that were attributable to clinical development of product candidates from our share of profits from commercialized IO Collaboration products. Under the A&R IO LCA, the amount of development costs incurred under the IO Collaboration for which we are obligated to reimburse Sanofi was $35.0 million as of the effective date of the A&R IO LCA, and we pay Sanofi a 0.5% royalty on net product sales of Libtayo until all such development costs have been reimbursed by us.

Bayer

We and Bayer are parties to a license and collaboration agreement for the global development and commercialization of EYLEA and aflibercept 8 mg outside the United States. Agreed-upon development expenses incurred by the Company and Bayer are generally shared equally. Bayer markets EYLEA outside the United States, and the companies share equally in profits and losses from such sales. In Japan, we were entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net sales through 2021, and, effective January 1, 2022, the companies share equally in profits and losses from sales.

We are obligated to reimburse Bayer for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the collaboration profits in the quarter unless we elect to reimburse Bayer at a faster rate.

Within the United States, we retain exclusive commercialization rights and are entitled to all profits from such sales.

Teva

We and Teva are parties to a collaboration agreement to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to our collaboration agreement with MTPC. In connection with the agreement, Teva made a $250.0 million non-refundable up-front payment in 2016. We led global development activities, including the manufacturing of fasinumab, and the parties shared development costs equally. As of December 31, 2022, we had received an aggregate $120.0 million of development milestones from Teva.

During the third quarter of 2022, we discontinued further clinical development of fasinumab.

Alnylam

In 2018, we and Alnylam Pharmaceuticals, Inc. entered into a collaboration to discover RNA interference ("RNAi") therapeutics for NASH and potentially other related diseases, as well as to research, co-develop and commercialize any therapeutic product candidates that emerge from these discovery efforts (including ALN-HSD, which is currently in clinical development). Under the terms of the collaboration agreement, the parties share development costs equally. During the fourth quarter of 2022, Alnylam elected to opt-out of further development activities related to ALN-HSD; as a result, we retain the exclusive right to develop and commercialize such product and Alnylam will receive a royalty on sales (if any).

In 2019, we and Alnylam entered into a global, strategic collaboration to discover, develop, and commercialize RNAi therapeutics for a broad range of diseases by addressing therapeutic disease targets expressed in the eye and central nervous system ("CNS"), in addition to a select number of targets expressed in the liver. In connection with the collaboration, the Company made an up-front payment of $400.0 million to Alnylam, and also purchased shares of Alnylam common stock for $400.0 million. For each program, we provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation, and Alnylam is eligible to receive up to an aggregate of $200.0 million in clinical proof-of-principle milestones for eye and CNS programs.

Under the collaboration, the parties plan to perform discovery research until designation of lead candidates. Following designation of a lead candidate, the parties may further advance such lead candidate under either a co-development/co-commercialization collaboration agreement ("Co-Co Collaboration Agreement") (under which the parties are advancing ALN-APP and ALN-PNP, which are currently in clinical development) or a License Agreement structure. The initial target nomination and discovery period is five years (which may under certain situations automatically be extended for up to seven years in the aggregate) (the "Research Term"). In addition, we have an option to extend the Research Term for an additional five-year period for a research extension fee ranging from $200.0 million to $400.0 million; the actual amount of the fee will be determined based on the acceptance of one or more Investigational New Drug Applications ("INDs") (or their equivalent in certain other countries) for programs in the eye and CNS.

At the stage of designation of a lead candidate for CNS programs and liver programs, the parties have alternating rights to be a lead party for collaboration products. At the stage of designation of a lead candidate for eye programs, we have the sole right to take the product forward as a licensee. The lead party is required to take the program forward under the License Agreement structure unless the other party exercises its rights to opt-in to a Co-Co Collaboration Agreement as a participating party, in which case the lead party is required to take the program forward under the Co-Co Collaboration Agreement structure. Alnylam does not have rights to opt-in to a Co-Co Collaboration Agreement for eye programs.

Under a License Agreement, the lead party is designated as the licensee and has the right to develop and commercialize the collaboration product under such program. The licensee will be responsible for its own costs and expenses incurred in connection with the development and commercialization of the collaboration products under the License Agreement. The licensee will pay to the licensor certain development and/or commercialization milestone payments, as well as certain tiered royalty payments to the licensor based on the aggregate annual net sales of the collaboration product.

For CNS programs and liver programs, under a Co-Co Collaboration Agreement, the party designated as the lead party will lead development and commercialization of the program and the parties will split profits and share costs equally, subject to certain co-funding opt-outs at specified clinical trial phases or under other conditions. If a party exercises its co-funding opt-out right, the lead party will be required to make certain tiered royalty payments to the other party based on the aggregate annual net sales of the collaboration product and the timing of the exercise of the co-funding opt-out right.

Under the collaboration, when we are the licensee under a License Agreement or the lead party under a Co-Co Collaboration Agreement, Alnylam will be responsible for the manufacture and supply of the product to us for Phase 1 and Phase 2 clinical trials.

In addition, during 2019, the parties entered into a Co-Co Collaboration Agreement for cemdisiran, an siRNA therapeutic targeting the C5 component of the human complement pathway being developed by Alnylam, with Alnylam as the lead party, and a License Agreement for a combination consisting of cemdisiran and pozelimab, with us as the licensee. Under the C5 siRNA Co-Co Collaboration Agreement, the parties shared costs equally, and under the License Agreement, we as the licensee are responsible for our own costs and expenses. The C5 siRNA License Agreement contains a flat low double-digit royalty payable to Alnylam on potential future net sales of the combination only subject to customary reductions, as well as up to $325.0 million in sales milestones.

During the fourth quarter of 2022, we elected to opt-out of further development activities pursuant to the Co-Co Collaboration Agreement for cemdisiran as a monotherapy; as a result, Alnylam retains the right to develop and commercialize such product and we will receive a royalty on sales (if any).

Intellia

In 2016, we entered into a license and collaboration agreement with Intellia Therapeutics, Inc. to advance CRISPR/Cas9 gene-editing technology for *in vivo* therapeutic development. NTLA-2001, which is in clinical development, is subject to a co-development and co-commercialization arrangement pursuant to which Intellia will lead development and commercialization activities and the parties share an agreed-upon percentage of development expenses and profits (if commercialized).

In 2020, we expanded our existing collaboration with Intellia to provide us with rights to develop products for additional *in vivo* CRISPR/Cas9-based therapeutic targets and for the companies to jointly develop potential products for the treatment of hemophilia A and B, with Regeneron leading development and commercialization activities. In addition, we also received non-exclusive rights to independently develop and commercialize *ex vivo* gene edited products. In connection with the 2020 agreement, we made a $70.0 million up-front payment to Intellia.

BARDA

We and BARDA are parties to agreements pursuant to which HHS provided certain funding to develop, test, and manufacture a treatment for Ebola virus infection. In 2020, HHS exercised its option under an existing agreement to provide additional funding for the manufacture and supply of Inmazeb. We expect to deliver a pre-specified number of Inmazeb treatment doses over the course of approximately six years.

See "Agreements Related to COVID-19 - U.S. Government" section above for information related to our COVID-19 agreements.

Kiniksa

Pursuant to a 2017 license agreement, we granted Kiniksa Pharmaceuticals, Ltd. the right to develop and commercialize certain new indications for ARCALYST. During the first quarter of 2021, Kiniksa received marketing approval in the United States for a new indication of ARCALYST, recurrent pericarditis. The quarterly period ended March 31, 2021 was the last quarter for which the Company recorded net product sales of ARCALYST.

Following this approval, Kiniksa is solely responsible for the U.S. development and commercialization of ARCALYST in all approved indications, and Regeneron will continue to supply clinical and commercial product to Kiniksa. Kiniksa will pay Regeneron 50% of its profits from sales of ARCALYST and the parties will not share in any losses incurred by Kiniksa in connection with commercialization of ARCALYST.

Ultragenyx

In January 2022, we entered into a license and collaboration agreement for Ultragenyx Pharmaceutical Inc. to develop and commercialize Evkeeza in countries outside of the United States. In connection with the agreement, Ultragenyx made a $30.0 million non-refundable up-front payment to the Company. Ultragenyx will share in certain costs for global trials led by the Company and also have the right to continue to clinically develop Evkeeza in countries outside of the U.S. We will supply commercial product to Ultragenyx at a tiered purchase price, which is calculated as a percentage of net sales of the product (subject to adjustment in certain circumstances), and are eligible to receive additional regulatory and sales milestone payments.

Checkmate

In May 2022, the Company completed its acquisition of Checkmate Pharmaceuticals, Inc. for a total equity value of approximately $250 million. In connection with the acquisition, the Company obtained the rights to vidutolimod, which is in clinical development for oncology.

Manufacturing

We currently manufacture bulk drug materials and products at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland. These facilities consist of owned and leased research, manufacturing, office, laboratory, and warehouse space. In addition, the construction of a fill/finish facility in Rensselaer, New York is in process.

We currently have approximately 100,000 liters of cell culture capacity at our Rensselaer facility and approximately 120,000 liters of cell culture capacity at our Limerick facility. Each of these facilities is approved by the FDA and certain other regulatory agencies to manufacture our bulk drug materials and products.

Certain bulk drug materials and products are also manufactured by our collaborators, and certain raw materials or products necessary for the manufacture and formulation of our products and product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on our collaborators or third parties to perform packaging, filling, finishing, labeling, distribution, laboratory testing, and other services related to the manufacture of our products and product candidates, and to supply various raw materials and other products. See Part I, Item 1A. "Risk Factors - Risks Related to Manufacturing and Supply" for further information.

Among the conditions for regulatory marketing approval of a medicine is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the good manufacturing practice ("GMP") regulations of the health authority. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, are also subject to inspections by or under the authority of the FDA and by other national, federal, state, and local agencies.

Commercial

Our medicines are marketed through our commercial group, which includes experienced professionals in the fields of marketing, sales, professional education, patient education, reimbursement and market access, trade and distribution, commercial operations, commercial analytics, and market research.

In the United States, we sell our marketed products primarily to wholesalers and specialty distributors that serve pharmacies, hospitals, government agencies, physicians, and other healthcare providers. We had sales to two customers (Besse Medical, a subsidiary of AmerisourceBergen Corporation, and McKesson Corporation) that each accounted for more than 10% of total gross product revenue for the year ended December 31, 2022. On a combined basis, our product sales to these customers accounted for 83% of our total gross product revenue for the year ended December 31, 2022. We promote approved medicines to healthcare professionals via our team of field employees, as well as medical journals, medical exhibitions, distribution of literature and samples, and online channels. In addition, we advertise certain products directly to consumers and maintain websites with information about our medicines. The commercial group also evaluates opportunities for our targets and product candidates and prepares for market launches of new medicines.

We have established certain commercial capabilities outside the United States in connection with co-commercializing some products in accordance with our collaboration agreements. In addition, we are in process of building additional commercial capabilities outside the United States as a result of us obtaining the rights, in 2022, to commercialize Libtayo outside the United States. Refer to "Collaboration, License, and Other Agreements" section above for additional information related to these agreements.

Competition

We face substantial competition from pharmaceutical, biotechnology, and chemical companies. Our ability to compete depends, to a great extent, on how fast we can develop safe and effective product candidates, complete clinical testing and approval processes, and supply commercial quantities of the product to the market. Competition among products approved for sale is based on efficacy, safety, reliability, availability, price, patent and other intellectual property position, and other factors.

Marketed Products

The table below provides an overview of the current competitive landscape for the key products marketed by us and/or our collaborators in such products' currently approved indications. The table below is provided for illustrative purposes only and is not exhaustive. For additional information regarding the substantial competition these marketed products face, including potential future competition from product candidates in clinical development, see also Part I, Item 1A. "Risk Factors - Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *The commercial success of our products and product candidates is subject to significant competition.*"

Marketed Product	Competitor Product	Competitor	Indication	Territory[(a)]
EYLEA	Lucentis® (ranibizumab injection)	Novartis AG and Genentech/Roche	Wet AMD, DME, macular edema following RVO (including CRVO and BRVO), diabetic retinopathy, mCNV, and ROP	Worldwide
	Byooviz™ (ranibizumab-nuna) (biosimilar referencing Lucentis)	Samsung Bioepis Co., Ltd. and Biogen Inc.	Wet AMD, DME, macular edema following RVO (including CRVO and BRVO), diabetic retinopathy, and mCNV	United States, EU
	Ximluci® (ranibizumab) (biosimilar referencing Lucentis)	Xbrane Biopharma AB, Bausch + Lomb, and STADA Arzneimittel AG	Wet AMD, DME, macular edema following RVO (including CRVO and BRVO), diabetic retinopathy, and CNV	EU
	Cimerli™ (ranibizumab-eqrn) (biosimilar referencing Lucentis)	Formycon AG, Bioeq AG, Coherus BioSciences, Inc., and Teva Ltd.	Wet AMD, DME, macular edema following RVO (including CRVO and BRVO), diabetic retinopathy, and CNV	United States, EU
	Susvimo® (ranibizumab ocular implant)	Genentech/Roche	Wet AMD	United States
	Vabysmo™ (faricimab-svoa)	Genentech/Roche	Wet AMD, DME	Worldwide
	Avastin® (bevacizumab) (off-label and repackaged)	Genentech/Roche	Wet AMD, DME, and macular edema following RVO	Worldwide
	Beovu® (brolucizumab) Injection	Novartis AG	Wet AMD, DME	Worldwide
	Ozurdex® (dexamethasone intravitreal implant)	Allergan/AbbVie Inc.	DME, RVO	United States, EU

Marketed Product *(continued)*	Competitor Product	Competitor	Indication	Territory[a]
EYLEA *(continued)*	Iluvien® (fluocinolone acetonide intravitreal implant)	Alimera Sciences, Inc.	DME	United States, EU
	Conbercept	Chengdu Kanghong Pharmaceutical Group Co., Ltd.	Wet AMD, DME, mCNV	China
Dupixent	Eucrisa®/Staquis® (crisaborole)	Pfizer Inc.	Mild-to-moderate atopic dermatitis	United States, EU
	Opzelura® (ruxolitinib)	Incyte Corporation	Mild-to-moderate atopic dermatitis	United States
	Olumiant® (baricitinib)	Eli Lilly and Company/Incyte Corporation	Moderate-to-severe atopic dermatitis	EU, Japan
	Cibinqo® (abrocitinib)	Pfizer	Moderate-to-severe atopic dermatitis	Worldwide
	Rinvoq® (upadacitinib)	AbbVie	Moderate-to-severe atopic dermatitis	Worldwide
	Adbry™/Adtralza® (tralokinumab)	LEO Pharma Inc.	Moderate-to-severe atopic dermatitis	Worldwide
	Corectim® (delgocitinib)	Japan Tobacco Inc./Torii Pharmaceutical Co., Ltd.	Atopic dermatitis	Japan
	Mitchga® (nemolizumab)	Maruho Co., Ltd./Chugai Pharmaceutical Co., Ltd.	Pruritus associated with atopic dermatitis	Japan
	Xolair® (omalizumab)	Roche/Novartis	Asthma, nasal polyps	Worldwide (asthma); United States, EU (nasal polyps)
	Nucala® (mepolizumab)	GlaxoSmithKline ("GSK")	Asthma, nasal polyps	Worldwide (asthma); United States, EU (nasal polyps)
	Cinqair® (reslizumab)	Teva	Asthma	United States, EU
	Fasenra® (benralizumab)	AstraZeneca	Asthma	Worldwide
	Tezspire™ (tezepelumab-ekko)	AstraZeneca/Amgen	Asthma	Worldwide
Libtayo	Keytruda® (pembrolizumab)	Merck & Co., Inc.	Various cancers	Worldwide
	Opdivo® (nivolumab)	Bristol-Myers Squibb	Various cancers	Worldwide
	Tecentriq® (atezolizumab)	Roche	Various cancers	Worldwide
	Imfinzi® (durvalumab)	AstraZeneca	Various cancers	Worldwide
	Bavencio® (avelumab)	Pfizer/Merck KGaA	Various cancers	Worldwide
	Jemperli® (dostarlimab)	GSK	Various cancers	United States, EU
Praluent	Repatha® (evolocumab)	Amgen	Reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease; primary hyperlipidemia; and HoFH	Worldwide

Marketed Product *(continued)*	Competitor Product	Competitor	Indication	Territory[(a)]
Praluent *(continued)*	Leqvio® (inclisiran)	Novartis	Primary hypercholesterolemia (heterozygous familial and non-familial) or mixed dyslipidemia	United States, EU
Kevzara	Actemra® (tocilizumab)	Genentech/Roche/Chugai Pharmaceutical Co., Ltd.	Rheumatoid arthritis	Worldwide
	Orencia® (abatacept)	Bristol-Myers Squibb	Rheumatoid arthritis	Worldwide
	Xeljanz® (tofacitinib)	Pfizer	Rheumatoid arthritis	Worldwide
	Olumiant® (baricitinib)	Eli Lilly/Incyte	Rheumatoid arthritis	Worldwide
	Rinvoq® (upadacitinib)	AbbVie	Rheumatoid arthritis	Worldwide
	Jyseleca® (filgotinib)	Gilead Sciences, Inc./Galapagos NV	Rheumatoid arthritis	EU, Japan

[(a)] This table focuses primarily on the United States, EU, and Japan. "Worldwide" indicates that the relevant product is approved in the United States, EU, Japan, and at least one other country.

Product Candidates

Our late-stage and earlier-stage clinical candidates (including those being developed in collaboration with our collaborators) face competition from many pharmaceutical and biotechnology companies. For example, we are aware of other pharmaceutical and biotechnology companies actively engaged in the research and development of antibody-based products against targets that are also the targets of our early- and late-stage product candidates. These companies are using various technologies in competition with our *VelocImmune* technology and our other antibody generation technologies, including their own antibody generation technologies and other approaches such as RNAi, chimeric antigen receptor T cell (CAR-T cell), and gene therapy technologies. We are also aware of several companies developing or marketing small molecules that may compete with our antibody product candidates in various indications, if such product candidates obtain regulatory approval in those indications.

For additional information regarding our product candidates (including those being developed in collaboration with our collaborators) and the substantial competition they face, see also Part I, Item 1A. "Risk Factors - Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *The commercial success of our products and product candidates is subject to significant competition*."

Other Areas

Many pharmaceutical and biotechnology companies are attempting to discover new therapeutics for indications in which we invest substantial time and resources. In these and related areas, intellectual property rights have been sought and certain rights have been granted to competitors and potential competitors of ours, and we may be at a substantial competitive disadvantage in such areas as a result of, among other things, our inferior intellectual property position or lack of experience, trained personnel, and expertise. A number of corporate and academic competitors are involved in the discovery and development of novel therapeutics that are the focus of other research or development programs we are now conducting. Some of these competitors are currently conducting advanced preclinical and clinical research programs in these areas. These and other competitors also may have established substantial intellectual property and other competitive advantages.

If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business, operating results, financial condition, cash flows, or future prospects.

We also compete with academic institutions, governmental agencies, and other public or private research organizations, which conduct research, seek patent and other intellectual property protection, and establish collaborative arrangements for the development and marketing of products that would provide royalties or other consideration for use of their technology. These institutions are becoming more active in seeking patent and other intellectual property protection and licensing arrangements to collect royalties or other consideration for use of the technology they have developed. Products developed in this manner may compete directly with products we develop. We also compete with others in acquiring technology from these institutions, agencies, and organizations.

Patents, Trademarks, and Trade Secrets

We rely on a combination of intellectual property laws, including patent, trademark, copyright, trade secret, and domain name protection laws, as well as confidentiality and license agreements, to protect our intellectual property and proprietary rights.

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing on the proprietary rights of third parties (see Part I, Item 1A. "Risk Factors - Risks Related to Intellectual Property and Market Exclusivity - *We may be restricted in our development, manufacturing, and/or commercialization activities by patents or other proprietary rights of others, and could be subject to awards of damages if we are found to have infringed such patents or rights*"; and Note 16 to our Consolidated Financial Statements). Our policy is to file patent applications to protect technology, inventions, and improvements that we consider important to our business and operations. We hold an ownership interest in a number of issued patents in the United States and foreign countries with respect to our products and technologies. In addition, we hold an ownership interest in thousands of patent applications in the United States and foreign countries.

Our patent portfolio includes granted patents and pending patent applications covering our *VelociSuite* technologies, including our *VelocImmune* mouse platform which produces fully human antibodies. Our issued patents covering these technologies generally expire between 2022 and 2032. However, we continue to file patent applications directed to improvements to these technology platforms.

Our patent portfolio also includes issued patents and pending applications relating to commercialized products and our product candidates in clinical development. These patents cover, among other things, proteins, DNA and RNA molecules, manufacturing patents, method of use patents, and pharmaceutical compositions and formulations.

The following table describes our U.S. patents, European patents ("EP"), and Japanese patents ("JP") that are of particular relevance to key products marketed or otherwise commercialized by us and/or our collaborators, including the territory, patent number, general subject matter class, and expected expiration dates. The noted expiration dates include any patent term adjustments. Certain of these patents may also be entitled to term extensions. We continue to pursue additional patents and patent term extensions in the United States and other jurisdictions covering various aspects of our products that may, if issued, extend exclusivity beyond the expiration of the patents listed in the table below. One or more patents with the same or earlier expiry date may fall under the same "general subject matter class" for certain products and may not be separately listed.

Product	Molecule	Territory	Patent No.	General Subject Matter Class	Expiration
EYLEA[a]	aflibercept	US	7,070,959	Composition of Matter	June 16, 2023[b]
		US	8,092,803	Formulation	June 21, 2027
		US	10,464,992	Formulation	June 14, 2027
		US	10,857,231	Formulation	March 22, 2026
		US	11,066,458	Formulation	June 14, 2027
		US	11,084,865	Formulation	June 14, 2027
		US	9,254,338	Methods of Treatment	May 22, 2032
		US	10,857,205	Methods of Treatment	January 11, 2032
		US	10,828,345	Methods of Treatment	January 11, 2032
		US	10,888,601	Methods of Treatment	January 11, 2032
		US	11,253,572	Methods of Treatment	January 11, 2032
		US	10,406,226	Method of Manufacturing	March 22, 2026
		EP	1183353	Composition of Matter (Supplementary Protection Certificate)	(May 23, 2025)[c]
		EP	2364691	Formulation	June 14, 2027
		EP	2944306	Formulation	June 14, 2027
		JP	4,723,140	Composition of Matter	December 29, 2022 – December 25, 2023[d]
		JP	5,273,746	Methods of Treatment	June 24, 2022
		JP	5,216,002	Formulation	February 27, 2028 – October 1, 2029[d]

Product *(continued)*	Molecule	Territory	Patent No.	General Subject Matter Class	Expiration
Dupixent	dupilumab	US	7,608,693	Composition of Matter	March 28, 2031[e]
		US	8,945,559	Formulation	October 17, 2032
		US	9,238,692	Formulation	October 5, 2031
		US	10,435,473	Formulation	October 5, 2031
		US	11,059,896	Formulation	October 5, 2031
		US	8,075,887	Methods of Treatment	April 17, 2028
		US	8,337,839	Methods of Treatment	October 2, 2027
		US	9,290,574	Methods of Treatment	July 10, 2034
		US	9,574,004	Methods of Treatment	December 22, 2033
		US	11,421,036	Methods of Treatment	July 10, 2034
		US	10,137,193	Methods of Treatment	March 18, 2036
		US	10,485,844	Methods of Treatment	September 21, 2037
		US	10,059,771	Methods of Treatment	June 20, 2034
		US	11,214,621	Methods of Treatment	March 11, 2036
		US	11,167,004	Methods of Treatment	September 21, 2037
		US	11,034,768	Methods of Treatment	March 23, 2039
		US	11,292,847	Methods of Treatment	May 10, 2039
		EP	2356151	Composition of Matter	October 27, 2029[c]
		EP	2356151	(Supplementary Protection Certificate)	(September 28, 2032)[c]
		EP	3010539	Methods of Treatment	June 20, 2034
		EP	2888281	Methods of Treatment	August 20, 2033
		EP	3064511	Methods of Treatment	October 27, 2029
		EP	3107575	Methods of Treatment	February 20, 2035
		EP	3470432	Methods of Treatment	August 20, 2033
		EP	3019191	Methods of Treatment	July 10, 2034
		EP	2624865	Formulation	October 5, 2031
		EP	3354280	Formulation	October 5, 2031
		JP	5,291,802	Composition of Matter	October 27, 2029 – October 27, 2034[d]
		JP	5,918,246	Formulation	October 5, 2031 – September 14, 2035[d]
		JP	6,306,588	Methods of Treatment	August 20, 2033 – August 29, 2034[d]
		JP	6,353,838	Methods of Treatment	September 4, 2033
		JP	6,673,840	Methods of Treatment	February 20, 2035
		JP	6,463,351	Methods of Treatment	June 20, 2034 – September 2, 2035[d]
		JP	6,861,630	Methods of Treatment	November 13, 2035
		JP	7,164,530	Methods of Treatment	September 21, 2037
Libtayo	cemiplimab	US	9,987,500	Composition of Matter	September 18, 2035
		US	10,737,113	Composition of Matter	April 10, 2035
		US	10,457,725	Methods of Treatment	May 12, 2037
		US	11,292,842	Methods of Treatment	July 18, 2038
		US	11,505,600	Methods of Treatment	July 2, 2038
		EP	3097119	Composition of Matter	January 23, 2035
		EP	3455258	Methods of Treatment	May 12, 2037
		EP	3932951	Methods of Treatment	May 12, 2037
		JP	6,425,730	Composition of Matter	January 23, 2035

Product *(continued)*	Molecule	Territory	Patent No.	General Subject Matter Class	Expiration
Libtayo *(continued)*		JP	6,999,577	Methods of Treatment	May 12, 2037
		JP	7,054,680	Methods of Treatment	May 12, 2037
Praluent[(a)(f)]	alirocumab	US	8,062,640	Composition of Matter	December 15, 2029
		US	10,023,654	Composition of Matter	December 15, 2029
		US	10,472,425	Formulation	July 27, 2032
		US	8,357,371	Methods of Treatment	December 21, 2029
		US	9,550,837	Methods of Treatment	December 15, 2029
		US	9,724,411	Methods of Treatment	January 15, 2031
		US	11,246,925	Methods of Treatment	April 11, 2032
		US	11,306,155	Methods of Treatment	July 16, 2035
		US	10,428,157	Methods of Treatment	December 26, 2037
		US	10,544,232	Methods of Treatment	March 13, 2035
		US	10,995,150	Methods of Treatment	June 6, 2034
		US	11,116,839	Methods of Treatment	June 14, 2033
		EP	2358756	Composition of Matter	December 15, 2029[(c)]
		EP	2358756	(Supplementary Protection Certificate)	(September 25, 2030)[(c)]
		EP	3156422	Composition of Matter	December 15, 2029
		EP	2756004	Methods of Treatment	September 12, 2032
		EP	3055333	Methods of Treatment	October 10, 2034
		EP	3689913	Methods of Treatment	October 10, 2034
		EP	3169353	Methods of Treatment	July 16, 2035
		EP	3169362	Methods of Treatment	July 16, 2035
		EP	3004171	Methods of Treatment	June 6, 2034
		EP	3068803	Methods of Treatment	November 12, 2034
		EP	3395836	Methods of Manufacturing	January 27, 2032
Kevzara	sarilumab	US	7,582,298	Composition of Matter	May 22, 2031[(g)]
		US	10,072,086	Formulation	September 19, 2031
		US	11,098,127	Formulation	January 7, 2031
		US	8,080,248	Methods of Treatment	June 1, 2027
		US	8,568,721	Methods of Treatment	June 1, 2027
		US	9,943,594	Methods of Treatment	December 28, 2033
		US	10,927,435	Methods of Treatment	October 10, 2032
		EP	2041177	Composition of Matter	June 1, 2027[(c)]
		EP	2041177	(Supplementary Protection Certificate)	(June 1, 2032)[(c)]
		EP	2766039	Methods of Treatment	October 10, 2032
		EP	3071230	Methods of Treatment	November 21, 2034
		EP	3409269	Formulation	January 7, 2031
		EP	3756652	Formulation	January 7, 2031
		JP	5,307,708	Composition of Matter	June 1, 2027 – August 22, 2031[(d)]
		JP	5,805,660	Formulation	January 7, 2031 – October 24, 2031[(d)]
		JP	6,122,018	Methods of Treatment	October 10, 2032 – March 29, 2033[(d)]
		JP	7,025,477	Methods of Treatment	October 10, 2032

Product *(continued)*	Molecule	Territory	Patent No.	General Subject Matter Class	Expiration
Kevzara *(continued)*		JP	6,657,089	Methods of Treatment	November 21, 2034
		JP	7,166,925	Methods of Treatment	March 7, 2037

(a) See Note 16 to our Consolidated Financial Statements for information regarding *inter partes* review and post-grant review petitions filed in the U.S. Patent and Trademark Office relating to EYLEA and patent infringement proceedings relating to Praluent.

(b) A patent term extension has been granted by the U.S. Patent and Trademark Office, extending the original patent term (May 23, 2020), insofar as it covers EYLEA, to June 16, 2023.

(c) Supplementary protection certificates ("SPCs") are pending and/or have been granted in various European countries, extending the original patent terms in those countries, where granted, to the applicable dates indicated in parentheses.

(d) The patent term extension ("PTE") system in Japan allows for a patent to be extended more than once provided the later approval is directed to a different indication from that of the previous approval. This may result in multiple PTE approvals for a given patent, each with its own expiration date. In this table, date ranges are shown for the expiration of Japanese patents for which multiple PTEs have been granted, with the later date indicating the latest expiring PTE for the corresponding patent.

(e) A patent term extension has been granted by the U.S. Patent and Trademark Office, extending the original patent term (October 2, 2027), insofar as it covers Dupixent, to March 28, 2031.

(f) This table excludes Japanese patents related to Praluent because Praluent is not being commercialized in Japan at this time.

(g) A patent term extension has been granted by the U.S. Patent and Trademark Office, extending the original patent term (June 1, 2027), insofar as it covers Kevzara, to May 22, 2031.

In addition to our patent portfolio, in the United States and certain other countries, our competitive position may be enhanced due to the availability of market exclusivity under relevant law (for additional information regarding market exclusivity, see Part I, Item 1A. "Risk Factors - Risks Related to Intellectual Property and Market Exclusivity - *Loss or limitation of patent rights, and regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products*"). For example, in the United States, the regulatory exclusivity period for EYLEA (i.e., the period during which no biosimilar product can be approved by the FDA) extends through May 17, 2024 following the pediatric exclusivity granted by the FDA. The effect of expiration of a patent relating to a particular product also depends upon other factors, such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product, and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

We also are the nonexclusive licensee of a number of additional patents and patent applications. These include a license agreement with Bristol-Myers Squibb, E. R. Squibb & Sons, L.L.C., and Ono Pharmaceutical Co., Ltd. to obtain a license under certain patents owned and/or exclusively licensed by one or more of these parties that includes the right to develop and sell Libtayo. Under the agreement, we pay royalties of 8.0% on worldwide sales of Libtayo through December 31, 2023, and royalties of 2.5% from January 1, 2024 through December 31, 2026.

Patent law relating to the patentability and scope of claims in the biotechnology field is evolving and our patent rights are subject to this additional uncertainty. The degree of patent protection that will be afforded to our products in the United States and other important commercial markets is uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts, and governments in these countries. There is no certainty that our existing patents or others, if obtained, will provide us protection from competition or provide commercial benefit.

Others may independently develop similar products or processes to those developed by us, duplicate any of our products or processes or, if patents are issued to us, design around any products and processes covered by our patents. We expect to continue, when appropriate, to file product and process applications with respect to our inventions. However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

We seek to file and maintain trademarks around the world based on commercial activities in most jurisdictions where we have, or desire to have, a business presence for a particular product or service. Trademark protection varies in accordance with local law, and continues in some countries as long as the trademark is used and in other countries as long as the trademark is registered. Trademark registrations generally are for fixed but renewable terms.

Defense and enforcement of our intellectual property rights is expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties (see Part I, Item 1A. "Risk Factors - Risks Related to Intellectual Property

and Market Exclusivity - *We may be restricted in our development, manufacturing, and/or commercialization activities by patents or other proprietary rights of others, and could be subject to awards of damages if we are found to have infringed such patents or rights*"; and Note 16 to our Consolidated Financial Statements).

Government Regulation

Regulation by government authorities in the United States and foreign countries is a significant factor in the research, development, manufacture, and marketing of our products and our product candidates. A summary of the primary areas of government regulation that are relevant to our business is provided below. For a description of material regulatory risks we face, also refer to Part I, Item 1A. "Risk Factors."

Preclinical Requirements

The activities required before a product candidate may be marketed in the United States or elsewhere begin with preclinical tests. Preclinical tests include laboratory evaluations of, among other things, product chemistry and formulation and toxicological and pharmacological studies in animal species to assess the toxicity and dosing of the product candidate. In the United States, certain preclinical trials must comply with the FDA's Good Laboratory Practice requirements ("GLPs") and the U.S. Department of Agriculture's Animal Welfare Act. The results of these studies must be submitted to the FDA or the relevant regulatory authority outside the United States as part of an IND or clinical trial application (as applicable), which must be reviewed by the FDA or the relevant government authority before proposed clinical testing can begin in the applicable country or jurisdiction. In the United States, unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA, and the clinical trial proposed in the IND may begin. The FDA or other regulatory authorities may ask for additional data in order to begin a clinical trial. Rules that are equivalent in scope but which vary in application apply in foreign countries.

Product Approval

All of our product candidates require regulatory approval by relevant government authorities before they can be commercialized. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials and other pre-market approval requirements by the FDA, EMA, and other foreign regulatory authorities. The structure and substance of the FDA and foreign pharmaceutical regulatory practices may evolve over time. The ultimate outcome and impact of such developments cannot be predicted.

Clinical trials involve the administration of a drug to healthy human volunteers or to patients under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and Good Clinical Practice requirements ("GCPs"), which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of, an Institutional Review Board ("IRB") for each clinical site within the United States or, where applicable, an Ethics Committee and/or the competent authority for clinical sites outside the United States. Companies sponsoring the clinical trials, investigators, and IRBs/Ethics Committees also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study patients, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of a BLA if the study was conducted in accordance with GCPs and the FDA is able to validate the data. The sponsor of a clinical trial or the sponsor's designated responsible party may be required to register certain information about the trial and disclose certain results on government or independent registry websites, such as clinicaltrials.gov.

Typically, clinical testing involves a three-phase process, which may overlap or be subdivided in some cases. Phase 1 trials are usually conducted with a small number of healthy volunteers to determine the early safety profile, metabolism, and pharmacological actions of the product candidate, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. Although Phase 1 trials are typically conducted in healthy human subjects, in some instances, the trial subjects are patients with the targeted disease or condition. Phase 2 clinical trials are conducted with a relatively small sample of the intended patient population to provide enough data to evaluate the preliminary safety, tolerability, and efficacy of different potential doses of the product candidate. Phase 3 clinical trials are larger trials conducted with patients with the target disease or disorder intended to gather additional information about dosage, safety, and effectiveness necessary to evaluate the drug's overall risk-benefit profile. Phase 3 data often form the core basis on which the FDA and comparable foreign regulatory authorities evaluate a product candidate's safety and effectiveness when considering the product application for regulatory approval. If concerns arise about the safety of the product candidate, the FDA or other regulatory authorities can stop clinical trials by placing them on a "clinical hold" pending receipt of additional data, which can result in a delay or termination of a clinical development

program. The sponsoring company, the FDA or other regulatory authorities, or the IRB or Ethics Committee and competent authority may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk.

The results of the preclinical and clinical testing of a biologic product candidate are then submitted to the FDA in the form of a BLA for evaluation to determine whether the product candidate may be approved for commercial sale under the Public Health Service Act. Under the Prescription Drug User Fee Act, we typically must pay fees to the FDA for review of any BLA. When a BLA is submitted, the FDA makes an initial determination as to whether the application is sufficiently complete to be accepted for review. If the application is not, the FDA may refuse to accept the BLA for filing and request additional information. A refusal to file, which requires resubmission of the BLA with the requested additional information, delays review of the application. If the application is accepted for review, the FDA reviews the application to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity.

FDA performance goals generally provide for action on a BLA within 10 months of the 60-day filing date (or within 12 months of the BLA submission). That deadline can be extended by FDA under certain circumstances, including by the FDA's requests for additional information. The targeted action date can be 6 months after the 60-day filing date (or 8 months after BLA submission) for product candidates that are granted priority review designation because they are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The FDA has other programs to expedite development and review of product candidates that address serious or life-threatening conditions.

For some BLAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. Although the FDA is not bound by the recommendation of an advisory committee, the agency considers such recommendations carefully when making decisions. Before approving a new drug or biologic product, the FDA also requires that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing, among other things, the manufacture, shipment, and storage of the product. The FDA also can audit the sponsor of the BLA to determine if the clinical studies were conducted in compliance with current GCPs. After review of a BLA, the FDA may grant marketing approval, request additional information, or issue a CRL outlining the deficiencies in the submission. The CRL may require additional testing or information, including additional preclinical or clinical data, for the FDA to reconsider the application. Even if such additional information and data are submitted, the FDA may decide that the BLA still does not meet the standards for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than the sponsor. If FDA grants approval, an approval letter authorizes commercial marketing of the product candidate with specific prescribing information for specific indications.

Any approval required by the FDA for any of our product candidates may not be obtained on a timely basis, or at all. The designation of a clinical trial as being of a particular phase is not necessarily indicative that such a trial will be sufficient to satisfy the parameters of a particular phase, and a clinical trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase. The results of preclinical studies or early-stage clinical trials may not predict long-term safety or efficacy of our compounds when they are tested or used more broadly in humans. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial prospects of a product and increase our costs, such as a Risk Evaluation and Mitigation Strategy ("REMS") to mitigate certain specific safety risks, and/or post-approval commitments or requirements to conduct additional clinical trials or non-clinical studies or to conduct surveillance programs to monitor the product's effects.

Approval of a product candidate by comparable regulatory authorities in foreign countries is generally required prior to commencement of marketing of the product in those countries. The approval procedure varies among countries and may involve different or additional testing, and the time required to obtain such approval may differ from that required for FDA approval. Approval by a regulatory authority in one jurisdiction does not guarantee approval by comparable regulatory authorities in other jurisdictions. In the European Economic Area ("EEA") (which is comprised of 27 Member States of the EU plus Norway, Iceland, and Liechtenstein), medicinal products can only be commercialized after a related Marketing Authorization has been granted. Marketing authorization for biologics must be obtained through a centralized procedure, which allows a company to submit a single application to the EMA. If a related positive opinion is provided by the EMA, the EC will grant a centralized marketing authorization that is valid in the EEA.

In many jurisdictions, pediatric data or an approved Pediatric Investigation Plan ("PIP"), or a waiver of such studies, is required to have been approved by regulatory authorities prior to submission of a marketing application. In some EU countries, we may also be required to have an approved PIP before we can begin enrolling pediatric patients in a clinical trial. In the United States, under the Pediatric Research Equity Act ("PREA"), certain applications for approval must include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject product in relevant pediatric populations, unless a waiver or

deferral is granted. However, a pediatric study plan is not required for orphan products and the timing of the submission is subject to negotiation with FDA, but such plan cannot be submitted later than submission of a BLA.

Various federal, state, and foreign statutes and regulations also govern or influence the research, manufacture, safety, labeling, storage, record keeping, marketing, transport, and other aspects of developing and commercializing pharmaceutical product candidates. The lengthy process of seeking these approvals and the compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the manufacturing or marketing of our products and our ability to receive product or royalty revenue.

For additional information regarding U.S. and foreign regulatory approval processes and requirements, see Part I, Item 1A. "Risk Factors - Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.*"

Emergency Use Authorization

The Secretary of HHS may authorize unapproved medical products to be marketed in the context of an actual or potential emergency that has been designated by the U.S. government. The COVID-19 pandemic has been designated as such a national emergency, with such designation currently expected to expire on May 11, 2023. After an emergency has been announced, the Secretary of HHS may authorize the issuance of, and the FDA Commissioner may issue, EUAs for the use of specific products based on criteria established by the Food, Drug, and Cosmetic Act, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. Although the criteria of an EUA differ from the criteria for approval of a BLA, EUAs nevertheless require the development and submission of data to satisfy the relevant FDA standards, as well as a number of ongoing compliance obligations. The FDA expects EUA holders to work toward submission of full applications, such as a BLA, as soon as possible. An EUA is also subject to additional conditions and restrictions and is product-specific. An EUA terminates when the emergency determination underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for a product. The FDA may revoke, revise, or restrict an EUA for a variety of reasons, including where it is determined that the underlying health emergency no longer exists or warrants such authorization or the medical product is no longer effective in diagnosing, treating, or preventing the underlying health emergency.

Post-Approval Regulation

The FDA and comparable regulatory authorities in other jurisdictions may also require us to conduct additional clinical trials or to make certain changes related to a product after granting approval of the product. The FDA has the explicit authority to require postmarketing studies (also referred to as post-approval or Phase 4 studies) and labeling changes based on new safety information, and may impose and enforce a REMS at the time of approval or after the product is on the market. Post-approval modifications to the drug, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical studies or clinical trials, to be submitted in a new or supplemental BLA, which would require FDA approval.

Following approval, the FDA and comparable regulatory authorities outside the United States regulate the marketing and promotion of our products, which must comply with the Food, Drug, and Cosmetic Act and applicable FDA regulations and standards thereunder and equivalent foreign laws. The review of promotional activities by the FDA and comparable regulatory authorities outside the United States includes, but is not limited to, healthcare provider-directed and direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, promotional activities involving the Internet, and sales representatives' communications. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA and comparable foreign regulatory authorities. FDA and comparable foreign regulatory authorities' regulations impose restrictions on manufacturers' communications regarding unapproved uses, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding such use. Failure to comply with applicable FDA and comparable foreign regulatory authorities' requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities and comparable regulatory authorities outside the United States. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug. See Part I, Item 1A. "Risk Factors - Other Regulatory and Litigation Risks - *Our business activities have been, and may in the future be, challenged under U.S. federal or state and foreign healthcare laws, which may subject us to civil or criminal proceedings, investigations, or penalties.*"

Adverse-event reporting and submission of periodic reports are required following marketing approval. The FDA requires BLA holders to employ a system for obtaining and reviewing safety information, adverse events, and product complaints associated with each drug and to submit safety reports to the FDA, with expedited reporting timelines in certain situations. Based on new safety information after approval, the FDA can, among other things, mandate product labeling changes, require new post-marketing studies, impose or modify a risk evaluation and mitigation strategy for the product, or suspend or withdraw approval of the product. We may be subject to audits by the FDA and other regulatory authorities to ensure that we are complying with the applicable requirements. Rules that are equivalent in scope but which vary in application apply in foreign countries in which we conduct clinical trials.

The holder of an EU marketing authorization for a medicinal product must also comply with the EU's pharmacovigilance legislation. This includes requirements to conduct pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. Marketing authorization holders are required to maintain a Pharmacovigilance System Master File ("PSMF"), which supports and documents the compliance of the marketing authorization holder with the requirements of EU pharmacovigilance legislation. Marketing authorization holders are also required to have a Qualified Person for Pharmacovigilance ("QPPV"), who, among other things, maintains the PSMF. A QPPV must reside in the EEA and must also prepare pharmacovigilance reports, respond to potential requests from competent authorities concerning pharmacovigilance on a 24 hour basis, and provide competent authorities with any other information that may be relevant to the safety of the medicinal product in accordance with Good Pharmacovigilance Practices.

The EC can also require marketing authorization holders to conduct post-authorization safety and/or efficacy studies. A post-authorization safety study ("PASS") is a study that is carried out after a medicinal product has been authorized to obtain further information on a medicinal product's safety, or to measure the effectiveness of risk-management measures. Such studies may be clinical trials or non-interventional studies. A post-authorization efficacy study ("PAES") is a study that is carried out for complementing available efficacy data in the light of well-reasoned scientific uncertainties on aspects of the evidence of benefits that is to be or only can be addressed post-authorization. The EC may, in particular, impose a PASS and/or PAES on marketing authorization holders when a marketing authorization is granted upon conditions. The EC may grant conditional marketing authorizations in the interest of public health, when there is less comprehensive clinical data available than would be required, if the EC considers that the benefit of immediate availability may outweigh the risk that the absence of the required clinical data poses.

In addition, we and our third-party suppliers are required to maintain compliance with cGMP, and are subject to inspections by the FDA or comparable regulatory authorities in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign regulatory authorities and acceptance of the change by the FDA or such comparable foreign regulatory authorities prior to release of product(s). FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and our third-party suppliers. Prescription drug manufacturers in the U.S. must comply with applicable provisions of the Drug Supply Chain Security Act and provide and receive product tracing information, maintain appropriate licenses, ensure they only work with other properly licensed entities, and have procedures in place to identify and properly handle suspect and illegitimate products. We may also be subject to state regulations related to the manufacturing and distribution of our products.

Failure to comply with these laws, regulations, and conditions of product approval may lead the FDA and comparable regulatory authorities in other jurisdictions to take regulatory action or seek sanctions, including fines, issuance of warning letters, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval of a product, seizure or recall of products, and criminal prosecution.

Pricing and Reimbursement

Sales in the United States of our marketed products are dependent, in large part, on the availability and extent of reimbursement 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. Sales of our marketed products in other countries are dependent, in large part, on coverage and reimbursement mechanisms and programs administered by health authorities in those countries. See Part I, Item 1A. "Risk Factors - Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *Sales of our marketed products are dependent on the availability and extent of reimbursement from third-party payors, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.*"

We participate in, and have certain price reporting obligations to, the Medicaid Drug Rebate program, state Medicaid supplemental rebate program(s), and other governmental pricing programs. We also have obligations to report the average sales price for certain drugs to the Medicare program. Under the Medicaid Drug Rebate program, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state

Medicaid program as a condition of having federal funds being made available for our drugs under Medicaid and Part B of the Medicare program.

Medicaid is a joint federal and state program that is administered by the states for low-income and disabled beneficiaries. Medicaid rebates are based on pricing data reported by us on a monthly and quarterly basis to the Centers for Medicare & Medicaid Services ("CMS"), the federal agency that administers the Medicaid and Medicare programs. These data include the average manufacturer price and, in the case of innovator products, the best price for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all sales and associated rebates, discounts, and other price concessions. The amount of the rebate is adjusted upward if average manufacturer price increases more than inflation (measured by reference to the Consumer Price Index - Urban). Currently, the rebate is capped at 100 percent of the average manufacturer price, but effective January 1, 2024, this cap on the rebate will be removed, and our rebate liability could increase accordingly.

If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due, which revisions could affect our rebate liability for prior quarters. The federal Patient Protection and Affordable Care Act (the "PPACA") made significant changes to the Medicaid Drug Rebate program, and CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate program under the PPACA. CMS recently modified Medicaid Drug Rebate program regulations to, among other things, permit reporting multiple best price figures with regard to value-based purchasing arrangements and provide definitions for "line extension," "new formulation," and related terms with the practical effect of expanding the scope of drugs considered to be line extensions (beginning in 2022).

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over or that are disabled as well as those with certain health conditions. Medicare Part B generally covers drugs that must be administered by physicians or other health care practitioners; are provided in connection with certain durable medical equipment; or are certain oral anti-cancer drugs and certain oral immunosuppressive drugs. Medicare Part B pays for such drugs under a payment methodology based on the average sales price of the drugs. Manufacturers, including us, are required to report average sales price information to CMS on a quarterly basis. The manufacturer-submitted information may be used by CMS to calculate Medicare payment rates. Starting in 2023, manufacturers must pay refunds to Medicare for single-source drugs or biological products, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties. Further, starting in 2023, the Inflation Reduction Act ("IRA") establishes a Medicare Part B inflation rebate scheme under which, generally speaking, manufacturers will owe rebates if the average sales price of a Part B drug increases faster than the pace of inflation. Failure to timely pay a Part B inflation rebate is subject to a civil monetary penalty.

The IRA also creates a drug price negotiation program under which, after being on the market for a certain period of time, the prices for certain high Medicare spending drugs and biological products provided to Medicare patients without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price, starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and a civil monetary penalty. This or any other legislative change could impact the market conditions for our products. See Part I, Item 1A. "Risk Factors - Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *Sales of our marketed products are dependent on the availability and extent of reimbursement from third-party payors, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.*"

Civil monetary penalties can be applied if we are found to have knowingly submitted any false pricing or other information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, or if we fail to submit the required data on a timely basis. Such conduct also could be grounds for CMS to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

Federal law requires that any company that participates in the Medicaid Drug Rebate program also participate in the Public Health Service's 340B drug pricing program (the "340B program") in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program, which is administered by the Health Resources and Services Administration ("HRSA"), requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. Covered entities include hospitals that serve a disproportionate share of financially needy patients, community health clinics, and other entities that receive certain types of grants under the Public Health Service Act. The PPACA expanded the list of covered entities to include certain free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals, but exempts "orphan drugs" from

the ceiling price requirements for these covered entities. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and Medicaid rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement.

HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. It is currently unclear how HRSA will apply its enforcement authority under this regulation. Any charge by HRSA that we have violated the requirements of the regulation could result in civil monetary penalties. Moreover, under a final regulation effective January 13, 2021, HRSA established a new administrative dispute resolution ("ADR") process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. On November 30, 2022, HRSA issued a notice of proposed rulemaking that proposes several changes to the ADR process. HRSA also implemented a price reporting system under which we are required to report our 340B ceiling prices to HRSA on a quarterly basis, which then publishes those prices to 340B covered entities. In addition, legislation could be passed that would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we participate in the U.S. Department of Veterans Affairs ("VA") Federal Supply Schedule ("FSS") pricing program. FSS participation is required for our products to be purchased by the VA, Department of Defense ("DoD"), Coast Guard, and Public Health Service ("PHS"). Prices for innovator drugs purchased by the VA, DoD, Coast Guard, and PHS are subject to a cap (known as the "Federal Ceiling Price") equal to 76% of the annual non-federal average manufacturer price ("non-FAMP") minus, if applicable, an additional discount. The additional discount applies if non-FAMP increases more than inflation (measured by reference to the Consumer Price Index - Urban). We also participate in the Tricare Retail Pharmacy Program, under which we pay quarterly rebates to DoD for prescriptions of our innovator drugs dispensed to Tricare beneficiaries through Tricare Retail network pharmacies. The governing statute provides for civil monetary penalties for failure to provide information timely or for knowing submission of false information to the government.

Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e., drugs that are not administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government and, subject to detailed program rules and government oversight, each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time to time. The prescription drug plans negotiate pricing with manufacturers and pharmacies, and may condition formulary placement on the availability of manufacturer discounts. In addition, manufacturers, including us, are required to provide to CMS a 70% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Part D benefit design. The IRA includes a sunset provision with respect to the coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program. In addition, as of October 2022, the IRA established a Medicare Part D inflation rebate scheme under which, generally speaking, manufacturers will owe additional rebates if the average manufacturer price of a Part D drug increases faster than the pace of inflation. Failure to timely pay a Part D inflation rebate is subject to a civil monetary penalty.

Private payor healthcare and insurance providers, health maintenance organizations, and pharmacy benefit managers in the United States are adopting more aggressive utilization management techniques and are increasingly requiring significant discounts and rebates from manufacturers as a condition to including products on formulary with favorable coverage and copayment/coinsurance. These payors may not cover or adequately reimburse for use of our products or may do so at levels that disadvantage them relative to competitive products.

Outside the United States, within the EU, our products are paid for by a variety of payors, with governments being the primary source of payment. Government health authorities in the EU determine or influence reimbursement of products, and set prices or otherwise regulate pricing. Negotiating prices with governmental authorities can delay commercialization of our products. Governments may use a variety of cost-containment measures to control the cost of products, including price cuts, mandatory rebates, value-based pricing, and reference pricing (i.e., referencing prices in other countries or prices of competitive products and using those reference prices to set a price). Budgetary pressures in many EU countries are continuing to cause governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates, and expanded generic substitution and patient cost-sharing.

Other Regulatory Requirements

We are subject to health care "fraud and abuse" laws, such as the federal civil False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds, or knowingly making, or causing to be made, a false statement to get a false claim paid. See Part I, Item 1A. "Risk Factors - Other Regulatory and Litigation Risks - *Our business activities have been, and may in the future be, challenged under U.S. federal or state and foreign healthcare laws, which may subject us to civil or criminal proceedings, investigations, or penalties*."

We are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. See Part I, Item 1A. "Risk Factors - Other Regulatory and Litigation Risks - *Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition*."

In the United States, there are numerous federal and state laws and regulations governing data privacy of personal data and the collection, use, disclosure, and protection of health data, genetic data, consumer data, and children's data. Such laws and regulations include the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (collectively, "HIPAA"), as well as state data breach notification laws, state health information and/or genetic privacy laws, and federal and state consumer protection laws (such as Section 5 of the Federal Trade Commission Act (the "FTC Act") and the California Consumer Privacy Act (the "CCPA")). Many of these laws differ from each other in significant ways and have different effects. Many of the state laws enable a state attorney general to bring actions and provide private rights of action to consumers as enforcement mechanisms. There is also heightened sensitivity around certain types of health data, which may be subject to additional protections. The landscape of federal and state laws regulating personal data is constantly evolving. Failure to comply with these laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation, and/or adverse publicity. Federal regulators, state attorneys general, and plaintiffs' attorneys have been active in this space.

HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses, as well as their "business associates" – certain persons or covered entities that create, receive, maintain, or transmit protected health information ("PHI") in connection with providing a specified service or performing a function on behalf of a covered entity. Most health care providers, including research institutions from which we or our collaborators obtain clinical trial data, are subject to HIPAA. Although we are not directly subject to HIPAA other than with respect to providing certain employee benefits, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly receive PHI maintained by a HIPAA-covered entity in a manner that is not permitted under HIPAA.

The Federal Trade Commission ("FTC") also sets expectations for failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individuals about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merit stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers' personal information; and any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. The FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

To the extent we collect California resident personal data, we are also subject to the CCPA. The CCPA, which became effective on January 1, 2020, created new transparency requirements and granted California residents several new rights with regard to their personal data. In addition, in November 2020, California voters approved the California Privacy Rights Act ("CPRA") ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency ("CPPA"). The amendments introduced by the CPRA go into effect on January 1, 2023, and new implementing regulations are expected to be introduced by the CPPA. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with data privacy incidents involving certain elements of personal data. These claims may result in significant liability and damages. Similarly, there are a number of legislative proposals in the United States, at both the federal and state level, that could impose new obligations or limitations in

the area of consumer protection. For example, states such as Virginia, Colorado, and Utah have enacted similar privacy laws that impose new obligations or limitations in areas affecting our business, and efforts at the federal level to enact similar laws have been ongoing. We may be subject to fines, penalties, or private actions in the event of non-compliance with such laws.

Outside the United States, our clinical trial programs, research collaborations, and other processing activities implicate international data protection laws, including the EU General Data Protection Regulation 2016/679 ("GDPR"). The GDPR has increased our responsibility and liability in relation to the processing of personal data of individuals located in the EU. The GDPR, together with the national legislation of the EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data and samples from clinical trials and adverse event reporting. In particular, these obligations and restrictions may concern the consent of the individuals to whom the personal data relate, the information provided to the individuals, the sharing of personal data with third parties, the transfer of personal data out of the EU, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for violations of the data protection obligations. With respect to the transfer of personal data outside of the EU, while there are legal mechanisms available to lawfully transfer personal data outside of the EU, including to the United States, there are certain unsettled legal issues regarding such data transfers, the resolution of which may adversely affect our ability to transfer personal data or otherwise may cause us to incur significant costs to come into compliance with applicable data transfer impact assessments and implementation of legal data transfer mechanisms. In 2021, the European Commission published new standard contractual clauses required to be incorporated into new and existing agreements within prescribed timeframes in order to continue to lawfully transfer personal data outside of the EU. Different EU member states, as well as the United Kingdom and Switzerland, have promulgated national privacy laws that impose additional requirements, which add to the complexity of processing and transferring EU personal data. In October 2022, the United States issued an executive order to implement EU-U.S. data privacy safeguards. The European Commission is now expected to review the executive order and could propose an adequacy decision concerning the level of personal data protection in the United States under which personal data could flow freely from the EU to the United States.

Some countries outside of the EU have reacted to the GDPR by promulgating and enacting new privacy legislation that reflects similar principles and obligations on companies that operate and process their citizens' personal data. Any failure or perceived failure to comply with privacy-related legal obligations, or any compromise of security of personal data, may result in governmental enforcement actions, litigation, contractual indemnity claims, or restraining orders that would impact our ability to process and share data globally. As we expand our presence into new countries, we must continue to assess our privacy controls to enable the processing of personal data. Guidance on implementation and compliance practices are often updated or otherwise revised. See Part I, Item 1A. "Risk Factors - Other Regulatory and Litigation Risks - *We face risks related to the personal data we collect, process, and share*."

In addition to the foregoing, our present business is, and our future business may be, subject to regulation under the United States Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Comprehensive Environmental Response, Compensation and Liability Act, the National Environmental Policy Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, national restrictions, and other current and potential future local, state, federal, and foreign regulations.

Business Segments

We manage our business as one segment which includes all activities related to the discovery, development, and commercialization of medicines for serious diseases. For financial information related to our one segment, see our Consolidated Financial Statements and related notes.

Human Capital Resources

We compete in the highly competitive biotechnology and pharmaceuticals industries. Attracting, developing, and retaining skilled and experienced employees in research and development, manufacturing, sales and marketing, and other positions is crucial to our ability to compete effectively. Our ability to recruit and retain such employees depends on a number of factors, including our corporate culture and work environment, informed by our values and behaviors (which we call The Regeneron Way) and our philosophy of "Doing Well by Doing Good"; talent development and career opportunities; and compensation and benefits.

Integrity is a core value at Regeneron. Both the Company and each of our employees have a responsibility to act ethically and with integrity at all times. Our Code of Business Conduct and Ethics brings together Regeneron's key policy principles and establishes the Company's expectations for all of our employees to act in accordance with applicable laws, rules, and regulations.

Employee Profile

As of December 31, 2022, we had 11,851 full-time employees, consisting of 9,843 employed in the United States, 1,721 employed in Ireland, and 287 employed in other countries (primarily in the United Kingdom and Germany). Of these employees, 2,174 were within our research and preclinical development organization, 1,669 were within our global clinical development and

regulatory affairs organization, and 5,534 were within our industrial operations and product supply organization. Company-wide, nearly 1,400 of our full-time employees hold a Ph.D. and/or M.D. We also supplement our workforce with independent contractors, contingent workers, and temporary workers, as needed. None of our employees are represented by a labor union, and our management considers its relations with our employees to be good.

Diversity, Equity, and Inclusion

Our employees represent a broad range of backgrounds, just like the people who take our medicines, and bring a wide array of perspectives and experiences that have helped us achieve our leadership position in the biotechnology and pharmaceuticals industries and the global marketplace. A key component of our culture is our commitment to diversity, equity, and inclusion ("DEI"). We believe this commitment allows us to better drive innovation and achieve our mission to repeatedly bring important new medicines to patients with serious diseases. Our DEI principles are reflected in our efforts in building a better workplace where employees can be themselves and succeed, advance medicine for all with better science, and use their voice and influence to create a better world. We empower employee-led cross-functional resource groups, functional/site-level DEI councils, and other interest groups, who connect around a common passion to build a culture of inclusion and collaborate to support under-served science and global communities. In 2022, we introduced inclusive leadership education for some of our most senior leaders and launched a pilot mentorship program focused on our diverse talent base to increase visibility, connection, and the leadership skills of underrepresented talent.

While we are proud of our workforce diversity representation shown in the table below, we seek to continuously improve in this area. In April 2020, we announced our 2025 global responsibility goals, including a commitment to increase diversity in leadership and foster inclusion. Making progress toward this goal, since then we hired our Chief DEI Officer; launched a DEI strategy focused on creating a better workplace, better science, and better world; and implemented a new governance model that includes both an executive DEI council and a DEI leadership council. These councils are comprised of senior leaders who provide oversight and guidance on our DEI efforts and support the execution of our DEI strategy. In order to better understand our employees' perspectives, we also measure inclusion and belonging as part of our annual employee engagement survey. Our board of directors receives a detailed update on our DEI efforts at least once a year and continues to monitor our progress.

2022 Workforce Diversity Representation*

Female Representation (Global)	49.8%
People of Color Representation (U.S. Only)**	28.7%

* Based on full-time employees as of December 31, 2022

** Represents the percentage of our full-time employees in the United States that self-identified as belonging to a racial or ethnic minority group. The denominator used in this calculation includes employees who did not disclose information related to their race or ethnicity. Excluding those that did not disclose such information, the percentage shown in this table would be 33.6%.

Externally, we support DEI efforts in our community, including by supporting young scientific talent in underrepresented communities. For example, as part of our $100 million, 10-year commitment to support the Regeneron Science Talent Search, we allocate $3.1 million annually to fund the Society for Science's science, technology, engineering, and math ("STEM") outreach and equity programs. In 2022, we also continued our $24 million, 5-year title sponsorship of Regeneron International Science and Engineering Fair, with representation from over 1,700 student scientists representing 63 countries and 49 U.S. states. In addition, we have developed a STEM pilot program with post-primary-school and high-school students in the New York State Capital Region and Limerick, Ireland that aspires to build long-term relationships with students from disadvantaged socio-economic groups, to encourage and support them in their studies, to inspire them to attend college, and, ultimately, to build a deeper more diverse talent pipeline. We also continue to take steps to further integrate diversity considerations into the design and selection of sites for our clinical studies to make sure they reflect the diversity of patients with the diseases under investigation.

Employee Wellness, Health, and Safety

The wellbeing of our employees is a primary focus as we believe that the most productive people are those who are at their best, both physically and mentally. We provide several programs related to employee health and wellness, including onsite amenities and programs such as meditation and prayer rooms and fitness centers. We also prioritize mental health initiatives and have taken further action to reduce or remove barriers to quality mental healthcare for our employees and their family members. In addition, we provide support for work-life balance through flex-time, remote working arrangements, child and elder care, and paid parental leave, among others.

Occupational health and safety is critical to our success. We are committed to meeting or exceeding all environmental, health, safety ("EHS") and security regulations and have a range of programs, plans, and procedures to ensure the safety of all people

who come to work at Regeneron. In addition, our 2025 global responsibility goals include a commitment to focus on workplace injury prevention in our drive toward zero incidents.

Employee Growth and Development

We invest significant resources to develop talent with the right capabilities to deliver the growth and innovation needed to support our continued success. Our Talent department is dedicated to promoting individual, leader, team, and organizational development through a number of tools and services. We offer a variety of professional development courses for our employees and support employee continuing education, including through educational reimbursement and tuition forgiveness programs. In addition, we continue to invest in our current and future leaders through a number of leadership development courses and programs and feedback and coaching opportunities. In 2022, nearly 30% of job openings were filled by existing employees who were seeking career development opportunities.

Employee Engagement

We believe engaging our employees, from their first day and throughout their career, is key to fostering new ideas and driving commitment and productivity. We communicate frequently and transparently with our employees through a variety of communication methods, including video and written communications, company forums and summits, annual engagement surveys, and pulse surveys.

We are also committed to fostering employee volunteerism to reach our 2025 global responsibility goal of driving employee volunteer levels above national standards. Employees are encouraged and empowered to support organizations and causes that are important to them including through, among other things, our matching gift program, volunteer-time-off policy, and our annual company-wide service event, *Day for Doing Good*. In 2022, nearly 7,000 employees volunteered approximately 31,200 hours, including approximately 55% of our employees who volunteered nearly 20,000 hours to approximately 190 nonprofits during our *Day for Doing Good*. Additionally, through our Matching Gift Program, we matched over $2 million in employee contributions in 2022, supporting over 2,000 charities. In 2022, we were named to the Civic 50 of most community-minded companies in the United States for the sixth consecutive year.

The success of our employee engagement efforts is demonstrated by our employee retention rate of 91% in 2022, as well as the fact that 87% of our employees who responded to our annual engagement survey said Regeneron is a great place to work. Additionally, we have placed in the top five for the past 12 years in *Science* magazine's annual "Top Employers Survey" of the global biotechnology and pharmaceutical industry.

Compensation and Benefits

We are committed to rewarding and supporting our employees in order to continue to attract and retain top talent. We believe this commitment supports our core strategy of creating and advancing a high-quality product pipeline and delivering medicines to people in need. Employee engagement, commitment, and achievements are key drivers of pipeline success and therefore our long-term performance. The primary underpinning of our pay philosophy is to award equity-based pay to all eligible employees to ensure that when we deliver for patients and for shareholders, everyone shares in the upside growth. Our practice, therefore, has been to award initial equity grants to all new hires, in addition to our comprehensive annual equity program. Total employee compensation packages (which varies by country and region) include market-competitive pay (with the opportunity to receive above-market rewards), broad-based grants of equity-based awards, comprehensive healthcare benefits, parental leave, child and elder care support, retirement savings options, and matching contributions. We annually review our workforce demographic and pay equity data to track our performance and inform new initiatives. Our analysis indicates favorable performance in these areas, and we are committed to continued monitoring.

Corporate Information

We were incorporated in the State of New York in 1988 and publicly listed in 1991. Our principal executive offices are located at 777 Old Saw Mill River Road, Tarrytown, New York 10591, and our telephone number at that address is (914) 847-7000.

We make available free of charge on or through our Internet website (*http://www.regeneron.com*) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC").

Investors and other interested parties should note that we use our media and investor relations website (*http://newsroom.regeneron.com*) and our social media channels to publish important information about Regeneron, including information that may be deemed material to investors. We encourage investors and other interested parties to review the

information we may publish through our media and investor relations website and the social media channels listed on our media and investor relations website, in addition to our SEC filings, press releases, conference calls, and webcasts.

The information contained on our websites and social media channels is not included as a part of, or incorporated by reference into, this report.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, prospects, operating results, and financial condition. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, prospects, operating results, and financial condition. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors. For purposes of this section (as well as this report in general), references to our products encompass products marketed or otherwise commercialized by us and/or our collaborators or licensees; and references to our product candidates encompass product candidates in development by us and/or our collaborators or licensees (in the case of collaborated or licensed products or product candidates under the terms of the applicable collaboration or license agreements), unless otherwise stated or required by the context. In this section, we first provide a summary of the more significant risks and uncertainties we face and then provide a full set of risk factors and discuss them in greater detail.

Summary of Risk Factors

As noted above, we are subject to a number of risks that if realized could materially harm our business, prospects, operating results, and financial condition. Some of the more significant risks and uncertainties we face include those summarized below. The summary below is not exhaustive and is qualified by reference to the full set of risk factors set forth in this "Risk Factors" section. Please carefully consider all of the information in this Form 10-K, including the full set of risks set forth in this "Risk Factors" section, and in our other filings with the SEC before making an investment decision regarding Regeneron.

Risks Related to the COVID-19 Pandemic

- Our business may be further adversely affected by the effects of the COVID-19 pandemic, including those impacting our manufacturing and supply chain operations, research and development efforts, commercial operations and sales force, administrative personnel, third-party service providers, and business partners and customers, as well as the demand for our marketed products.
- We face risks related to the development, manufacturing, and potential future commercialization of monoclonal antibodies targeting SARS-CoV-2.

Commercialization Risks

- We are substantially dependent on the success of EYLEA and Dupixent.
- Sales of our products are dependent on the availability and extent of reimbursement from third-party payors, including private payors and government programs such as Medicare and Medicaid, which could change due to various factors such as drug price control measures that have been or may be enacted or introduced in the United States by various federal and state authorities.
- The commercial success of our products is subject to significant competition from products or product candidates that may be superior to, or more cost effective than, our products or product candidates.
- We and our collaborators on which we rely to commercialize some of our marketed products may be unable to continue to successfully commercialize or co-commercialize our products, both in the United States and abroad.

Regulatory and Development Risks

- Drug development and obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.
- Serious complications or side effects in connection with the use or development of our products or product candidates could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products.
- We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use, which would delay or prevent continued development of such candidates and/or receipt of regulatory approval or commercial sale.
- Many of our products are intended to be used in combination with drug-delivery devices, which may result in additional regulatory, commercialization, and other risks.

Intellectual Property and Market Exclusivity Risks

- We may not be able to protect the confidentiality of our trade secrets, and our patents or other means of defending our intellectual property may be insufficient to protect our proprietary rights.
- Patents or proprietary rights of others may restrict our development, manufacturing, and/or commercialization efforts and subject us to patent litigation and other proceedings that could find us liable for damages.
- Loss or limitation of patent rights, and regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products, including EYLEA.

Manufacturing and Supply Risks

- We rely on limited internal and contracted manufacturing and supply chain capacity, which could adversely affect our ability to commercialize our products and to advance our clinical pipeline. As we increase our production in response to higher product demand or in anticipation of a potential regulatory approval, our current manufacturing capacity will likely not be sufficient, and our dependence on our collaborators and/or contract manufacturers may increase, to produce adequate quantities of drug material for both commercial and clinical purposes.
- Expanding our manufacturing capacity and establishing fill/finish capabilities will be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our products approved for marketing and could jeopardize our clinical development programs.
- Our ability to manufacture products may be impaired if any of our or our collaborators' manufacturing activities, or the activities of other third parties involved in our manufacture and supply chain, are found to infringe patents of others.
- If sales of our marketed products do not meet the levels currently expected, or if the launch of any of our product candidates is delayed or unsuccessful, we may face costs related to excess inventory or unused capacity at our manufacturing facilities and at the facilities of third parties or our collaborators.
- Third-party service or supply failures, failures at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, or failures at the facilities of any other party participating in the supply chain would adversely affect our ability to supply our products.
- Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if regulatory approval is obtained, and a reduction in sales.

Other Regulatory and Litigation Risks

- If the testing or use of our products harms people, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims.
- Our business activities have been, and may in the future be, challenged under U.S. federal or state and foreign healthcare laws, which may subject us to civil or criminal proceedings, investigations, or penalties.
- If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions, and fines.
- We face risks from the improper conduct of our employees, agents, contractors, or collaborators, including those relating to potential non-compliance with relevant laws and regulations such as the Foreign Corrupt Practices Act and the U.K. Bribery Act.
- Our operations are subject to environmental, health, and safety laws and regulations, including those governing the use of hazardous materials.
- Changes in laws and regulations affecting the healthcare industry could adversely affect our business.
- Tax liabilities and risks associated with our operations outside of the United States could adversely affect our business.
- We face risks related to the personal data we collect, process, and share.

Risks Related to Our Reliance on or Transactions with Third Parties

- If our collaborations with Sanofi or Bayer or other third parties are terminated or breached, our ability to develop, manufacture, and commercialize certain of our products and product candidates in the time expected, or at all, would be materially harmed.
- Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and current and future products.
- We have undertaken and may in the future undertake strategic acquisitions, and any difficulties from integrating such acquisitions could adversely affect our business, operating results, and financial condition.

Other Risks Factors – Risks Related to Employees, Information Technology, Financial Results and Liquidity, and Our Common Stock

- Our business is dependent on our key personnel and will be harmed if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations.
- Significant disruptions of information technology systems or breaches of data security could adversely affect our business.
- We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce, or eliminate our product development programs or commercialization efforts.
- Our indebtedness could adversely impact our business.
- Our stock price is extremely volatile.
- Our existing shareholders may be able to exert substantial influence over matters requiring shareholder approval and over our management.

* * *

Risks Related to the COVID-19 Pandemic

Our business may be further adversely affected by the effects of the COVID-19 pandemic.

In December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. It has since spread around the world, evolved into multiple new variants, and caused a global pandemic. This pandemic has adversely affected and/or has the potential to adversely affect, among other things, the economic and financial markets and labor resources of the countries in which we operate; our manufacturing and supply chain operations, research and development efforts, commercial operations and sales force, administrative personnel, third-party service providers, and business partners and customers; and the demand for our marketed products.

The COVID-19 pandemic has previously resulted and may again result in the imposition of various restrictions and mandates around the world to reduce the spread of the disease, including governmental orders that direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, maintain social distancing, order cessation of non-essential travel, and require proof of vaccination and/or negative COVID-19 test results. The COVID-19 pandemic has continued to ebb and flow, with different jurisdictions having higher levels of infections than others and new variants of the SARS-CoV-2 virus (such as the Omicron-lineage variants) emerging and spreading more easily and quickly than other variants. The trajectory and the ultimate impact of the pandemic are highly uncertain and subject to change and we do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems, or the global economy as a whole. These effects could have a material impact on our operations.

By way of example, continuation or re-imposition of various government-imposed or private-sector measures relating to the COVID-19 pandemic (including those we previously implemented, such as work-from-home policies for some employees) may further negatively impact productivity, disrupt our business, and delay our clinical programs and development timelines beyond the delays we have already experienced and disclosed. Such restrictions and limitations may also further negatively impact our access to regulatory authorities (which are affected, among other things, by applicable travel restrictions and may be delayed in responding to inquiries, reviewing filings, and conducting inspections); our ability to perform regularly scheduled quality checks and maintenance; and our ability to obtain services from third-party specialty vendors and other providers or to access their expertise as fully and timely as needed. The COVID-19 pandemic may also result in the loss of some of our key personnel, either temporarily or permanently. We and our employees may also be subject to government vaccine mandates, which may have a negative impact on our ability to retain employees or hire new employees and could adversely impact our business. In addition, our sales and marketing efforts were previously negatively impacted and may be further negatively impacted by postponement or cancellation of face-to-face meetings and restrictions on access by non-essential personnel to hospitals or clinics to the extent such measures slow down adoption or further commercialization of our marketed products. The demand for our marketed products may also be adversely impacted by the restrictions and limitations adopted in response to the COVID-19 pandemic, particularly to the extent they affect the patients' ability or willingness to start or continue treatment with our marketed products. Any of the foregoing factors may result in lower net product sales of our marketed products. For example, net product sales of EYLEA in the United States decreased for the three months ended June 30, 2020, compared to the same period in 2019, due in part to the impact of the COVID-19 pandemic. Demand for some or all of our marketed products may be further reduced if shelter-in-place, social distancing, or similar orders remain in effect or are re-implemented and, as a result, some of our inventory may become obsolete and may need to be written off, impacting our operating results. These and similar, and perhaps more severe, disruptions in our operations may materially adversely impact our business, prospects, operating results, and financial condition.

Various government-imposed or private-sector measures relating to the COVID-19 pandemic (or the perception that such restrictions or limitations on the conduct of business operations could occur) previously impacted, and may impact in the future, personnel at our research and manufacturing facilities, our suppliers, and other third parties on which we rely, as well as the availability or cost of materials produced by or purchased from such parties, resulting in supply chain strains or disruptions that may become material. While some materials and services may be obtained from more than one supplier or provider, port closures and other restrictions, whether resulting from the COVID-19 pandemic or otherwise (including any government restrictions or limitations, such as those that may be imposed under the Defense Production Act), could materially disrupt our supply chain or limit our ability to obtain sufficient materials or services (including fill/finish services) required for the development and manufacturing of our products and product candidates as well as our research efforts. If microbial, viral (including COVID-19), or other contaminations are discovered in our products, product candidates, the materials used for their production, or in our facilities, or in the facilities of our collaborators, third-party contract manufacturers, or other providers or suppliers, the affected facilities may need to be closed or may otherwise be affected for an extended period of time, or the contamination may result in other delays or disruptions in our direct or indirect supply chain.

In addition, infections, hospitalizations, and deaths related to COVID-19 previously disrupted and may in the future disrupt the healthcare and healthcare regulatory systems in the United States and abroad. These and other possible disruptions relating to the COVID-19 pandemic could divert healthcare resources away from, or materially delay, regulatory review and potential approval of our product candidates and new indications for our marketed products. In addition, some of our clinical trials were previously and may in the future be affected by the COVID-19 pandemic. This impact could result in further delays in site initiation and patient enrollment due to prioritization of hospital resources toward the COVID-19 pandemic, patients' inability to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, and restrictions on trial initiations imposed by hospitals and other trial sites as a result of the COVID-19 pandemic. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, was previously and may in the future be delayed or disrupted. Any such disruptions may further negatively impact the progress of our clinical trials, including the readouts of trial results, the timing of regulatory review, and any anticipated program milestones.

While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, it previously caused significant disruption of global financial markets and could cause more economic disruption in the future, making it more difficult for us to access capital if needed. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our Common Stock.

To the extent the COVID-19 pandemic adversely affects our business, prospects, operating results, or financial condition, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

We face risks related to the development, manufacturing, and potential future commercialization of monoclonal antibodies targeting SARS-CoV-2.

In response to the COVID-19 pandemic, we developed REGEN-COV (known as Ronapreve in countries outside the United States), a novel investigational antibody cocktail treatment designed to prevent and treat infection from the SARS-CoV-2 virus. REGEN-COV received an EUA from the FDA in November 2020 for the treatment of mild to moderate COVID-19 in certain patients, which was revised in January 2022 to exclude its use in geographic regions (currently including all U.S. states, territories, and jurisdictions) where infection or exposure is likely due to a variant such as an Omicron-lineage variant that is not susceptible to the treatment. In December 2022, the FDA issued a complete response letter concerning our BLA for REGEN-COV to treat COVID-19 in non-hospitalized patients and as prophylaxis in certain individuals. In light of these developments, we cannot predict whether (if at all) or to what extent REGEN-COV may be reauthorized or approved for use by the FDA in the future.

As discussed in this report, we are progressing "next generation" monoclonal antibodies targeting SARS-CoV-2 (together with REGEN-COV referred to below as "our COVID-19 monoclonal antibodies"). There can be no assurance as to the timing or success of any of these efforts or studies evaluating "next generation" antibodies and whether any of such antibodies will retain activity against present or future variants of concern.

We also face risks related to our significant investment in the development, supply, allocation, distribution, pricing, and potential future commercialization of our COVID-19 monoclonal antibodies. We have committed and may continue to commit significant capital and resources to fund and supply clinical trials and to accelerate and scale up the production of our COVID-19 monoclonal antibodies, which involves a complex manufacturing process that is both resource- and time-sensitive. For example, the impact of prioritizing certain manufacturing-related resources for our COVID-19 monoclonal antibodies has included and may in the future include, among other things, drawing down inventory safety stock levels for certain of our other products (including Dupixent and EYLEA). Depending on the demand for our products (including any future demand for our COVID-19 monoclonal antibodies), our ability to re-establish successfully our customary manufacturing cadence, and other relevant factors, we may not be able to replenish our inventory safety stock to the levels we deem prudent or supply our products and product candidates in sufficient

quantities to satisfy our commercial and development needs. We expect our investment in the development and manufacture of our COVID-19 monoclonal antibodies to continue in 2023 and potentially beyond, although the magnitude of our investment will be subject to clinical data results, the duration of the COVID-19 pandemic, and other factors, including regulatory outcomes. If we are unable to obtain a new EUA for any of our "next generation" monoclonal antibodies, or obtain regulatory approvals for any of the foregoing, or if we make a strategic decision to discontinue development of, or not commercialize, our "next generation" COVID-19 monoclonal antibodies or are otherwise not successful in their commercialization, we may be unable to recoup our significant expenses incurred to date and/or in the future related to the development and production of such antibodies. While we previously recognized significant revenues in connection with sales of REGEN-COV, the degree to which any future sales of our COVID-19 monoclonal antibodies will continue to impact our results of operations is highly uncertain.

Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products

We are substantially dependent on the success of EYLEA and Dupixent.

EYLEA net product sales represent a substantial portion of our revenues and this concentration of our net sales in a single product makes us substantially dependent on that product. For the years ended December 31, 2022 and 2021, EYLEA net product sales in the United States represented 51% and 36% of our total revenues, respectively, with EYLEA net product sales as a percentage of our total revenues for the year ended December 31, 2021 being significantly lower due to the net product sales of REGEN-COV we recorded in that period under our agreements with the U.S. government. If we were to experience difficulty with the commercialization of EYLEA in the United States or if Bayer were to experience any difficulty with the commercialization of EYLEA outside the United States (including as a result of the COVID-19 pandemic discussed above), or if we and Bayer are unable to maintain current marketing approvals of EYLEA, we may experience a reduction in revenue and may not be able to sustain profitability, and our business, prospects, operating results, and financial condition would be materially harmed. In the United States, the regulatory exclusivity period for EYLEA (i.e., the period during which no biosimilar product can be approved by the FDA) will expire after May 17, 2024. See "Risks Related to Intellectual Property and Market Exclusivity - *Loss or limitation of patent rights, and regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products*" below. As a result, we face the risk of lower EYLEA net product sales due to biosimilar competition following such expiration, which may have a material adverse impact on our results of operations. While we have submitted a BLA for aflibercept 8 mg with the FDA, the degree to which any future net product sales of aflibercept 8 mg (if approved) may offset any potential decrease in EYLEA net product sales is highly uncertain.

In addition, we are dependent on our share of profits from the commercialization of Dupixent under our Antibody Collaboration with Sanofi. If we or Sanofi were to experience any difficulty with the commercialization of Dupixent or if we or Sanofi are unable to maintain current marketing approvals of Dupixent, we may experience a reduction in revenue and our business, prospects, operating results, and financial condition would be materially harmed.

If we or our collaborators are unable to continue to successfully commercialize our products, our business, prospects, operating results, and financial condition will be materially harmed.

We expect that the degree of commercial success of our marketed products will continue to depend on many factors, including the following (as applicable):

- any continued or future impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on our business and the demand for our marketed products, as well as any continued or future impact on, among other things, our employees, collaborators, suppliers, and other third parties on which we rely, our ability to continue to manage our supply chain, and the global economy (as further discussed above under "Risks Related to the COVID-19 Pandemic - *Our business may be further adversely affected by the effects of the COVID-19 pandemic*");
- effectiveness of the commercial strategy in and outside the United States for the marketing of our products, including pricing strategy;
- sufficient coverage of, and reimbursement for, our marketed products by third-party payors, including Medicare and Medicaid in the United States and other government and private payors in the United States and foreign jurisdictions, as well as U.S. and foreign payor restrictions on eligible patient populations and the reimbursement process (including drug price control measures that have been or may be enacted or introduced in the United States by various federal and state authorities);
- our ability and our collaborators' ability to maintain sales of our marketed products in the face of competitive products and to differentiate our marketed products from competitive products, including as applicable product candidates currently in clinical development (such as aflibercept 8 mg); and, in the case of EYLEA, the existing and potential new branded and biosimilar competition for EYLEA (discussed further under "*The commercial success of our products and product candidates is subject to significant competition* - Marketed Products" below) and the willingness of retinal specialists and patients to start or continue treatment with EYLEA or to switch from another product to EYLEA;

- the effect of existing and new health care laws and regulations currently being considered or implemented in the United States, including measures requiring the U.S. government in the future to negotiate the prices of certain drugs and price reporting and other disclosure requirements and the potential impact of such requirements on physician prescribing practices and payor coverage;
- serious complications or side effects in connection with the use of our marketed products, as discussed under "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition*" below;
- maintaining and successfully monitoring commercial manufacturing arrangements for our marketed products with third parties who perform fill/finish or other steps in the manufacture of such products to ensure that they meet our standards and those of regulatory authorities, including the FDA, which extensively regulate and monitor pharmaceutical manufacturing facilities;
- our ability to meet the demand for commercial supplies of our marketed products;
- the outcome of the pending proceedings relating to EYLEA, Praluent, and REGEN-COV (described further in Note 16 to our Consolidated Financial Statements included in this report), as well as other risks relating to our marketed products and product candidates associated with intellectual property of other parties and pending or future litigation relating thereto (as discussed under "Risks Related to Intellectual Property and Market Exclusivity" below);
- the outcome of the pending government proceedings and investigations and other matters described in Note 16 to our Consolidated Financial Statements included in this report (including the civil complaint filed against us on June 24, 2020 in the U.S. District Court for the District of Massachusetts by the U.S. Attorney's Office for the District of Massachusetts); and
- the results of post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and studies of other products that could implicate an entire class of products or are perceived to do so.

More detailed information about the risks related to the commercialization of our marketed products is provided in the risk factors below.

We and our collaborators are subject to significant ongoing regulatory obligations and oversight with respect to the products we or our collaborators commercialize. If we or our collaborators fail to maintain regulatory compliance for any of such products, the applicable marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition.

We and our collaborators are subject to significant ongoing regulatory obligations and oversight with respect to the products we or they commercialize for the products' currently approved indications in the United States, EU, and other countries where such products are approved. If we or our collaborators fail to maintain regulatory compliance or satisfy other obligations for such products' currently approved indications (including because the product does not meet the relevant endpoints of any required post-approval studies (such as those required under an accelerated approval by the FDA or other similar type of approval), or for any of the reasons discussed below under "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain*"), the applicable marketing approval may be withdrawn, which would materially harm our business, prospects, operating results, and financial condition. Failure to comply may also subject us to sanctions, product recalls, or withdrawals of previously approved marketing applications. See also "Risks Related to Manufacturing and Supply - *Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if regulatory approval is obtained, and a reduction in sales*" below.

Sales of our marketed products are dependent on the availability and extent of reimbursement from third-party payors, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition.

Sales of our marketed products in the United States are dependent, in large part, on the availability and extent of reimbursement from third-party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies ("PBMs"), and government programs such as Medicare and Medicaid. Sales of our marketed products in other countries are dependent, in large part, on similar reimbursement mechanisms and programs in those countries.

Our future revenues and profitability will be adversely affected in a material manner if such third-party payors do not adequately defray or reimburse the cost of our marketed products. If these entities do not provide coverage and reimbursement with respect to

our marketed products or provide an insufficient level of coverage and reimbursement, such products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payors cover only selected drugs, or may prefer selected drugs, making drugs that are not covered or preferred by such payors more expensive for patients. Third-party payors may also require prior authorization for reimbursement, or require failure on another type of treatment before covering a particular drug, particularly with respect to higher-priced drugs. As our currently marketed products and most of our product candidates are biologics, bringing them to market may cost more than bringing traditional, small-molecule drugs to market due to the complexity associated with the research, development, production, supply, and regulatory review of such products. Given cost sensitivities in many health care systems (which may continue to be exacerbated as a result of the COVID-19 pandemic), our currently marketed products and product candidates are likely to be subject to continued pricing pressures, which may have an adverse impact on our business, prospects, operating results, and financial condition.

In addition, in order for private insurance and governmental payors (such as Medicare and Medicaid in the United States) to reimburse the cost of our marketed products, we must maintain, among other things, our FDA registration and our National Drug Code, formulary approval by PBMs, and recognition by insurance companies and CMS. There is no certainty that we will be able to obtain or maintain the applicable requirements for reimbursement (including relevant formulary coverage, as discussed further below) of our current and future marketed products, which may have a material adverse effect on our business.

Government and other third-party payors (including PBMs) are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs, such as by requiring outcomes-based or other pay-for-performance pricing arrangements. They are also imposing restrictions on eligible patient populations and the reimbursement process, including by means of required prior authorizations and utilization management criteria, such as step therapy (i.e., requiring the use of less costly medications before more costly medications are approved for coverage). Some states are also considering legislation that would control the prices and reimbursement of prescription drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any prescription drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform measures in the future that will impose additional constraints on prices and reimbursements for our marketed products.

Further, there have been several recent U.S. Congressional inquiries and recently approved or proposed federal and state legislation and policies (in addition to those already in effect) designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs, and reform government program reimbursement methodologies for drugs. Notably, the U.S. Congress recently passed the IRA, which includes measures requiring the government to negotiate, with respect to drugs provided to Medicare patients and subject to a specified cap, the prices of a set number of certain high Medicare spending drugs and biological products per year starting in 2026 (including those covered under Medicare Part B, such as EYLEA and, potentially in the future, aflibercept 8 mg), measures penalizing manufacturers of certain Medicare Parts B and D drugs for price increases above inflation, and measures redesigning the Medicare Part D benefit to limit patient out-of-pocket drug costs and shift liabilities among stakeholders, including manufacturers. While enacted into law, it is unclear how the provisions of the IRA will be implemented and the extent to which the policy changes will ultimately impact reimbursement levels of our marketed products, including those covered under Medicare Part B (such as EYLEA) or our product candidates that may in the future be covered under Medicare Part B (such as aflibercept 8 mg). At the state level, legislatures are becoming increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and price and marketing cost disclosure and transparency measures. In some cases, these measures are designed to encourage importation from other countries and bulk purchasing. A reduction in the availability or extent of reimbursement from U.S. government programs (including as a result of the legislation, proposals, initiatives, and developments described above) could have a material adverse effect on the sales of EYLEA or our other marketed products. Economic pressure on state budgets may also have a similar impact.

In addition, PBMs and other managed-care organizations often develop formularies to reduce their cost for medications. The breadth of the products covered by formularies varies considerably from one PBM to another. Failure to be included in such formularies or to achieve favorable formulary status may negatively impact the utilization and market share of our marketed products. If our marketed products are not included within an adequate number of formularies, adequate reimbursement levels are not provided, the eligible insured patient population for our products is limited, or a key payor refuses to provide reimbursement for our products in a particular jurisdiction altogether, this could have a material adverse effect on our and our collaborators' ability to commercialize the applicable product.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we and our collaborators may be unable to obtain coverage, pricing, and/or reimbursement on terms that are favorable to us or necessary for us or our collaborators to successfully commercialize our marketed products in those countries. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements

governing drug pricing and reimbursement vary widely from country to country, and may take into account the clinical effectiveness, cost, and service impact of existing, new, and emerging drugs and treatments. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we or our collaborators are unable to market our products in foreign countries or if coverage and reimbursement for our marketed products in foreign countries is limited or delayed.

The commercial success of our products and product candidates is subject to significant competition.

Marketed Products

There is substantial competition in the biotechnology and pharmaceutical industries from biotechnology, pharmaceutical, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, as well as financial, marketing, and human resources, than we do. Our competitors, regardless of their size, may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with other pharmaceutical or biotechnology companies. There is significant actual and potential future competition for each of our marketed products.

EYLEA and (if approved) aflibercept 8 mg. EYLEA faces and, if approved, aflibercept 8 mg will face, significant competition in the marketplace. For example, EYLEA competes in one or more of its approved indications with other VEGF inhibitors, including Novartis and Genentech/Roche's Lucentis, Novartis' Beovu, and Genentech/Roche's Susvimo and Vabysmo, as well as biosimilar versions of Lucentis commercialized in the United States by Biogen Inc. and Coherus BioSciences, Inc. Ophthalmologists are also using off-label, third-party repackaged versions of Genentech/Roche's approved VEGF antagonist, bevacizumab, for the treatment of certain of EYLEA's indications, and we are aware of another company developing an ophthalmic formulation of such product. In DME and RVO, EYLEA also competes with intravitreal implants of corticosteroids. We are also aware of a number of companies working on the development of product candidates and extended delivery devices for the potential treatment of one or more of EYLEA's indications, including those that act by blocking VEGF and VEGF receptors (including therapies designed to extend the treatment interval) and/or other targets. In addition, we are aware of several companies developing biosimilar versions of EYLEA and other approved anti-VEGF treatments. Other potentially competitive products in development include products for use in combination with EYLEA and/or other anti-VEGF treatments, small-molecule tyrosine kinase inhibitors, gene therapies, and other eye-drop formulations, devices, and oral therapies. There also is a risk that third parties repackage ZALTRAP for off-label use and sale for the treatment of diseases of the eye, even though ZALTRAP has not been manufactured and formulated for use in intravitreal injections. We are aware of claims by third parties, including those based on published clinical data, alleging that ZALTRAP may be safely administered to the eye. If approved, we expect that aflibercept 8 mg will be entering a highly competitive environment; and our success in potentially commercializing aflibercept 8 mg will depend on a number of factors, including the extent to which we and our collaborators are able to differentiate aflibercept 8 mg from competitive products and the applicability of any restrictions imposed by payors at the time, such as step therapy.

Dupixent. The market for Dupixent's current and potential future indications is also increasingly competitive. In atopic dermatitis, there are topical and systemic JAK inhibitors and an antibody against IL-13 approved for atopic dermatitis and others are in development. In addition, a number of companies are developing antibodies against IL-4Ra, IL-13Ra1, OX40(L), and/or IL-31R that may compete with Dupixent in atopic dermatitis and other indications (including asthma and/or prurigo nodularis), as applicable. In asthma, competitors to Dupixent include antibodies against the IL-5 ligand or the IL-5 receptor, immunoglobulin E, or thymic stromal lymphopoietin ("TSLP"); and some of these antibodies are either approved or in development for indications that also compete or may compete in the future with Dupixent in CRSwNP and EoE. There are several other potentially competitive products in development that may compete with Dupixent in asthma, as well as potential future indications, including antibodies against the IL-33 ligand or receptor. Dupixent also faces competition from inhaled products in asthma and potential future indications.

Libtayo. Libtayo also faces significant competition. There are several competitors that are marketing and/or developing antibodies against PD-1 and/or PDL-1 (some of which were approved in the relevant indications and commercialized before Libtayo), including Merck's Keytruda, Bristol-Myers Squibb's Opdivo, Roche's Tecentriq, and AstraZeneca's Imfinzi.

Other marketed products. There is also significant actual and potential future competition for other products marketed or otherwise commercialized by us and/or our collaborators under our collaboration agreements with them. For example, there are several companies that are marketing and/or developing antibodies or other molecules (such as small interfering RNA molecules, or siRNAs) against PCSK9, ANGPTL3 and IL-6 and/or IL-6R, which currently (or, for product candidates in development, may in the future if approved) compete with Praluent, Evkeeza, and Kevzara, respectively.

Product Candidates

Our *VelocImmune* technology, other antibody generation technologies, and late-stage and earlier-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies, including antibody generation technologies and other approaches such as RNAi, chimeric antigen receptor T cell (CAR-T cell), and gene therapy technologies. For example, we are aware of other pharmaceutical and biotechnology companies actively engaged in the research and development of antibody-based products against targets that are also the targets of our early- and late-stage product candidates. We are also aware of other companies developing or marketing small molecules or other treatments that may compete with our antibody-based product candidates in various indications, if such product candidates obtain regulatory approval in those indications. If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our business or future prospects. In addition, the first product to reach the market in a therapeutic area is often at a significant competitive advantage relative to later entrants to the market. Accordingly, the relative speed with which we, or our collaborators, can develop our product candidates, complete the clinical trials and approval processes, and, if such product candidates are approved for marketing and sale, supply commercial quantities to the market is expected to continue to be an important competitive factor. Due to the uncertainties associated with developing biopharmaceutical products, we may not be the first to obtain marketing approval for a product against any particular target, which may have a material adverse effect on our business or future prospects.

We rely on our collaborations with Bayer and Sanofi for commercializing some of our marketed products.

While we have established our own sales and marketing organization for EYLEA in the United States for its currently approved indications, we have no sales, marketing, commercial, or distribution capabilities for EYLEA outside the United States. Under the terms of our license and collaboration agreement with Bayer (which is terminable by Bayer at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination), we rely on Bayer (and, in Japan, Santen pursuant to a Co-Promotion and Distribution Agreement with Bayer's Japanese affiliate) for sales, marketing, and distribution of EYLEA (and, if approved, will rely on Bayer for such activities relating to aflibercept 8 mg) in countries outside the United States.

In addition, under the terms of our Antibody Collaboration, we and Sanofi co-commercialize Dupixent in the United States and, as further discussed below, certain jurisdictions outside the United States. As a result, we rely in part on Sanofi's sales and marketing organization for Dupixent. If we and Sanofi fail to coordinate our sales and marketing efforts effectively, sales of Dupixent may be materially affected. Sanofi also maintains other important responsibilities relating to Dupixent. For example, Sanofi records product sales for Dupixent in the United States and leads negotiations with payors relating to this product. We also rely on Sanofi for sales, marketing, and distribution of Dupixent in countries outside the United States. While we exercised our option under the Antibody Collaboration to co-commercialize Dupixent in certain jurisdictions outside the United States, we will continue to rely in part on Sanofi's sales and marketing organization in such jurisdictions.

If we and our collaborators are unsuccessful in continuing to commercialize the marketed products subject to such collaborations, or if Bayer or Sanofi terminate their respective collaborations with us, our business, prospects, operating results, and financial condition would be materially impaired. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities. Therefore, termination of the Bayer collaboration agreement or our Antibody Collaboration would create substantial new and additional risks to the successful commercialization of the applicable products, particularly outside the United States. For additional information regarding our collaborations with Bayer and Sanofi, see "Risks Related to Our Reliance on or Transactions with Third Parties - *If our collaboration with Bayer for EYLEA is terminated, or Bayer materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to commercialize EYLEA outside the United States would be materially harmed*" below and "Risks Related to Our Reliance on or Transactions with Third Parties - *If our Antibody Collaboration with Sanofi is terminated, or Sanofi materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to develop, manufacture, and commercialize certain of our products and product candidates in the time expected, or at all, would be materially harmed*" below.

Sales of our marketed products recorded by us and our collaborators could be reduced by imports from countries where such products may be available at lower prices.

Our sales of products we commercialize in the United States and our collaborators' sales of products they commercialize or co-commercialize with us under our collaboration agreements with them in the United States and other countries (which impact our share of any profits or losses from the commercialization of these products under the relevant collaboration agreements and, therefore, our results of operations) may be reduced if the applicable product is imported into those countries from lower priced markets, whether legally or illegally (a practice known as parallel trading or reimportation). Parallel traders (who may repackage or otherwise alter the original product or sell it through alternative channels such as mail order or the Internet) take advantage of

the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices. Under our arrangement with Bayer, pricing and reimbursement for EYLEA outside the United States is the responsibility of Bayer. Similarly, under our Antibody Collaboration with Sanofi, pricing and reimbursement for the products commercialized or co-commercialized thereunder outside the United States are the responsibility of Sanofi. Prices for our marketed products in jurisdictions outside the United States are based on local market economics and competition and are likely to differ from country to country. In the United States, prices for pharmaceuticals are generally higher than in the bordering nations of Canada and Mexico and sales of our marketed products in the United States may be reduced if the applicable product marketed in those bordering nations is imported into the United States. In addition, there are proposals to legalize the import of pharmaceuticals from outside the United States into the United States. If such proposals were implemented, our future revenues derived from sales of our marketed products could be reduced. Parallel-trading practices also are of particular relevance to the EU, where they have been encouraged by the current regulatory framework. These types of imports may exert pressure on the pricing of our marketed products in a particular market or reduce sales recorded by us or our collaborators, thereby adversely affecting our results of operations.

We may be unsuccessful in continuing the commercialization of our marketed products or in commercializing our product candidates or new indications for our marketed products, if approved, which would materially and adversely affect our business, profitability, and future prospects.

Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates or new indications for our marketed products will depend upon, among other things, their acceptance by patients, the medical community, and third-party payors and on our and our collaborators' ability to successfully manufacture, market, and distribute those products in substantial commercial quantities or to establish and manage the required infrastructure to do so, including large-scale information technology systems and a large-scale distribution network. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time-consuming. Even if we obtain regulatory approval for our product candidates or new indications, if they are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business, prospects, operating results, and financial condition would be severely harmed.

The commercial success of our products may also be adversely affected by guidelines or recommendations to healthcare providers, administrators, payors, and patient communities that result in decreased use of our products. Such guidelines or recommendations may be published not only by governmental agencies, but also professional societies, practice management groups, private foundations, and other interested parties.

Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery and this could adversely affect the commercial success of those products if they receive marketing approval.

We are dependent upon a small number of customers for a significant portion of our revenue, and the loss of or significant reduction in sales to these customers would adversely affect our results of operations.

We sell our marketed products for which we record net product sales in the United States to several distributors and specialty pharmacies, as applicable, which generally sell the product directly to healthcare providers or other pharmacies (as applicable). For the years ended December 31, 2022 and 2021, our gross product sales of such products to two customers accounted on a combined basis for 83% and 48% of our total gross product revenue, respectively, and gross product sales of REGEN-COV to the U.S. government accounted for an additional 43% of our total gross product revenue for the year ended December 31, 2021. We expect significant customer concentration to continue for the foreseeable future. Our ability to generate and grow sales of these products will depend, in part, on the extent to which our distributors and specialty pharmacies are able to provide adequate distribution of these products to healthcare providers. Although we believe we can find additional distributors, if necessary, our revenue during any period of disruption could suffer and we might incur additional costs. In addition, these customers are responsible for a significant portion of our net trade accounts receivable balances. The loss of any large customer, a significant reduction in sales we make to them, any cancellation of orders they have made with us, or any failure to pay for the products we have shipped to them could adversely affect our results of operations.

If we are unable to establish commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected.

We have limited commercial capabilities outside the United States and do not currently have a fully established organization for the sales, marketing, and distribution of marketed products outside the United States. We will need to establish some or all of these capabilities outside the United States for any product we decide to independently commercialize or co-commercialize outside the United States. For example, following the exercise of our option under the Antibody Collaboration to co-

commercialize Dupixent in certain jurisdictions outside the United States, we have established certain commercial capabilities for Dupixent in some of these jurisdictions and are in the process of establishing these capabilities in others. In addition, in 2022, we and Sanofi amended the IO Collaboration to transfer all rights to develop, commercialize, and manufacture Libtayo exclusively to our Company, on a worldwide basis, over the course of a defined transition period, and we will need to establish certain sales, marketing, distribution, and manufacturing capabilities for Libtayo to support certain markets outside the United States. See Part I, Item 1. "Business - Collaboration, License, and Other Agreements - Sanofi." We will also need to obtain and/or maintain regulatory approvals for Libtayo in many jurisdictions outside of the United States. There may be other circumstances in which we need to establish commercial capabilities outside the United States, including because we decide to commercialize a particular product independently; we are unable to find an appropriate collaborator; or an existing collaborator decides to opt out or breaches its obligations to us with respect to a particular product.

In order to commercialize or co-commercialize any products outside the United States, we must build our sales, marketing, distribution, regulatory, managerial, and other capabilities in the relevant markets or make arrangements with third parties to perform these services, any of which will likely be expensive and time consuming and could delay product launch or the co-commercialization of a product in one or more markets outside the United States. We cannot be certain that we will be able to successfully develop commercial capabilities outside the United States (including as it relates to Dupixent and Libtayo) within an acceptable time frame, without incurring substantial expenses, or at all. These and other difficulties relating to commercializing our products outside the United States may harm our business, prospects, operating results, and financial condition.

Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products

If we or our collaborators do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications for our marketed products, we will not be able to market or sell them, which would materially and negatively impact our business, prospects, operating results, and financial condition.

We cannot sell or market products without regulatory approval or other authorization. If we or our collaborators do not maintain regulatory approval for our marketed products, and obtain regulatory approval for our product candidates or new indications of our marketed products (or are materially delayed in doing so), the value of our Company and our business, prospects, operating results, and financial condition may be materially harmed.

Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.

In the United States, we (which, for purposes of this risk factor, includes our collaborators, unless otherwise stated or required by the context) must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval for a new drug or indication is typically a lengthy and expensive process, and approval is highly uncertain. We cannot predict with certainty if or when we might submit for regulatory approval for any of our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval. Also, an approval might contain significant limitations in the form of narrow indications, warnings, precautions, or contra-indications with respect to conditions of use. Additionally, the FDA may determine that a REMS is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. The FDA has substantial discretion in the approval process (including with respect to setting specific conditions for submission) and may either refuse to accept an application for substantive review or may form the opinion after review of an application that the application is insufficient to allow approval of a product candidate. If the FDA does not accept our application for review or approve our application, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit the data before it will reconsider our application. Depending on the extent of these or any other studies that might be required, approval of any applications that we submit may be delayed significantly, or we may be required to expend more resources. It is also possible that any such additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to delay or abandon our applications for approval.

In certain instances (such as when we use a biomarker-based test to identify and enroll specific patients in a clinical trial), regulatory approval of a companion diagnostic to our therapeutic product candidate may be required as a condition to regulatory approval of the therapeutic product candidate. We may need to rely on third parties to provide companion diagnostics for use with our product candidates. Such third parties may be unable or unwilling on terms acceptable to us to provide such companion diagnostics or to obtain timely regulatory approval of or product labeling updates for such companion diagnostics, which could negatively impact regulatory approval of our product candidates or may result in increased development costs or delays.

The FDA may also require us to conduct additional clinical trials after granting approval of a product. The FDA has the explicit authority to require post-marketing studies (also referred to as post-approval or Phase 4 studies), labeling changes based on new

safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. Post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about our marketed products (or data about products similar to our marketed products that implicate an entire class of products or are perceived to do so) may result in changes in product labeling, restrictions on use, product withdrawal or recall, loss of approval, or lower sales of our products. Obligations equivalent in scope, but which can vary widely in application, apply in foreign countries.

According to the FDA policies under the Prescription Drug User Fee Act, the FDA system of review times for new drugs includes standard review and priority review. The FDA's goal for a standard review is to review the application within a 10-month time frame from the time the application is filed by the FDA (filing date), which typically occurs approximately 60 days following submission of the application by the applicant. The FDA has stated the goal to act on 90% of standard new molecular entity ("NME") New Drug Application ("NDA") and original BLA submissions within 10 months of the filing date. A priority review designation is given to drugs that treat a serious condition and offer major advances in treatment, or provide a treatment where no adequate therapy exists, and may also be afforded to a human drug application based on a priority review voucher. The FDA has stated the goal to act on 90% of priority NME NDA and original BLA submissions within six months of the filing date. However, the FDA's review goals are subject to change and the duration of the FDA's review depends on a number of factors, including the number and types of other applications that are submitted to the FDA around the same time period or are pending, and may be delayed for reasons beyond our control. For example, an FDA travel complication related to scheduling a routine clinical trial site inspection in eastern Europe recently delayed the FDA's approval of our sBLA for the combination treatment of Libtayo with chemotherapy in NSCLC.

If we believe we meet eligibility requirements, we may apply for various regulatory incentives in the United States, such as breakthrough therapy designation, fast track designation, accelerated approval, or priority review, where available, that serve to expedite drug development and/or review, and we may also seek similar designations elsewhere in the world. Often, regulatory agencies have broad discretion in determining whether or not product candidates qualify for such regulatory incentives and benefits, and we cannot guarantee we would be successful in obtaining beneficial regulatory designations by the FDA or other regulatory agencies. Even if obtained, such designations may not result in faster development processes, reviews, or approvals compared to drugs considered for approval under conventional FDA procedures. In addition, the FDA may later decide that any of our development programs no longer meets the conditions for a beneficial regulatory designation (including due to factors beyond our control, such as intervening competitive developments) or decide that the time period for FDA review or approval will not be shortened.

The FDA and comparable foreign regulatory authorities enforce GCPs and other regulations and legal requirements through periodic inspections of trial sponsors, clinical research organizations ("CROs"), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in those studies may be deemed unreliable. This and similar instances of non-compliance with GCPs could result in non-approval of our product candidates by the FDA or foreign regulatory authorities such as the EC, or we or the FDA or such other regulatory authorities may decide to conduct additional inspections or require additional clinical studies, which would delay our development programs, require us to incur additional costs, and could substantially harm our business, prospects, operating results, and financial condition.

Before approving a new drug or biologic product, the FDA and such comparable foreign regulatory authorities require that the facilities at which the product will be manufactured or advanced through the supply chain be in compliance with current Good Manufacturing Practices, or cGMP, requirements and regulations governing the manufacture, shipment, and storage of the product. Additionally, manufacturers of biological products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and adherence to any commitments made in the applicable BLA. These cGMP requirements and regulations are not prescriptive instructions on how to manufacture products, but rather a series of principles that must be observed during manufacturing; as a result, their implementation may not be clearly delineated and may present a challenging task. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured in compliance with regulatory requirements, and at competitive costs. If we or any of our third-party manufacturers, product packagers, labelers, or other parties performing steps in the supply chain are unable to maintain regulatory compliance with cGMP, the FDA and comparable foreign regulatory authorities can impose monetary penalties or other civil or criminal sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. For additional information, see "Risks Related to Manufacturing and Supply - *Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if regulatory approval is obtained, and a reduction in sales.*" Our business, prospects, operating results, and financial condition may be materially harmed as a result of noncompliance with the requirements and regulations described in this paragraph.

We are also subject to ongoing requirements imposed by the FDA and comparable foreign regulatory authorities governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping, and reporting of safety and other post-marketing information. The holder of an approved BLA or foreign equivalent is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA or foreign equivalent must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Advertising and promotional materials must comply with FDA regulations and those of foreign regulatory authorities and may be subject to other potentially applicable federal and state laws. The applicable regulations in countries outside the U.S. grant similar powers to the competent authorities and impose similar obligations on companies.

In addition to the standard drug approval process, the Secretary of HHS may authorize the issuance of, and the FDA Commissioner may issue, an EUA to allow an unapproved medical product to be used in an emergency based on criteria established by the Food, Drug, and Cosmetic Act, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. An EUA terminates when the emergency determination underlying the EUA terminates. The FDA may also revoke, revise, or restrict an EUA for a variety of reasons, including where it is determined that the underlying health emergency no longer exists or warrants such authorization or the medical product is no longer effective in diagnosing, treating, or preventing the underlying health emergency. For example, in January 2022, the FDA revised the EUA previously granted for REGEN-COV to exclude its use in geographic regions (currently including all U.S. states, territories, and jurisdictions) where, based on available information including variant susceptibility and regional variant frequency, infection or exposure is likely due to a variant such as an Omicron-lineage variant that is not susceptible to the treatment. Any such termination, revocation, or revision of an EUA could adversely impact our business in a variety of ways, including by having to absorb related manufacturing and overhead costs as well as potential inventory write-offs if regulatory approval is not obtained timely or at all. For example, we have recorded a charge to write down inventory related to REGEN-COV as described in Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations."

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process is similarly a lengthy and expensive process, the result of which is highly uncertain, and foreign regulatory requirements include all of the risks associated with FDA approval as well as country specific regulations. We and our collaborators must maintain regulatory compliance for the products we or they commercialize in foreign jurisdictions. From time to time, we may hold a product's marketing approval in a jurisdiction outside the United States where we may have less experience and where our regulatory capabilities may be more limited. In addition, actions by a regulatory agency in a country or region with respect to a product candidate may have an impact on the approval process for that product candidate in another country or region. Foreign regulatory authorities may ask for additional data in order to begin a clinical study, including Phase 3 clinical trials required to submit a Marketing Authorization Application ("MAA") in the EU. In addition, such authorities often have the authority to require post-approval studies, such as a PASS and/or PAES, which involve various risks similar to those described above. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can market that product or any other product in those countries.

Furthermore, we are subject to pharmacovigilance reporting and other pharmacovigilance requirements, which may differ in the numerous countries in which we conduct clinical trials. Failure to comply with any such requirements may result in the premature closure of the clinical trials and other enforcement actions by the relevant regulatory authorities. For example, if we do not manage to retain a QPPV, to maintain a PSMF, or to comply with other pharmacovigilance obligations in the EEA, we may be at risk of our clinical trials being closed prematurely, our marketing authorization being suspended, and we may be subject to other enforcement actions by the national competent authorities of the EEA or the EC.

Preclinical and clinical studies required for our product candidates and new indications of our marketed products are expensive and time-consuming, and their outcome is highly uncertain. If any such studies are delayed or yield unfavorable results, regulatory approval for our product candidates or new indications of our marketed products may be delayed or become unobtainable.

As described above, we must conduct extensive testing of our product candidates and new indications of our marketed products before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting such studies is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate (or prior or concurrent exposure to other products or product candidates), difficulty in enrolling and maintaining subjects in a clinical trial, clinical trial design that may not make it possible to enroll or retain a sufficient number of

patients to achieve a statistically significant result or the desired level of statistical significance for the endpoint in question, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to the FDA's GLPs or GCPs. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

Additionally, conducting clinical trials in foreign countries presents additional risks, including political and economic risks that are not present in the United States, such as armed conflict and economic embargoes or boycotts. For example, we and our collaborators are currently conducting and may in the future conduct or initiate clinical trials with sites in Russia and/or Ukraine. While we currently do not expect the conflict between Russia and Ukraine and related developments to have a significant impact on our ability to obtain results from clinical trials conducted by us or our collaborators, actions taken by Russia or potentially other countries in Ukraine and surrounding areas may adversely affect our ability to adequately conduct certain clinical trials and maintain compliance with relevant protocols due to, among other reasons, the prioritization of hospital resources away from clinical trials, reallocation or evacuation of site staff and subjects, or as a result of government-imposed curfews, warfare, violence, or other governmental action or other events that restrict movement. These developments may also result in our inability to access sites for monitoring or to obtain data from affected sites or patients going forward. We could also experience disruptions in our supply chain or limits to our ability to provide sufficient investigational materials in Ukraine and surrounding regions. Clinical trial sites may suspend or terminate the trials being conducted and patients could be forced to evacuate or choose to relocate, making them unavailable for initial or further participation in such trials. Alternative sites in these areas may not be available and we may need to find other countries to conduct the relevant trials. Furthermore, military action may prevent the FDA or other regulatory agencies from inspecting clinical sites in these countries. Such interruptions may delay our plans for clinical development and approvals for our product candidates.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new studies, which are expensive and time consuming, or abandon that drug development program. If preclinical testing yields unfavorable results, product candidates may not advance to clinical trials. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, prospects, operating results, and financial condition may be materially harmed.

Furthermore, some of our products and product candidates (such as Libtayo) are studied in combination with agents and treatments developed by us or our collaborators. There may be additional risks and unforeseen safety issues resulting from such combined administration, any of which may materially adversely impact clinical development of these product candidates and our ability to obtain regulatory approval.

In some jurisdictions such as the EU, initiating Phase 3 clinical trials and clinical trials in the pediatric population is subject to a requirement to obtain approval or a waiver from the competent authorities of the EU Member States and/or the EMA. If we do not obtain such approval, our ability to conduct clinical trials and obtain marketing authorizations or approvals may be severely impaired and our business may be adversely impacted.

Certain of our research and development activities are conducted at our existing facilities primarily located in Tarrytown, New York. As we continue to expand, we may lease, operate, purchase, or construct additional facilities to expand our research and development capabilities in the future. Expanding our research and laboratory facilities may require significant time and resources. Further, we may be unable to pursue our research and development efforts if the relevant facility were to cease operations due to fire, climate change, natural disasters, acts of war or terrorism, or other disruptions. Any related delays may interfere with our research and development efforts and our business may be adversely impacted.

Successful development of our current and future product candidates is uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates in these indications. Many companies in the biopharmaceutical industry, including our Company, have suffered significant setbacks in clinical trials, even after promising results had been obtained in earlier trials. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness and/or safety concerns, and clinical trials evaluating our product candidates have failed to meet the relevant endpoints. Moreover, even if we obtain positive results from preclinical testing or clinical trials, we may not achieve the same success in future trials, or the FDA and analogous foreign regulatory authorities may deem the results insufficient for an approval.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees ("IDMCs"). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to

recommendations made by responsible IDMCs based on their review of such interim trial results. For example, we previously discontinued actively treating patients with fasinumab following a recommendation from the responsible IDMC that the program be terminated based on available evidence to date; and we later discontinued further clinical development of fasinumab. The recommended termination or material modification of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business, prospects, operating results, and financial condition may be materially harmed.

We are studying our product candidates in a wide variety of indications in clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied, which would diminish our clinical "pipeline" and could negatively affect our future prospects and the value of our Company.

Serious complications or side effects in connection with the use of our products and in clinical trials for our product candidates and new indications for our marketed products could cause our regulatory approvals to be revoked or limited or lead to delay or discontinuation of development of our product candidates or new indications for our marketed products, which could severely harm our business, prospects, operating results, and financial condition.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates and new indications for our marketed products. It is possible that as we test our drug candidates or new indications in larger, longer, and more extensive clinical programs, or as use of these drugs becomes more widespread if they receive regulatory approval, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates or new indications for our marketed products has many side effects or causes serious or life-threatening side effects, the development of the product candidate may be delayed or fail, or, if the product candidate has received regulatory approval, such approval may be revoked, which would severely harm our business, prospects, operating results, and financial condition.

With respect to EYLEA and aflibercept 8 mg, there are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to further successfully commercialize EYLEA and to obtain regulatory approval for aflibercept 8 mg. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. Other VEGF blockers have reported side effects that became evident only after large-scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like aflibercept (such as intraocular inflammation ("IOI"), sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, and retinal tear), which can cause injury to the eye and other complications. The side effects previously reported for aflibercept include conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. There is no guarantee that we will be able to successfully obtain regulatory approval for aflibercept 8 mg. In addition, commercialization of EYLEA or our other products and potential future commercialization of aflibercept 8 mg or our other product candidates may be impacted by actions of third parties on which we rely, such as manufacturers of syringes or other devices used in the administration of our products. These and other complications or issues or side effects could harm further development and/or commercialization of EYLEA as well as further development and potential future commercialization of aflibercept 8 mg.

Dupixent and Libtayo are being studied in additional indications, as shown in the table under Part I, Item 1. "Business - Programs in Clinical Development." There is no guarantee that regulatory approval of Dupixent or Libtayo (as applicable) in any of these indications will be successfully obtained. The side effects previously reported for Dupixent include hypersensitivity reactions, eye problems (including conjunctivitis and keratitis), injection-site reactions, eye and eyelid inflammation, cold sores, oropharyngeal pain, eosinophilia, insomnia, toothache, gastritis, joint pain (arthralgia), parasitic (helminth) infections, and facial rash or redness; and the side effects previously reported for Libtayo include certain immune-mediated adverse reactions that may occur in any organ system or tissue, including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, and dermatologic reactions, as well as infusion-related reactions, cellulitis, sepsis, pneumonia, urinary tract infection, fatigue, rash, and diarrhea. These and other complications or side effects could harm further development and/or commercialization of Dupixent and Libtayo (as applicable).

There also are risks inherent in subcutaneous injections (which are used for administering most of our antibody-based products and product candidates), such as injection-site reactions (including redness, itching, swelling, pain, and tenderness) and other side effects. In addition, there are risks inherent in intravenous administration (which are used for some of our antibody-based products and product candidates), such as infusion-related reactions (including nausea, pyrexia, rash, and dyspnea). These and other

complications or side effects could harm further development and/or commercialization of our antibody-based products and product candidates utilizing this method of administration.

Many of our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, sometimes resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross-react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so neutralizing antibodies may be detected at a later date, in some cases even after pivotal clinical trials have been completed.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use, which would delay or prevent continued development of such candidates and/or receipt of regulatory approval or commercial sale, which could materially harm our business, prospects, operating results, and financial condition.

If we are unable to continue to develop suitable product formulations or manufacturing processes to support large-scale clinical testing of our product candidates, including our antibody-based product candidates, we may be unable to supply necessary materials for our clinical trials, which would delay or prevent the development of our product candidates. Similarly, if we are unable, directly or through our collaborators or third parties, to supply sufficient quantities of our products or develop formulations of our product candidates suitable for commercial use, we will be unable to obtain regulatory approval for those product candidates.

Many of our products are intended to be used and, if approved, our product candidates may be used in combination with drug-delivery devices, which may result in additional regulatory, commercialization, and other risks.

Many of our products are used and some of our products and product candidates may be used, if approved, in combination with a drug-delivery device, including a pre-filled syringe, patch pump, auto-injector, or other delivery system. For example, in the United States and the EU, EYLEA is approved in the 2mg pre-filled syringe. The success of our products and product candidates may depend to a significant extent on the performance of such devices, some of which may be novel or comprised of complex components. Given the increased complexity of the review process when approval of the product and device is sought under a single marketing application and the additional risks resulting from a product candidate's designation as a combination product discussed below, our product candidates used with such drug-delivery devices may be substantially delayed in receiving regulatory approval or may not be approved at all. The FDA review process and criteria for such applications are not well established, which could also lead to delays in the approval process. In addition, some of these drug-delivery devices may be provided by single-source, third-party providers or our collaborators. In any such case, we may be dependent on the sustained cooperation of those third-party providers or collaborators to supply and manufacture the devices; to conduct the studies and prepare related documentation required for approval or clearance by the applicable regulatory agencies; and to continue to meet the applicable regulatory and other requirements to maintain approval or clearance once it has been received. In addition, other parties may allege that our drug-delivery devices infringe patents or other intellectual property rights. For example, we are currently party to patent infringement and other proceedings relating to the EYLEA pre-filled syringe, as described in Note 16 to our Consolidated Financial Statements. Failure to successfully develop or supply the devices, delays in or failure of the studies conducted by us, our collaborators, or third-party providers, or failure of our Company, our collaborators, or the third-party providers to obtain or maintain regulatory approval or clearance of the devices could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in a product or product candidate reaching the market. Loss of regulatory approval or clearance of a device that is used with our product may also result in the removal of our product from the market. Further, failure to successfully develop or supply and manufacture these devices, or to gain or maintain their approval, could adversely affect sales of the related products.

In the United States, each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic, or device. The determination whether a product is a combination product or two separately regulated products is made by the FDA on a case-by-case basis. Although a single marketing application is generally sufficient for the approval, clearance, or licensure of a combination product, the FDA may determine that separate marketing applications are necessary. In addition, submitting separate marketing applications may be necessary to receive some benefit that accrues only from approval under a particular type of application. This could significantly increase the resources and time required to bring a particular combination product to market.

Risks Related to Intellectual Property and Market Exclusivity

For purposes of this subsection, references to our intellectual property (including patents, trademarks, copyrights, and trade secrets) include that of our collaborators and licensees, unless otherwise stated or required by the context.

If we cannot protect the confidentiality of our trade secrets, or our patents or other means of defending our intellectual property are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements and other means. If our trade secrets are improperly disclosed, by our current or former employees, our collaborators, or otherwise, it could help our competitors and adversely affect our business. We will be able to protect our proprietary rights only to the extent that our proprietary technologies and other information are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our Company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, held to be unenforceable, or circumvented. For example, certain of our U.S. patents (including those pertaining to our key products, such as EYLEA) have been and may in the future be challenged by parties who file a request for post-grant review or *inter partes* review under the America Invents Act of 2011 or *ex parte* reexamination, as described in Note 16 to our Consolidated Financial Statements included in this report. Post-grant proceedings are increasingly common in the United States and are costly to defend. In addition, patent applications filed outside the United States may be challenged by other parties, for example, by filing pre-grant third-party observations that argue against patentability or a post-grant opposition. Such opposition proceedings are increasingly common in Europe and are costly to defend. For example, in 2021, anonymous parties initiated opposition proceedings in the European Patent Office ("EPO") against our European Patent No. 2,944,306 (which concerns pre-filled syringes comprising ophthalmic formulations containing VEGF antagonists such as aflibercept for intravitreal administration), as described in Note 16 to our Consolidated Financial Statements included in this report. We have pending patent applications in the United States Patent and Trademark Office (the "USPTO"), the EPO, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend patents from challenges by others from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions or our ability to obtain, maintain, and enforce our intellectual property rights. Any such changes could also affect the value of our intellectual property or narrow the scope of our patents. For example, the World Trade Organization ("WTO") is currently considering an extension of a recently adopted waiver of certain intellectual property rights under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights for COVID-19 vaccines to include therapeutics. The timing of a decision on whether or not to extend the waiver is unknown. We cannot be certain that our intellectual property rights related to our COVID-19 monoclonal antibodies or any other current or future product or product candidate or technology would not be eliminated, narrowed, or weakened by any such extension or other rulemaking.

Additionally, the United States and other government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution, and maintenance of patent applications in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. Further, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patent holders from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia.

We also currently hold issued trademark registrations and have trademark applications pending in the United States and other jurisdictions, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the trademark. As our products mature, our reliance on our trademarks to differentiate us from our competitors increases and as a result, if we are unable to prevent third parties from adopting, registering, or using trademarks that infringe, dilute or otherwise violate our trademark rights, our business could be adversely affected.

We may be restricted in our development, manufacturing, and/or commercialization activities by patents or other proprietary rights of others, and could be subject to awards of damages if we are found to have infringed such patents or rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of others (including those relating to trademarks, copyrights, and trade secrets). Other parties may allege that they own blocking patents to our products in clinical development or even to products that have received regulatory approval and are being or have been commercialized, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or the way it is used. Moreover, other parties may allege that they have blocking patents to antibody-based products

made using our *VelocImmune* technology, or any other of our technologies, either because of the way the antibodies are discovered or produced or because of a proprietary composition covering an antibody or the antibody's target.

We have been in the past, are currently, and may in the future be involved in patent litigation and other proceedings involving patents and other intellectual property. For example, we and/or Sanofi are currently party to patent infringement proceedings initiated by Amgen against us and/or Sanofi relating to Praluent, as described in Note 16 to our Consolidated Financial Statements. In addition, we are currently party to patent infringement and other proceedings relating to EYLEA and REGEN-COV, as described in Note 16 to our Consolidated Financial Statements.

We are aware of patents and pending patent applications owned by others that claim compositions and methods of treatment relating to targets and conditions that we are also pursuing with our products and/or product candidates. Although we do not believe that any of our products or our late-stage antibody-based product candidates infringe any valid claim in these patents or patent applications, these other parties could initiate lawsuits for patent infringement and assert that their patents are valid and cover our products or our late-stage antibody-based product candidates, similar to the patent infringement proceedings referred to above. Further, we are aware of a number of patent applications of others that, if granted with claims as currently drafted, may cover our current or planned activities. It could be determined that our products and/or actions in manufacturing or selling our products or product candidates infringe such patents.

Patent holders could assert claims against us for damages and seek to prevent us from manufacturing, selling, or developing our products or product candidates, and a court may find that we are infringing validly issued patents of others. In the event that the manufacture, use, or sale of any of our products or product candidates infringes on the patents or violates other proprietary rights of others, we may be prevented from pursuing product development, manufacturing, and commercialization of those drugs and may be required to pay costly damages. In addition, in the event that we assert our patent rights against other parties that we believe are infringing our patent rights, such parties may challenge the validity of our patents and we may become the target of litigation, which may result in an outcome that is unfavorable to us. Any of these adverse developments may materially harm our business, prospects, operating results, and financial condition. In any event, legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed or advisable. For example, in 2018, we and Sanofi entered into a license agreement with Bristol-Myers Squibb, E. R. Squibb & Sons, and Ono Pharmaceutical to obtain a license under certain patents owned and/or exclusively licensed by one or more of these parties that includes the right to develop and sell Libtayo. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our products or product candidates, which could severely harm our business.

In addition, other parties may have regulatory exclusivity in the United States or foreign jurisdictions for products relating to targets or conditions we are also pursuing, which could prevent or delay our ability to apply for or obtain regulatory approval for our product candidates in such jurisdictions. For example, in the EU, a designated orphan drug is provided up to 10 years of market exclusivity in the orphan indication, during which time the EMA is generally precluded from accepting a MAA for a similar medicinal product unless it can be demonstrated that it is safer, more effective, or otherwise clinically superior to the original orphan medicinal product.

Loss or limitation of patent rights, and regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products.

In the pharmaceutical and biotechnology industries, the majority of an innovative product's commercial value is usually realized during the period in which it has market exclusivity. In the United States and some other countries, when market exclusivity expires and generic versions of a product are approved and marketed, there usually are very substantial and rapid declines in the product's sales.

If our late-stage product candidates or other clinical candidates are approved for marketing in the United States or elsewhere, market exclusivity for those products will generally be based upon patent rights and/or certain regulatory forms of exclusivity. As described above under " *If we cannot protect the confidentiality of our trade secrets, or our patents or other means of defending our intellectual property are insufficient to protect our proprietary rights, our business and competitive position will be harmed,*" the scope and enforceability of our patent rights may vary from country to country. The failure to obtain patent and other intellectual property rights, or limitations on the use, or the loss, of such rights could materially harm us. Absent patent protection or regulatory exclusivity for our products, it is possible, both in the United States and elsewhere, that generic, biosimilar, and/or interchangeable versions of those products may be approved and marketed, which would likely result in substantial and rapid reductions in revenues from sales of those products.

Under the PPACA, there is an abbreviated path in the United States for regulatory approval of products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-approved biological product. The PPACA provides a regulatory mechanism that allows for FDA approval of biologic drugs that are similar to innovative drugs on the basis of less extensive data than is required by a full BLA. Under this regulation, an application for approval of a biosimilar may be filed four years after approval of the innovator product. However, qualified innovative biological products receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. However, the term of regulatory exclusivity may not remain at 12 years in the United States and could be shortened if, for example, the PPACA is amended.

A number of jurisdictions outside of the United States have also established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier versions of biological products. For example, the EU has had an established regulatory pathway for biosimilars since 2005.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. Due to this risk, and uncertainties regarding patent protection, it is not possible to predict the length of market exclusivity for any particular product we currently or may in the future commercialize with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. We are aware of several companies developing biosimilar versions of EYLEA, as discussed further under "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *The commercial success of our products and product candidates is subject to significant competition* - Marketed Products" above. In the United States, the regulatory exclusivity period for EYLEA (i.e., the period during which no biosimilar product can be approved by the FDA) extends through May 17, 2024 following the pediatric exclusivity granted by the FDA. The loss of market exclusivity for a product (such as EYLEA) would likely materially and negatively affect revenues from product sales of that product and thus our financial results and condition.

Risks Related to Manufacturing and Supply

We rely on limited internal and contracted manufacturing and supply chain capacity, which could adversely affect our ability to commercialize our marketed products and, if approved, our product candidates and to advance our clinical pipeline.

We have large-scale manufacturing operations in Rensselaer, New York and Limerick, Ireland. Manufacturing facilities operated by us and by third-party contract manufacturers engaged by us would be inadequate to produce the active pharmaceutical ingredients of our current marketed products and our product candidates in sufficient clinical quantities if our clinical pipeline advances as planned. In addition to expanding our internal capacity, we intend to continue to rely on our collaborators, and may also rely on contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products. For example, as described in Part I, Item 1. "Business," in 2020, we entered into a collaboration agreement with Roche to develop, manufacture, and distribute REGEN-COV (known as Ronapreve in other countries outside the United States). As we increase our production in anticipation of potential regulatory approval for our product candidates, our current manufacturing capacity will likely not be sufficient, and our dependence on our collaborators and/or contract manufacturers may increase, to produce adequate quantities of drug material for both commercial and clinical purposes. The COVID-19 pandemic has exacerbated and may in the future further exacerbate certain of these risks. For example, the impact of prioritizing certain manufacturing-related resources for our COVID-19 monoclonal antibodies has included and may in the future include, among other things, drawing down inventory safety stock levels for certain of our other products (including Dupixent and EYLEA). Depending on the demand for our products (including any future demand for our COVID-19 monoclonal antibodies), our ability to re-establish successfully our customary manufacturing cadence, and other relevant factors, we may not be able to replenish our inventory safety stock to the levels we deem prudent or supply our products and product candidates in sufficient quantities to satisfy our commercial and development needs. We also rely entirely on other parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through other parties manufacture and supply sufficient commercial and clinical quantities of our products on acceptable terms, or if we should encounter delays or other difficulties with our collaborators, contract manufacturers, warehouses, shipping, testing laboratories, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products or product candidates, our business, prospects, operating results, and financial condition may be materially harmed.

Expanding our manufacturing capacity and establishing fill/finish capabilities will be costly and we may be unsuccessful in doing so in a timely manner, which could delay or prevent the launch and successful commercialization of our marketed products and product candidates or other indications for our marketed products if they are approved for marketing and could jeopardize our current and future clinical development programs.

In addition to our existing manufacturing facilities in Rensselaer, New York and Limerick, Ireland, we may lease, operate, purchase, or construct additional facilities to conduct expanded manufacturing or other related activities in the future. Expanding our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our marketed products and our product candidates if they are approved for marketing, and to supply clinical drug material to support the continued growth of our clinical programs, will require substantial additional expenditures, time, and various regulatory approvals and permits. This also holds true for establishing fill/finish capabilities in the future, for which we are in the process of constructing fill/finish facilities (refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources" for information about expected capital expenditures relating to this and other projects). In addition, we may need to develop or acquire additional manufacturing capabilities to the extent we or our collaborators pursue the development of drugs generated by means other than our existing "Trap" or *VelociSuite* technologies, such as siRNA gene silencing, genome editing, and targeted viral-based gene delivery and expression. Further, we will need to hire and train significant numbers of employees and managerial personnel to staff our expanding manufacturing and supply chain operations, as well as any future fill/finish activities. Start-up costs can be large, and scale-up entails significant risks related to process development and manufacturing yields. In addition, we may face difficulties or delays in developing or acquiring the necessary production equipment and technology to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable regulatory requirements. The FDA and analogous foreign regulatory authorities must determine that our existing and any expanded manufacturing facilities and any future fill/finish activities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly, and such facilities must also comply with applicable environmental, safety, and other governmental permitting requirements. We may not successfully expand or establish sufficient manufacturing or any future fill/finish capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the required timeframe to meet commercial demand for our product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize our marketed products, and it could also delay or require us to discontinue one or more of our clinical development programs. As a result, our business, prospects, operating results, and financial condition could be materially harmed.

Our ability to manufacture products may be impaired if any of our or our collaborators' manufacturing activities, or the activities of other third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Our ability to continue to manufacture products in our Rensselaer, New York and Limerick, Ireland facilities and at additional facilities (if any) in the future (including our ability to conduct any fill/finish activities in the future), the ability of our collaborators to manufacture products at their facilities, and our ability to utilize other third parties to produce our products, to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents or other intellectual property rights of others. Other parties may allege that our or our collaborators' manufacturing activities, or the activities of other third parties involved in our manufacture and supply chain (which may be located in jurisdictions outside the United States), infringe patents or other intellectual property rights. For example, we are currently party to patent infringement and other proceedings relating to the EYLEA pre-filled syringe, as described in Note 16 to our Consolidated Financial Statements. A judicial or regulatory decision in favor of one or more parties making such allegations could directly or indirectly preclude the manufacture of our products to which those intellectual property rights apply on a temporary or permanent basis, which could materially harm our business, prospects, operating results, and financial condition.

If sales of our marketed products do not meet the levels currently expected, or if the launch of any of our product candidates is delayed or unsuccessful, we may face costs related to excess inventory or unused capacity at our manufacturing facilities and at the facilities of third parties or our collaborators.

We use our manufacturing facilities primarily to produce bulk product for commercial supply of our marketed products and clinical and preclinical candidates for ourselves and our collaborations. We also plan to use such facilities to produce bulk product for commercial supply of new indications of our marketed products and new product candidates if they are approved for marketing or otherwise authorized for use. If our clinical candidates are discontinued or their clinical development is delayed, if the launch of new indications for our marketed products or new product candidates is delayed or does not occur, or if such products are launched and the launch is unsuccessful or the product is subsequently recalled or marketing approval is rescinded, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing services for us. In addition, if we or our collaborators experience excess inventory, it may be necessary to write down or write off such excess inventory or incur an impairment charge with respect to the facility where such product is manufactured, which could adversely affect our operating results. For example, during each of the years ended December 31, 2022 and 2021, we recorded a charge to write down inventory related to REGEN-COV as described in Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations."

Third-party service or supply failures, or other failures, business interruptions, or other disasters affecting our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, the manufacturing facilities of our collaborators, or the facilities of any other party participating in the supply chain, would adversely affect our ability to supply our products.

Bulk drug materials are currently manufactured at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland, as well as at our collaborators' facilities. We and our collaborators would be unable to manufacture these materials if the relevant facility were to cease production due to regulatory requirements or actions, business interruptions, labor shortages or disputes, supply chain interruptions or constraints (including with respect to natural gas and other raw materials), contaminations, fire, climate change, natural disasters, acts of war or terrorism, or other problems.

Many of our products and product candidates are very difficult to manufacture. As our products and most of our product candidates are biologics, they require processing steps that are more difficult than those required for many other chemical pharmaceuticals. Accordingly, multiple steps are needed to control the manufacturing processes. Problems with these manufacturing processes, even minor deviations from the normal process or from the materials used in the manufacturing process (which may not be detectable by us or our collaborators in a timely manner), could lead to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims, and insufficient inventory. Also, the complexity of our manufacturing process may make it difficult, time-consuming, and expensive to transfer our technology to our collaborators or contract manufacturers.

Also, certain raw materials or other products necessary for the manufacture and formulation of our marketed products and product candidates, some of which are difficult to source, are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties or our collaborators to perform filling, finishing, distribution, laboratory testing, and other services related to the manufacture of our marketed products and product candidates, and to supply various raw materials and other products. We would be unable to obtain these raw materials, other products, or services for an indeterminate period of time if any of these third parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMPs, contaminations, business interruptions, or labor shortages or disputes (in each case, including as a result of the COVID-19 pandemic and Russia's invasion of Ukraine, which have exacerbated many of these issues). In any such circumstances, we may not be able to engage a backup or alternative supplier or service provider in a timely manner or at all. This, in turn, could materially and adversely affect our or our collaborators' ability to manufacture or supply marketed products and product candidates, which could materially and adversely affect our business and future prospects.

Certain of the raw materials required in the manufacture and testing of our products and product candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain regulatory restrictions on using these biological source materials. If we or our collaborators are required to substitute for these sources to comply with such regulatory requirements, our clinical development or commercial activities may be delayed or interrupted.

Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if regulatory approval is obtained, and a reduction in sales.

We and our collaborators and other third-party providers are required to maintain compliance with cGMPs, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product(s). Because we produce multiple products and product candidates at our facilities in Rensselaer, New York and Limerick, Ireland, there are increased risks associated with cGMP compliance. Our inability, or the inability of our collaborators and third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our product candidates or new indications for our marketed products. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of our collaborators or other third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition. Significant noncompliance could also result in the imposition of monetary penalties or other civil or criminal sanctions and damage our reputation.

Other Regulatory and Litigation Risks

If the testing or use of our products harms people, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who enroll in our clinical trials may not protect us from liability or the cost of litigation. We may also be subject to claims by patients who use our approved products, or our product candidates if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. Even in a circumstance in which we do not believe that an adverse event is related to our products or product candidates, the related investigation may be time consuming or inconclusive and may have a negative impact on our reputation or business. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of third parties who provide fill/finish or other services. To the extent we maintain product liability insurance in relevant periods, such insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our business activities have been, and may in the future be, challenged under U.S. federal or state and foreign healthcare laws, which may subject us to civil or criminal proceedings, investigations, or penalties.

The FDA regulates the marketing and promotion of our products, which must comply with the Food, Drug, and Cosmetic Act and applicable FDA implementing standards. The FDA's review of promotional activities includes healthcare provider-directed and direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and sales representatives' communications. Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug. Any such failures could also cause significant reputational harm. The FDA may take enforcement action for promoting unapproved uses of a product or other violations of its advertising laws and regulations. The applicable regulations in countries outside the U.S. grant similar powers to the competent authorities and impose similar obligations on companies.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal civil False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. The U.S. federal healthcare program anti-kickback statute (the "AKS") prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving payments or other remuneration, directly or indirectly, to induce or reward someone to purchase, prescribe, endorse, arrange for, or recommend a product or service that is reimbursed under federal healthcare programs such as Medicare or Medicaid. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws. The Bipartisan Budget Act of 2018 has increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the federal anti-kickback statute.

The federal civil False Claims Act prohibits any person from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the statute and to share in any monetary recovery. Pharmaceutical companies have been investigated and/or prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate program. Pharmaceutical and other healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal fraud and false statement statutes that extend to non-government health benefit programs.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, damages, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment for individuals and the curtailment or restructuring of operations. Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business, prospects, operating results, and financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws. As described further in Note 16 to our Consolidated Financial Statements included in this report, we are party to civil litigation initiated in 2020 by the U.S. Attorney's Office for the District of Massachusetts concerning our support of a 501(c)(3) organization that provides financial assistance to patients; and we are cooperating with pending government investigations concerning certain other business activities. Any adverse decision, finding, allegation, or exercise of enforcement or regulatory discretion in any such proceedings or investigations could harm our business, prospects, operating results, and financial condition.

As part of the PPACA, the federal government requires that pharmaceutical manufacturers record any "transfers of value" made to U.S. licensed physicians and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members. Information provided by companies is aggregated and posted annually on an "Open Payments" website, which is managed by CMS, the agency responsible for implementing these disclosure requirements. Applicable manufacturers also are required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives. We also have similar reporting obligations in other countries based on laws, regulations, and/or industry trade association requirements.

We continue to dedicate significant resources to comply with these requirements and need to be prepared to comply with additional reporting obligations outside the United States that may apply in the future. In addition, several states have legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities; restrict when pharmaceutical companies may provide meals or gifts to prescribers or engage in other marketing-related activities; require identification or licensing of sales representatives; and restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs. Many of these requirements and standards are new or uncertain, and the penalties for failure to comply with these requirements may be unclear. If we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business, prospects, operating results, and financial condition. Additionally, access to such data by fraud-and-abuse investigators and industry critics may draw scrutiny to our collaborations with reported entities.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations, and future prospects.

We participate in the Medicaid Drug Rebate program, the Public Health Service's 340B drug pricing program (the "340B program") (which is administered by the Health Resources and Services Administration ("HRSA")), the U.S. Department of Veterans Affairs ("VA") Federal Supply Schedule ("FSS") pricing program, and the Tricare Retail Pharmacy Program. See Part I, Item 1, "Business - Government Regulation - Pricing and Reimbursement" for a description of these programs.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. Such interpretation can change and evolve over time. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also decide to terminate our Medicaid drug rebate agreement, or HRSA could decide to terminate our 340B program participation agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs.

Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate program and other governmental programs could negatively impact our financial results. The final regulation governing the Medicaid Drug Rebate program issued by CMS has increased and will continue to increase our costs and the complexity of compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS challenges the approach we have taken in our implementation of the final regulation. Other regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate program may have a similar impact.

In addition, the final regulation issued by HRSA regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities has affected our obligations and potential liability under the 340B program. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that we have violated the requirements of the program or the regulation could negatively impact our financial results. Moreover, under a final regulation effective January 13, 2021, HRSA established an ADR process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. On November 30, 2022, HRSA issued a notice of proposed rulemaking that proposes several changes to the ADR process. Further, any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the PPACA or otherwise could affect our 340B ceiling price calculations and negatively impact our results of operations.

We have obligations to report the average sales price for certain of our drugs to the Medicare program. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Starting in 2023, manufacturers must pay refunds to Medicare for single-source drugs or biological products, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125 percent of the refund amount.

Pursuant to applicable law, knowing provision of false information in connection with price reporting or contract-based requirements under the VA/FSS and/or Tricare programs can subject a manufacturer to civil monetary penalties. These program and contract-based obligations also contain extensive disclosure and certification requirements. If we overcharge the government in connection with our arrangements with FSS or Tricare, we are required to refund the difference to the government. Failure to make necessary disclosures or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and/or response to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations, and future prospects.

Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, and privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

In particular, our business activities outside the United States (which have recently increased, and are expected to continue to increase, due to, in part, our efforts to establish our commercialization and co-commercialization capabilities in certain jurisdictions outside the United States) are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our ability to expand internationally, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Our operations are subject to environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Compliance with these laws and regulations is costly, and we may incur substantial liability arising from our activities involving the use of hazardous materials.

As a fully integrated biotechnology company with significant research and development and manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, infectious agents (such as viruses, bacteria, and fungi), radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business, operating results, and financial condition.

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our Common Stock is listed. These entities, including the SEC and The NASDAQ Stock Market LLC, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations. For example, in March 2022, the SEC proposed new rules for extensive and prescriptive climate-related disclosure in annual reports and registration statements, which would also require inclusion of certain climate-related financial metrics in companies' audited financial statements. Also in March 2022, the SEC proposed rules that are intended to enhance and standardize disclosures regarding cybersecurity risk management, strategy, and governance, as well as cybersecurity incident reporting, by public companies. Our efforts to comply with these requirements and regulations (as well as corporate governance and disclosure expectations of investors and other stakeholders) have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from other business activities.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, intellectual property rights, and the framework for dispute resolution and asserting our rights against others, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a materially negative impact on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign cGMP requirements that may make it more difficult and costly for us to maintain regulatory compliance and/or manufacture our marketed product and product candidates in accordance with cGMPs.

As described above, the PPACA and potential regulations thereunder easing the entry of competing follow-on biologics into the marketplace, other new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

The U.S. federal or state governments could carry out other significant changes in legislation, regulation, or government policy, including with respect to government reimbursement changes or drug price control measures (such as those discussed above under "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *Sales of our marketed products are dependent on the availability and extent of reimbursement from third-party payors, and changes to such reimbursement may materially harm our business, prospects, operating results, and financial condition*") or the PPACA or other healthcare reform laws. While it is not possible to predict whether and when any such changes will occur, changes in the laws, regulations, and policies governing the development and approval of our product candidates and the commercialization, importation, and reimbursement of our products could adversely affect our business. In addition, our development and commercialization activities could be harmed or delayed by a shutdown of the U.S. government, including the FDA. For example, a prolonged shutdown may significantly delay the FDA's ability to timely review and process any submissions we have filed or may file or cause other regulatory delays, which could materially and adversely affect our business.

Risks associated with our operations outside the United States could adversely affect our business.

We have operations and conduct business in several countries outside the United States and we plan to expand these activities. For example, as discussed above, we perform co-commercialization activities under the Antibody Collaboration related to Dupixent in certain jurisdictions outside the United States and we will need to establish commercial capabilities related to Libtayo in certain markets outside the United States following the amendment to the IO Collaboration. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries, and many of these risks will increase as we expand our activities in such jurisdictions. These risks include:

- unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements, including those with which we and/or our collaborators must comply in order to maintain our marketing authorizations outside the United States;
- other laws and regulatory and industry trade association requirements to which our business activities abroad are subject, such as the FCPA and the U.K. Bribery Act (discussed in greater detail above under "*Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition*");
- changes in the political or economic condition of a specific country or region, including as a result of Russia's invasion of Ukraine;
- fluctuations in the value of foreign currency versus the U.S. dollar;
- tariffs, trade protection measures, import or export licensing requirements, trade embargoes, and sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), and other trade barriers;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

We have large-scale manufacturing operations in Limerick, Ireland and have also established offices in the United Kingdom, Germany, and other countries outside the United States. Changes impacting our ability to conduct business in the those countries,

or changes to the regulatory regime applicable to our operations in those countries (such as with respect to the approval of our product candidates), may materially and adversely impact our business, prospects, operating results, and financial condition.

We may incur additional tax liabilities related to our operations.

We are subject to income tax in the United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities, and our effective tax rate is derived from a combination of the applicable statutory rates in the various jurisdictions in which we operate. We record liabilities for uncertain tax positions that involve significant management judgment as to the application of law. The Internal Revenue Service or other domestic or foreign taxing authorities have previously disagreed, and may in the future disagree, with our interpretation of tax law as applied to the operations of Regeneron and its subsidiaries or with the positions we may take with respect to particular tax issues on our tax returns (see also Note 15 to our Consolidated Financial Statements included in this report). Consequently, our reported effective tax rate and our after-tax cash flows may be materially and adversely affected by tax assessments or judgments in excess of accrued amounts we have estimated in preparing our financial statements. Further, our effective tax rate may also be adversely affected by numerous other factors, including changes in the mix of our profitability from country to country, changes in tax laws and regulations, and tax effects of the accounting for stock-based compensation (which depend in part on the price of our stock and, therefore, are beyond our control). For example, the IRA has created a new corporate alternative minimum tax of 15% on adjusted financial statement income that applies to certain corporations for tax years beginning after December 31, 2022. Further specifics of this legislation will be outlined in Treasury regulations and any impact to the Company will depend on a number of factors, including any offsets for foreign tax credits or general business credits. The IRA also created an excise tax of 1% of the value of certain stock repurchases after December 31, 2022 that generally applies to publicly traded domestic corporations. We are in the process of evaluating the potential impact of these alternative minimum and excise tax provisions of the IRA. Other changes to U.S. tax laws and/or recommendations from the Organization for Economic Co-operation and Development (the "OECD") regarding a global minimum tax and other changes being considered and/or implemented in countries where we operate could materially impact our tax provision, cash tax liability, and effective tax rate. In addition, recommendations by the OECD and the EU could require companies to disclose more information to tax authorities on operations around the world, which may lead to greater audit scrutiny. Even though we regularly assess the information provided to tax authorities in determining the appropriateness of our tax reserves, such tax authorities could take a position that is contrary to our expectations, and the result could adversely affect our provision for income tax and our current rate.

We face risks related to the personal data we collect, process, and share.

Our ability to conduct our business is significantly dependent on the data that we collect, process, and share in discovering, developing, and commercializing drug products. These data are often considered personal data and are therefore regulated by data privacy laws in applicable jurisdictions.

Our activities outside the U.S., including clinical trial programs and research collaborations (such as our consortium with a group of companies to fund the generation of genetic exome sequence data from the UK Biobank health resource), implicate non-U.S. data protection laws, including the EU's General Data Protection Regulations ("GDPR"). The GDPR has a wide range of compliance obligations, including increased transparency requirements and data subject rights. Violations of the GDPR carry significant financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher)). In addition to the GDPR, certain EU Member States have issued or will be issuing their own implementation legislation. In June 2021, the European Commission introduced new standard contractual clauses required to be incorporated into certain new and existing agreements within prescribed timeframes in order to continue to lawfully transfer personal data outside the EU. Compliance with these requirements has been and is expected to continue to be costly and time consuming.

We conduct clinical trials in many countries around the world, which have new or evolving data privacy laws that have resulted in increased liability in the management of clinical trial data, and additional contractual and due-diligence obligations that could lead to a delay in clinical trial site start-up. There is an increase of enforcement activities in various EU countries that require evidence of compliance with local data privacy requirements. While we continue to monitor these developments, there remains some uncertainty surrounding the legal and regulatory environment for these evolving privacy and data protection laws. Complying with varying jurisdictional requirements could increase the costs and complexity of compliance, including the risk of substantial financial penalties for insufficient notice and consent, failure to respond to data subject rights requests, lack of a legal basis for the transfer of personal information out of the EU, or improper processing of personal data under the GDPR. Failure by our collaborators to comply with the strict rules on the transfer of personal data outside the EU into the U.S. may result in the imposition of criminal and administrative sanctions on such collaborators or impact the flow of personal data outside the EU, which could adversely affect our business and could create liability for us.

Most U.S. health care providers, including research institutions from which we or our collaborators obtain clinical trial data, are subject to privacy and security regulations promulgated under HIPAA. For example, as part of our human genetics initiative, our

wholly-owned subsidiary, Regeneron Genetics Center LLC, has entered into collaborations with many research institutions, which are subject to HIPAA. Regeneron is not a covered entity or business associate under HIPAA and thus is not subject to its requirements. However, we could be subject to criminal penalties if we, our affiliates, or our agents knowingly receive PHI in a manner that is not permitted under HIPAA. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive PHI from a health care provider or research institution that has not satisfied HIPAA's requirements for its disclosure. There are instances where we collect and maintain personal data, which may include health information that is outside the scope of HIPAA but within the scope of state health privacy laws or similar state level privacy legislation. This information may be received throughout the clinical trial process, in the course of our research collaborations, directly from individuals who enroll in our patient assistance programs, and from our own employees in a pandemic response process (such as in connection with the COVID-19 pandemic).

Consumer protection laws impact the manner in which we develop and maintain processes to support our patient assistance programs, product marketing activities, and the sharing of employee and clinical data for internal and third-party commercial activities. Several U.S. states have proposed and passed consumer privacy laws, which were modeled after the CCPA and influenced by the GDPR. The CCPA is a consumer protection law that establishes requirements for data use and sharing transparency and provides California residents with personal data privacy rights regarding the use, disclosure, and retention of their personal data. Amendments to the CCPA have, among other things, imposed new obligations to provide notice where personal data will be de-identified. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with data privacy incidents involving certain elements of personal data. These claims may result in significant liability and damages. These laws and regulations are constantly evolving and may impose limitations on our business activities. Several other U.S. states have introduced similar consumer protection laws, some of which are set to go into effect in the near future. At the federal level, Section 5 of the FTC Act is a consumer protection law that bars unfair and deceptive acts and practices and requires, among other things, companies to notify individuals that they will safeguard their personal data and that they will fulfil the commitments made in their privacy notices. The FTC has brought legal actions against organizations that have violated consumers' privacy rights or have misled them by failing to maintain appropriate security.

Furthermore, health privacy laws, data breach notification laws, consumer protection laws, data localization laws, and genetic privacy laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use, and dissemination of individuals' health and other personal data. New state level genetic privacy and consumer protection laws in the United States may require additional transparency and permissions in our informed consent forms. Moreover, individuals about whom we or our collaborators obtain health or other personal data, as well as the providers and third parties who share this information with us, may have statutory or contractual limits that impact our ability to use and disclose the information. We are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws both inside and outside the United States. Many of these laws differ from each other in significant ways and have different effects. Many of the state laws enable a state attorney general to bring actions and provide private rights of action to consumers as enforcement mechanisms. Compliance with these laws requires a flexible privacy framework as they are constantly evolving. Failure to comply with these laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation, and/or adverse publicity. Federal regulators, state attorneys general, and plaintiffs' attorneys have been active in this space. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

If we or any collaborators fail to comply with applicable federal, state, local, or foreign regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to commercialize our products and could harm, prevent, or substantially increase the cost of marketing and sales of any affected products that we are able to commercialize. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Increasing use of social media could give rise to liability, breaches of data security, or reputational damage.

We and our employees are increasingly utilizing social media tools as a means of communication both internally and externally. Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is a risk that the use of social media by us or our employees to communicate about our products or business may cause us to be found in violation of applicable requirements. In addition, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our social media policy or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal data of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image, and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our Common Stock.

Risks Related to Our Reliance on or Transactions with Third Parties

If our Antibody Collaboration with Sanofi is terminated, or Sanofi materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to develop, manufacture, and commercialize certain of our products and product candidates in the time expected, or at all, would be materially harmed.

We rely on support from Sanofi to develop, manufacture, and commercialize certain of our products and product candidates. With respect to the products that we are co-developing with Sanofi under our Antibody Collaboration (currently consisting of Dupixent, Kevzara, and itepekimab), Sanofi funds a significant portion of development expenses incurred in connection with the development of these products. In addition, we rely on Sanofi to lead much of the clinical development efforts, assist with or lead efforts to obtain and maintain regulatory approvals, and lead the commercialization efforts for these products and product candidates.

If Sanofi terminates the Antibody Collaboration or fails to comply with its payment obligations under any of our collaborations, our business, prospects, operating results, and financial condition would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. If Sanofi does not perform its obligations with respect to the product candidates it is co-developing with us, our ability to develop, manufacture, and commercialize these product candidates will be significantly adversely affected. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities for products commercialized under our Antibody Collaboration (see also "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *If we are unable to establish commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected*" above). Termination of the Antibody Collaboration would create substantial new and additional risks to the successful development and commercialization of the products subject to such collaborations, particularly outside the United States.

If our collaboration with Bayer for EYLEA is terminated, or Bayer materially breaches its obligations thereunder, our business, prospects, operating results, and financial condition, and our ability to continue to commercialize EYLEA outside the United States would be materially harmed.

We rely heavily on Bayer with respect to the commercialization of EYLEA outside the United States (and, if approved, will rely on Bayer with respect to any potential future commercialization of aflibercept 8 mg outside the United States, including the activities discussed below). Bayer is responsible for obtaining and maintaining regulatory approval outside the United States, as well as providing all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer has responsibility for selling EYLEA outside the United States using its sales force and, in Japan, in cooperation with Santen pursuant to a Co-Promotion and Distribution Agreement with Bayer's Japanese affiliate. If Bayer and, in Japan, Santen do not perform their obligations in a timely manner, or at all, our ability to commercialize EYLEA outside the United States will be significantly adversely affected. Bayer has the right to terminate its collaboration agreement with us at any time upon six or twelve months' advance notice, depending on the circumstances giving rise to termination. If Bayer were to terminate its collaboration agreement with us, we may not have the resources or skills to replace those of our collaborator, which could require us to seek another collaboration that might not be available on favorable terms or at all, and could cause significant issues for the commercialization of EYLEA outside the United States and result in substantial additional costs and/or lower revenues to us. We have limited commercial capabilities outside the United States and would have to develop or outsource these capabilities (see also "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *If we are unable to establish commercial capabilities outside the United States for products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely*

affected" above). Termination of the Bayer collaboration agreement would create substantial new and additional risks to the successful commercialization of EYLEA and, if approved, any potential future commercialization of aflibercept 8 mg outside the United States.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates and current and future products.

We depend upon third-party collaborators, including Sanofi and Bayer, and service providers such as CROs, outside testing laboratories, clinical investigator sites, third-party manufacturers, fill/finish providers, and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. We also depend, or will depend, on some of these or other third parties in connection with the commercialization of our marketed products and our product candidates and new indications for our marketed products if they are approved for marketing. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner (including as a result of its inability to perform due to financial or other relevant constraints, such as due to Russia's invasion of Ukraine) or in compliance with applicable GMPs, GLPs, or GCP standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for, or successfully commercializing our product candidates.

We and our collaborators rely on third-party service providers to support the distribution of our marketed products and for many other related activities in connection with the commercialization of these marketed products. Despite our or our collaborators' arrangements with them, these third parties may not perform adequately. If these service providers do not perform their services adequately, sales of our marketed products will suffer.

We have undertaken and may in the future undertake strategic acquisitions, and any difficulties from integrating such acquisitions could adversely affect our business, operating results, and financial condition.

We may acquire companies, businesses, products, or product candidates that complement or augment our existing business. For example, in May 2022, we completed our acquisition of Checkmate Pharmaceuticals, Inc. The process of proposing, negotiating, completing, and integrating any such acquisition is lengthy and complex. Other companies may compete with us for such acquisitions. In addition, we may not be able to integrate any acquired business successfully or operate any acquired business profitably. Integrating any newly acquired business could be expensive and time consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational, and financial resources, result in a loss of key personnel of the acquired business, and could prove to be more difficult or expensive than we predict. The diversion of our management’s attention and any delay or difficulties encountered in connection with any acquisitions we may consummate could result in the disruption of our ongoing business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, products, or product candidates, which may result in dilution for shareholders or the incurrence of indebtedness.

As part of our efforts to acquire companies, businesses, products, or product candidates or to enter into other significant transactions, we will conduct business, legal, and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits from acquisitions we have consummated or may consummate in the future, whether as a result of unidentified risks or liabilities, integration difficulties, regulatory setbacks, litigation with current or former employees and other events, our business, operating results, and financial condition could be adversely affected. For any acquired product candidates, we will also need to make certain assumptions about, among other things, development costs, the likelihood of receiving regulatory approval, and the market for any such product candidates. Our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of these transactions.

In addition, we may experience significant charges to earnings in connection with our efforts, if any, to consummate acquisitions. For transactions that are ultimately not consummated, these charges may include fees and expenses for investment bankers, attorneys, accountants, and other advisors in connection with our efforts. Even if our efforts are successful, we may incur, as part of a transaction, substantial charges for closure costs associated with elimination of duplicate operations and facilities and acquired in-process research and development charges. In either case, the incurrence of these charges could adversely affect our operating results for particular periods.

Risks Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers, other key members of our senior management team, and the Chair of our board of directors. If we are not able to retain (or for any other reason lose the services of) any of these persons, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chair of our board of directors; Leonard S. Schleifer, M.D., Ph.D., our President and Chief Executive Officer; and George D. Yancopoulos, M.D., Ph.D., our President and Chief Scientific Officer. We are also highly dependent on the expertise and services of other senior management members leading our research, development, manufacturing, and commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the research, development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

Information Technology Risks

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex, and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. These systems are also critical to enable remote working arrangements, which have been growing in importance due in part to the COVID-19 pandemic and related developments. The size and complexity of our computer systems make us potentially vulnerable to IT system breakdowns, internal and external malicious intrusion, and computer viruses and ransomware, which may impact product production and key business processes. We also have outsourced significant elements of our information technology infrastructure and operations to third parties, which may allow them to access our confidential information and may also make our systems vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by such third parties or others.

In addition, our systems are potentially vulnerable to data security breaches - whether by employees or others - which may expose sensitive data to unauthorized persons. Data security breaches could lead to the loss of trade secrets or other intellectual property, result in demands for ransom or other forms of blackmail, or lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage or extortion) and expertise, including by organized criminal groups, "hacktivists," nation states, and others. As a company with an increasingly global presence, our systems are subject to frequent attacks. There is the potential that our systems may be directly or indirectly affected as nation-states conduct global cyberwarfare, including in connection with the current Russia-Ukraine hostilities.

Due to the nature of some of these attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, and to oversee and monitor the security measures of our suppliers and/or service providers, there can be no assurance that our efforts will prevent service interruptions or security breaches. In addition, we depend in part on third-party security measures over which we do not have full control to protect against data security breaches.

If we or our suppliers and/or service providers fail to maintain or protect our information technology systems and data security effectively and in compliance with U.S. and foreign laws, or fail to anticipate, plan for, or manage significant disruptions to these systems, we or our suppliers and/or service providers could have difficulty preventing, detecting, or controlling such disruptions or security breaches, which could result in legal proceedings, liability under U.S. and foreign laws that protect the privacy of personal information, disruptions to our operations, government investigations, breach of contract claims, and damage to our reputation (in each case in the U.S. or globally), which could have a material adverse effect on our business, prospects, operating results, and financial condition.

Risks Related to Our Financial Results, Liquidity, and Need for Additional Financing

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We expend substantial resources for research and development, including costs associated with clinical testing of our product candidates and new indications of our marketed products, the commercialization of products, and capital expenditures. We believe our existing capital resources and borrowing availability under our revolving credit facility, together with funds generated by our current and anticipated EYLEA net product sales and funding we are entitled to receive under our collaboration agreements and other similar agreements (including our share of profits in connection with commercialization of EYLEA and Dupixent under our collaboration agreements with Bayer and Sanofi, respectively), will enable us to meet our anticipated operating needs for the foreseeable future. However, one or more of our collaboration agreements may terminate, our revenues may fall short of our projections or be delayed, or our expenses may increase, any of which could result in our capital being consumed significantly faster than anticipated. Our expenses may increase for many reasons, including expenses in connection with the commercialization of our marketed products and the potential commercial launches of our product candidates and new indications for our marketed products, manufacturing scale-up, expenses related to clinical trials testing of antibody-based product candidates we are developing on our own (without a collaborator), and expenses for which we are responsible in accordance with the terms of our collaboration agreements.

We cannot be certain that our existing capital resources and our current and anticipated revenues will be sufficient to meet our operating needs. We may require additional financing in the future and we may not be able to raise additional funds on acceptable terms or at all. For example, there is no guarantee that we will have the ability to pay the principal amount due on our senior unsecured notes at maturity or redeem, repurchase, or refinance the notes prior to maturity on acceptable terms or at all. In addition, in March 2022, we completed an extension of the $720.0 million lease financing for our existing corporate headquarters and other rentable area consisting of approximately 150 acres of predominately office buildings and laboratory space located in Tarrytown, New York, which is set to expire in March 2027. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - *Tarrytown, New York Leases*" for further details. Our ability to refinance or to obtain additional financing could be adversely affected if there is a significant decline in the demand for our products or other significantly unfavorable changes in economic conditions. Volatility in the financial markets could increase borrowing costs or affect our ability to raise capital. If additional financing is necessary and we obtain it through the sale of equity securities, such sales will likely be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may be at interest rates and contain other terms that are not favorable to our shareholders. Should we require and be unable to raise sufficient funds (i) to complete the development of our product candidates, (ii) to successfully commercialize our product candidates or new indications for our marketed products if they obtain regulatory approval, and (iii) to continue our manufacturing and marketing of our marketed products, we may face delay, reduction, or elimination of our research and development or preclinical or clinical programs and our commercialization activities, which would significantly limit our potential to generate revenue.

Our indebtedness could adversely impact our business.

We have certain indebtedness and contingent liabilities, including milestone and royalty payment obligations. As of December 31, 2022, we had an aggregate of $2.701 billion of outstanding indebtedness under our senior unsecured notes and the lease financing facility. We may also incur additional debt in the future. Any such indebtedness could:

- limit our ability to access capital markets and incur additional debt in the future;
- require us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow for other purposes, including business development efforts, research and development, and mergers and acquisitions; and
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate, thereby placing us at a competitive disadvantage compared to competitors that have less debt.

Changes in foreign currency exchange rates could have a material adverse effect on our operating results.

Our revenue from outside the United States will increase as our products, whether marketed or otherwise commercialized by us or our collaborators, gain marketing approval in such jurisdictions. Our primary foreign currency exposure relates to movements in the Japanese yen, euro, British pound sterling, Canadian dollar, and Australian dollar. If the U.S. dollar weakens against a specific foreign currency, our revenues will increase, having a positive impact on net income, but our overall expenses will increase, having a negative impact. Conversely, if the U.S. dollar strengthens against a specific foreign currency, our revenues will decrease, having a negative impact on net income, but our overall expenses will decrease, having a positive impact. Therefore, significant changes in foreign exchange rates can impact our operating results and the financial condition of our Company. See Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - *Results of Operations*."

Our investments are subject to risks and other external factors that may result in losses or affect the liquidity of these investments.

As of December 31, 2022, we had $3.106 billion in cash and cash equivalents and $11.228 billion in marketable securities (including $1.210 billion in equity securities). Our investments consist primarily of debt securities, including investment-grade corporate bonds. These fixed-income investments are subject to external factors that may adversely affect their market value or liquidity, such as interest rate, liquidity, market, and issuer credit risks, including actual or anticipated changes in credit ratings. The equity securities we hold may experience significant volatility and may decline in value or become worthless if the issuer experiences an adverse development. Furthermore, our equity investments could be subject to dilution (and decline in value) as a result of the issuance of additional equity interests by the applicable issuer. If any of our investments suffer market price declines, such declines may have an adverse effect on our financial condition and operating results.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- net product sales of our marketed products (as recorded by us or our collaborators), in particular EYLEA, Dupixent, and Libtayo, as well as our overall operating results;
- if any of our product candidates (such as aflibercept 8 mg) or our new indications for our marketed products receive regulatory approval, net product sales of, and profits from, these product candidates and new indications;
- market acceptance of, and the market share for, our marketed products, especially EYLEA, Dupixent, and Libtayo;
- whether our net product sales and net profits underperform, meet, or exceed the expectations of investors or analysts;
- announcement of actions by the FDA or foreign regulatory authorities or their respective advisory committees regarding our, or our collaborators', or our competitors', currently pending or future application(s) for regulatory approval of product candidate(s) or new indications for marketed products;
- announcement of submission of an application for regulatory approval of one or more of our, or our competitors', product candidates or new indications for marketed products;
- progress, delays, or results in clinical trials of our or our competitors' product candidates or new indications for marketed products;
- impact of the COVID-19 pandemic on our business, including the degree of success (if any) of our efforts to develop "next generation" COVID-19 monoclonal antibodies and any potential future sales of our COVID-19 monoclonal antibodies;
- announcement of technological innovations or product candidates by us or competitors;
- claims by others that our products or technologies infringe their patents;
- challenges by others to our patents in the EPO and in the USPTO;
- public concern as to the safety or effectiveness of any of our marketed products or product candidates or new indications for our marketed products;
- pricing or reimbursement actions, decisions, or recommendations by government authorities, insurers, or other organizations (such as health maintenance organizations and PBMs) affecting the coverage, reimbursement, or use of any of our marketed products or competitors' products;
- our ability to raise additional capital as needed on favorable terms;
- developments in our relationships with collaborators or key customers;
- developments in the biotechnology industry or in government regulation of healthcare, including those relating to compounding (i.e., a practice in which a pharmacist, a physician, or, in the case of an outsourcing facility, a person under the supervision of a pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient);
- large sales of our Common Stock by our executive officers or other employees, directors, or significant shareholders (or the expectation of any such sales);
- changes in tax rates, laws, or interpretation of tax laws;
- arrivals and departures of key personnel;
- general market conditions;
- our ability to repurchase our Common Stock under any share repurchase program on favorable terms or at all;
- trading activity that results from the rebalancing of stock indices in which our Common Stock is included, or the inclusion or exclusion of our Common Stock from such indices;
- other factors identified in these "Risk Factors"; and
- the perception by the investment community or our shareholders of any of the foregoing factors.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. As discussed in greater detail under "*Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings*" below, a large percentage of our Common Stock is owned by a small number of our principal shareholders. As a result, the public float of our Common Stock (i.e., the portion of our Common Stock held by public investors, as opposed to the Common Stock held by our directors, officers, and principal shareholders) may be lower than the public float of other large public companies with broader public ownership. Therefore, the trading price of our Common Stock may fluctuate significantly more than the stock market as a whole. These factors may exacerbate the volatility in the trading price of our Common Stock and may negatively impact your ability to liquidate your investment in Regeneron at the time you wish at a price you consider satisfactory. Broad market fluctuations may also adversely affect the market price of our Common Stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock

price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation, which may harm our business, prospects, operating results, and financial condition.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of December 31, 2022, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39.4% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2022. If our significant shareholders or we sell substantial amounts of our Common Stock in the public market, or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

There can be no assurance that we will repurchase shares of our Common Stock or that we will repurchase shares at favorable prices.

In November 2021, our board of directors authorized a share repurchase program to repurchase up to $3.0 billion of our Common Stock (of which $745.2 million remained available as of December 31, 2022); and, in January 2023, our board of directors authorized an additional $3.0 billion for share repurchases. There can be no assurance of any future share repurchases or share repurchase program authorizations. Any share repurchases will depend upon, among other factors, our cash balances and potential future capital requirements, our results of operations and financial condition, the price of our Common Stock on the NASDAQ Global Select Market, and other factors that we may deem relevant. We can provide no assurance that we will repurchase shares of our Common Stock at favorable prices, if at all.

Our existing shareholders may be able to exert substantial influence over matters requiring shareholder approval and over our management.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of December 31, 2022, holders of Class A Stock held 14.4% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to substantially influence the election of our directors and the vote on certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of December 31, 2022:

- our current executive officers and directors beneficially owned 7.1% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2022, and 18.5% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2022; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39.4% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2022. In addition, these five shareholders plus our Chief Executive Officer held approximately 46.6% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of December 31, 2022.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, as well as the contractual provisions in our investor and collaboration agreements and certain provisions of our compensation plans and agreements, could deter, delay, or prevent an acquisition or other "change of control" of us and could adversely affect the price of our Common Stock.

Our certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our Company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our Common Stock and Class A Stock;
- a staggered board of directors, so that it would take three successive annual shareholder meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- a provision whereby any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- a requirement that any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving our Company and an "interested shareholder," a plan of merger or consolidation of our Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor above captioned "*Our existing shareholders may be able to exert substantial influence over matters requiring shareholder approval and over our management.*"

Further, certain of our collaborators are currently bound by "standstill" provisions under their respective agreements with us. These include the January 2014 amended and restated investor agreement between us and Sanofi, as amended, and our 2016 ANG2 license and collaboration agreement with Bayer, which contractually prohibit Sanofi and Bayer, respectively, from seeking to directly or indirectly exert control of our Company or acquiring more than a specified percentage of our Class A Stock and Common Stock, taken together (30% in the case of Sanofi and 20% in the case of Bayer).

In addition, our Change in Control Severance Plan and the employment agreement with our Chief Executive Officer, each as amended and restated, provide for severance benefits in the event of termination as a result of a change in control of our Company. Also, equity awards issued under our long-term incentive plans may become fully vested in connection with a "change in control" of our Company, as defined in the plans. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We conduct our research, development, manufacturing, and administrative activities at our owned and leased facilities. A summary of our significant owned and leased properties is provided below.

Tarrytown, New York

At our Tarrytown, New York location, we lease approximately 1,467,000 square feet of laboratory and office space. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - *Tarrytown, New York Leases*" for further details. We also own an approximate 100-acre parcel of land adjacent to our Tarrytown, New York location, which we are in the process of developing, primarily in connection with expanding our research and support facilities to accommodate our growth.

Rensselaer, New York

We own facilities in Rensselaer, New York totaling approximately 1,189,000 square feet of manufacturing, research, office, and warehouse space. This includes approximately 452,000 square feet of warehouse, laboratory, and office space which we

constructed on a 130-acre parcel of land near our Rensselaer facility. We are in the process of further developing this property, primarily in connection with constructing a fill/finish facility.

Limerick, Ireland

We own a facility in Limerick, Ireland totaling approximately 555,000 square feet of manufacturing, warehouse, laboratory, and office space.

Item 3. Legal Proceedings

The information called for by this item is incorporated herein by reference to the information set forth in Note 16 to our Consolidated Financial Statements included in this report.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Market for Registrant's Common Equity

Our Common Stock, par value $.001 per share, is quoted on The NASDAQ Global Select Market under the symbol "REGN." Our Class A Stock, par value $.001 per share, is not publicly quoted or traded.

As of January 26, 2023, there were 161 shareholders of record of our Common Stock and 14 shareholders of record of our Class A Stock.

We have never paid cash dividends on our Common Stock or Class A Stock and do not anticipate paying any in the foreseeable future.

STOCK PERFORMANCE GRAPH

Set forth below is a line graph comparing the cumulative total shareholder return on Regeneron's Common Stock with the cumulative total return of (i) the NASDAQ US Benchmark Pharmaceuticals Total Return Index ("NQ US Pharma TR Index"), and (ii) Standard & Poor's 500 Stock Index ("S&P 500") for the period from December 31, 2017 through December 31, 2022. The comparison assumes that $100 was invested on December 31, 2017 in our Common Stock and in both of the foregoing indices. All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices. The historical stock price performance of our Common Stock shown in the graph below is not necessarily indicative of future stock price performance.

	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022
Regeneron	$ 100.00	$ 99.35	$ 99.87	$ 128.50	$ 167.98	$ 191.91
S&P 500	$ 100.00	$ 93.76	$ 120.84	$ 140.49	$ 178.27	$ 143.61
NQ US Pharma TR Index	$ 100.00	$ 106.80	$ 122.30	$ 135.17	$ 168.13	$ 187.21

This performance graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference into any filing of ours under the Securities Act of 1933, as amended, or the Securities Exchange Act, except as shall be expressly set forth by specific reference to such filing.

Issuer Purchases of Equity Securities

The table below reflects shares of Common Stock we repurchased under our share repurchase programs, as well as Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted stock granted under one of our long-term incentive plans, during the three months ended December 31, 2022. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources" for further details of our share repurchase programs.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Programs[b] *(in millions)*
10/1/2022–10/31/2022	48,078	$ 719.10	48,078	$ 1,151.7
11/1/2022–11/30/2022	236,526	$ 737.86	234,834	$ 978.4
12/1/2022–12/31/2022	418,427	$ 737.15	317,470	$ 745.2
Total	703,031 [a]		600,382 [a]	

[a] The difference between the total number of shares purchased and the total number of shares purchased as part of publicly announced programs relates to Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted stock granted under one of our long-term incentive plans.

[b] In January 2023, our board of directors authorized a new share repurchase program to repurchase up to an additional $3.0 billion of our Common Stock. See Item 7. "Liquidity and Capital Resources - Share Repurchase Programs" for further details.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results and Results of Operations

The following discussion should be read in conjunction with the consolidated financial statements and related notes included elsewhere in this report. Refer to Part II, Item 7 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (filed with the SEC on February 7, 2022) for additional discussion of our financial condition and results of operations for the year ended December 31, 2020, as well as our financial condition and results of operations for the year ended December 31, 2021 compared to the year ended December 31, 2020.

Overview

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

We currently have nine FDA-approved products that have received marketing approval and approximately 35 product candidates in clinical development, almost all of which were homegrown in our laboratories. In addition, REGEN-COV was authorized under an EUA for COVID-19 from November 2020 until January 2022 when the EUA was revised to exclude its use in geographic regions where infection or exposure is likely due to a variant that is not susceptible to the treatment (see Part I, Item 1. "Business - Additional Information - Clinical Development Programs"). Refer to Part I, Item 1. "Business - Products" and "Business - Programs in Clinical Development" for additional information related to marketed products and product candidates.

Our ability to generate profits and to generate positive cash flow from operations over the next several years depends significantly on the continued success in commercializing EYLEA and Dupixent, as well as on whether we are able to obtain regulatory approval for aflibercept 8 mg and are successful in commercializing it. We expect to continue to incur substantial expenses related to our research and development activities, a portion of which we expect to be reimbursed by our collaborators. In addition, our research and development activities and related costs which are not reimbursed are expected to expand and require additional resources. We also expect to incur substantial costs related to the commercialization of our marketed products. Our financial results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of our products; the scope and progress of our research and development efforts; the timing of certain expenses; the continuation of our collaborations, in particular with Sanofi and Bayer, including our share of collaboration profits from sales of commercialized products and the amount of reimbursement of our research and development expenses that we receive from collaborators; and the amount of income tax expense we incur, which is partly dependent on the profits or losses we earn in each of the countries in which we operate. We cannot predict whether or when new products or new indications for marketed products will receive regulatory approval or, if any such approval is received, whether we will be able to successfully commercialize such product(s) and whether or when they may become profitable.

Critical Accounting Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP") requires management to make estimates and assumptions that affect reported amounts and related disclosures in the financial statements. Critical accounting estimates are those estimates made in accordance with GAAP that involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our results of operations or financial condition.

Management believes the current assumptions used to estimate amounts reflected in our Consolidated Financial Statements are appropriate. However, if actual experience differs from the assumptions used in estimating amounts reflected in our Consolidated Financial Statements, the resulting changes could have a material adverse effect on our results of operations, and, in certain situations, could have a material adverse effect on our liquidity and financial condition. The critical accounting estimates that impact our Consolidated Financial Statements are described below.

Revenue Recognition - Product Revenue

We recognize revenue from product sales at a point in time when our customer is deemed to have obtained control of the product, which generally occurs upon receipt or acceptance by our customer. The amount of revenue we recognize from product sales may vary due to rebates, chargebacks, and discounts provided under governmental and other programs, distribution-related fees, and other sales-related deductions. In order to determine the transaction price, we estimate, utilizing the expected value method, the amount of variable consideration to which we will be entitled. This estimate is based upon contracts with customers, healthcare providers, payors and government agencies, statutorily-defined discounts applicable to government-funded programs, historical experience, estimated payor mix, and other relevant factors. Calculating these provisions involves estimates and judgments. We

review our estimates of rebates, chargebacks, and other applicable provisions each period and record any necessary adjustments in the current period's net product sales. Refer to the "Results of Operations - Revenues - Net Product Sales" section below for further details regarding our provisions, and credits/payments, for sales-related deductions.

Collaborative Arrangements

We have entered into various collaborative arrangements to research, develop, manufacture, and commercialize products and/or product candidates. Our collaboration agreements may require us to deliver various rights, services, and/or goods across the entire life cycle of a product or product candidate. In agreements involving multiple goods or services promised to be transferred to our collaborator, we must assess, at the inception of the contract, whether each promise represents a separate obligation (i.e., is "distinct"), or whether such promises should be combined as a single unit of account. When we have a combined unit of account which includes a license and providing research and development services to our collaborator, recognition of up-front payments and development milestones earned from our collaborator is deferred (as a liability) and recognized over the development period (i.e., over time) typically using an input method on the basis of our research and development costs incurred relative to the total expected cost which determines the extent of our progress toward completion (see "Results of Operations - Expenses - Other Operating (Income) Expense" below for further information related to amounts recognized in connection with such estimates). We review our estimates each period and make revisions to such estimates as necessary. Due to the variability in the scope of activities and length of time necessary to develop a drug product, potential delays in development programs, changes to development plans and budgets as programs progress, including if we and our collaborators decide to expand or contract our clinical plans for a drug candidate in various disease indications, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to our estimates are likely to occur periodically, potentially resulting in material changes to amounts recognized.

If our collaborator performs research and development work or commercialization-related activities and the parties share the related costs, we also recognize, as expense (e.g., research and development expense or selling, general and administrative expense, as applicable) in the period when our collaborator incurs such expenses, the portion of the collaborator's expenses that we are obligated to reimburse. Our collaborators provide us with estimated expenses for the most recent fiscal quarter. The estimates are revised, if necessary, in subsequent periods if actual expenses differ from those estimates.

Under certain of the Company's collaboration agreements, product sales and cost of sales may be recorded by the Company's collaborators as they are deemed to be the principal in the transaction. In arrangements where we:

- supply commercial product to our collaborator, we may be reimbursed for our manufacturing costs as commercial product is shipped to the collaborator (however, recognition of such cost reimbursements may be deferred until the product is sold by our collaborator to third-party customers);
- share in any profits or losses arising from the commercialization of such products, we record our share of the variable consideration, representing net product sales less cost of goods sold and shared commercialization and other expenses, in the period in which such underlying sales occur and costs are incurred by the collaborator; and
- receive royalties and/or sales-based milestone payments from our collaborator, we recognize such amounts in the period earned.

Our collaborators provide us with estimates of product sales and our share of profits or losses, as applicable, for each quarter. The estimates are revised, if necessary, in subsequent periods if our actual share of profits or losses differ from those estimates.

Stock-based Compensation

We recognize stock-based compensation expense for equity grants under our long-term incentive plans to employees and non-employee members of our board of directors (as applicable) based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In addition, we reassess our forfeiture rate assumptions at least annually, considering both historical forfeiture experience and an estimate of future forfeitures for currently outstanding unvested awards. The assumptions used in computing the fair value of equity awards reflect our best estimates but involve uncertainties related to market and other conditions, many of which are outside our control. Changes in any of these assumptions may materially affect the fair value of awards granted and the amount of stock-based compensation recognized in future periods.

We use the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for

securities with maturities approximating the options' expected lives. Expected volatility is estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our historical exercise experience with previously issued employee and board of director option grants. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future.

We use a Monte Carlo simulation to compute the estimated fair value of performance-based restricted stock units that are subject to vesting based on the Company's attainment of pre-established performance criteria that include a market condition.

For performance-based restricted stock units that contain a performance condition, we recognize stock-based compensation expense if and when we determine that it is probable the performance condition will be achieved (based on the number of shares expected to be vested and issued). We reassess the probability of achievement at each reporting period and adjust compensation cost, as necessary. If there are any changes in our probability assessment, we recognize a cumulative catch-up adjustment in the period of the change in estimate, with the remaining unrecognized expense recognized prospectively over the remaining requisite service period. If we subsequently determine that the performance criteria are not met or are not expected to be met, any amounts previously recognized as compensation expense are reversed in the period when such determination is made.

See Note 13 to our Consolidated Financial Statements for stock-based compensation expense and related assumptions used in determining the fair value of our awards.

Income Taxes

We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns, including deferred tax assets and liabilities for expected amounts of global intangible low-taxed income ("GILTI") inclusions. Deferred tax assets and liabilities are determined as the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which it is more likely than not that some portion or all of the deferred tax assets will not be realized. We periodically re-assess the need for a valuation allowance against our deferred tax assets based on all available evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, results of recent operations, and our historical earnings experience by taxing jurisdiction. Significant judgment is required in making this assessment.

The Company recognizes the financial statement effects of a tax position when management's assessment is that there is more than a 50% probability that the position will be sustained upon examination by a taxing authority based upon its technical merits. Uncertain tax positions are recorded based upon certain recognition and measurement criteria. Significant judgment is required in making this assessment, and, therefore, we re-evaluate uncertain tax positions and consider various factors, including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, and changes in facts or circumstances related to a tax position. We adjust the amount of the liability to reflect any subsequent changes in the relevant facts and circumstances surrounding the uncertain tax positions.

Inventories

We capitalize inventory costs associated with our products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed. The determination to capitalize inventory costs is based on various factors, including status and expectations of the regulatory approval process, any known safety or efficacy concerns, potential labeling restrictions, and any other impediments to obtaining regulatory approval.

We periodically analyze our inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and write down such inventories as appropriate. In addition, our products are subject to strict quality control and monitoring which we perform throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, we record a charge to write down such inventory to its estimated realizable value.

See "Results of Operations - Expenses - Cost of Goods Sold" below for further information related to our inventory write-offs and reserves.

Intangible Assets

Intangible assets acquired in connection with an asset acquisition are recorded at cost. Intangible assets are amortized over the estimated useful lives of the assets based on the pattern in which the economic benefits of the intangible assets are consumed; if that pattern cannot be reliably determined, a straight-line basis is used. If contingent consideration is recognized subsequent to the acquisition date in an asset acquisition, the amount of such consideration is recorded as an addition to the cost basis of the

intangible asset with a cumulative catch-up adjustment for amortization expense as if the additional amount of consideration had been accrued from the outset of the acquisition.

Our intangible assets are reviewed for recoverability whenever events or changes in circumstances (e.g., changes in economic, regulatory, or legal conditions) indicate that the carrying amount of the asset may not be recoverable. If an indicator of impairment exists, we compare the projected undiscounted cash flows to be generated by the asset to the intangible asset's carrying amount. If the projected undiscounted cash flows of the intangible asset are less than the carrying amount, the intangible asset is written down to its fair value in the period in which the impairment occurs.

As described in Part I, Item 1. "Business - Collaboration, License, and Other Agreements - Sanofi - Immuno-Oncology," effective July 1, 2022, the Company obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide under the A&R IO LCA with Sanofi. The transaction was accounted for as an asset acquisition and amounts paid to Sanofi in connection with obtaining the worldwide rights to Libtayo, including the up-front payment and any contingent consideration, are recorded as an intangible asset. Due to the complexity of the terms of the amendments to the collaboration agreements in contemplation of the acquisition of the worldwide rights to Libtayo, significant judgment was applied in identifying the elements of the transaction and evaluating the timing and recognition of contingent consideration.

See Note 8 to our Consolidated Financial Statements for further information related to our intangible assets.

Contingencies

We accrue, based on management's judgment, for an estimated loss when the potential loss from claims or legal proceedings is considered probable and the amount can be reasonably estimated. As additional information becomes available, or, based on specific events such as the outcome of litigation or settlement of claims, we reassess the potential liability related to pending claims and litigation, and may change our estimates.

Results of Operations

Net Income

	Year Ended December 31,		
(In millions, except per share data)	**2022**	**2021**	**2020**
Revenues	$ 12,172.9	$ 16,071.7	$ 8,497.1
Operating expenses	7,434.0	7,124.9	4,920.5
Income from operations	4,738.9	8,946.8	3,576.6
Other income (expense)	119.9	379.0	233.8
Income before income taxes	4,858.8	9,325.8	3,810.4
Income tax expense	520.4	1,250.5	297.2
Net income	$ 4,338.4	$ 8,075.3	$ 3,513.2
Net income per share - diluted	$ 38.22	$ 71.97	$ 30.52

Revenues

(In millions)	Year Ended December 31, 2022	2021	2020	$ Change 2022 vs. 2021	2021 vs. 2020
Net product sales:					
EYLEA - U.S.	$ 6,264.6	$ 5,792.3	$ 4,947.2	$ 472.3	$ 845.1
Libtayo - U.S.	374.5	306.3	270.7	68.2	35.6
Libtayo - ROW	73.0	—	—	*	*
Praluent - U.S.**	130.0	170.0	150.9	(40.0)	*
REGEN-COV - U.S.	—	5,828.0	185.7	(5,828.0)	5,642.3
Evkeeza - U.S.	48.6	18.4	—	30.2	18.4
Inmazeb - U.S.	3.0	—	—	3.0	—
ARCALYST - U.S.***	—	2.2	13.1	*	*
Total net product sales	$ 6,893.7	$ 12,117.2	$ 5,567.6	$ (5,294.3)	$ 6,541.4
Collaboration revenue:					
Sanofi	$ 2,855.7	$ 1,902.2	$ 1,186.4	$ 953.5	$ 715.8
Bayer	1,430.7	1,409.3	1,186.1	21.4	223.2
Roche	627.3	361.8	—	265.5	361.8
Other	0.4	—	—	0.4	—
Other revenue	365.1	281.2	557.0	83.9	(275.8)
Total revenues	$ 12,172.9	$ 16,071.7	$ 8,497.1	$ (3,969.6)	$ 7,566.4

* Not meaningful

** Net product sales of Praluent in the United States were recorded by Sanofi prior to April 1, 2020.

*** Effective April 1, 2021, Kiniksa records net product sales of ARCALYST in the United States. Previously, the Company recorded net product sales of ARCALYST in the United States.

Net Product Sales

Net product sales of EYLEA in the United States increased in 2022, compared to 2021, due to higher sales volume partly offset by an increase in sales-related deductions.

As described in Part I, Item. 1. "Business - Collaboration, License, and Other Agreements - Sanofi - Immuno-oncology", effective July 1, 2022, the Company became solely responsible for the research, development, and commercialization of Libtayo worldwide and began recording net product sales of Libtayo outside the United States.

During the years ended December 31, 2021 and 2020, we recorded net product sales of REGEN-COV in connection with our agreements with the U.S. government. As of December 31, 2021, the Company had completed its final deliveries of drug product under its agreements with the U.S. government; as a result, there were no net product sales of REGEN-COV in the United States recorded during the year ended December 31, 2022. Refer to Part I, Item 1. "Business - Agreements Related to COVID-19 - *U.S. Government*" for further details.

Revenue from product sales is recorded net of applicable provisions for rebates, chargebacks, and discounts; distribution-related fees; and other sales-related deductions. The following table summarizes the provisions, and credits/payments, for sales-related deductions.

(In millions)	Rebates, Chargebacks, and Discounts	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2019	$ 80.3	$ 46.4	$ 29.4	$ 156.1
Provisions	762.9	279.9	94.1	1,136.9
Credits/payments	(641.0)	(249.1)	(78.7)	(968.8)
Balance as of December 31, 2020	202.2	77.2	44.8	324.2
Provisions	1,047.1	363.6	150.4	1,561.1
Credits/payments	(1,034.7)	(360.8)	(127.6)	(1,523.1)
Balance as of December 31, 2021	214.6	80.0	67.6	362.2
Provisions	1,537.3	431.1	141.1	2,109.5
Credits/payments	(1,398.0)	(399.7)	(127.2)	(1,924.9)
Balance as of December 31, 2022	$ 353.9	$ 111.4	$ 81.5	$ 546.8

Sanofi Collaboration Revenue

	Year Ended December 31,		
(In millions)	2022	2021	2020
Antibody:			
Regeneron's share of profits in connection with commercialization of antibodies	$ 2,082.0	$ 1,363.0	$ 785.2
Sales-based milestones earned	100.0	50.0	50.0
Reimbursement for manufacturing of commercial supplies[(a)]	633.7	488.8	368.0
Other	28.7	—	—
Total Antibody	2,844.4	1,901.8	1,203.2
Total Immuno-oncology	11.3	0.4	(16.8)
Total Sanofi collaboration revenue	$ 2,855.7	$ 1,902.2	$ 1,186.4

[(a)] Corresponding costs incurred by the Company in connection with such production is recorded within Cost of collaboration and contract manufacturing

As the A&R IO LCA became effective July 1, 2022, the three months ended June 30, 2022 was the last period in which Sanofi collaboration revenue was recognized in connection with the immuno-oncology collaborative arrangement.

Antibody

Global net product sales of Dupixent and Kevzara are recorded by Sanofi. The increase in our share of profits in connection with commercialization of antibodies during the year ended December 31, 2022, compared to 2021, was driven by profits associated with higher Dupixent sales, partly offset by the impact of the amendment to the Antibody License and Collaboration Agreement. As described in Part I, Item 1. "Business - Collaboration, License, and Other Agreements - Sanofi - Antibody", on July 1, 2022, an amendment to the Antibody License and Collaboration Agreement became effective, pursuant to which the percentage of Regeneron's share of profits in any calendar quarter used to reimburse Sanofi for development costs which were funded by Sanofi increased from 10% to 20%. In addition, the amount of our share of profits we earned in connection with commercialization of antibodies outside the United States was adversely impacted in 2022 by the U.S. dollar strengthening against foreign currencies, including the Japanese yen and the euro.

Regeneron's share of profits in connection with the commercialization of Dupixent, Praluent (through March 31, 2020), and Kevzara is summarized below:

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**2020**
Dupixent, Praluent, and Kevzara net product sales[(a)]	$ 9,039.2	$ 6,536.3	$ 4,394.5
Regeneron's share of collaboration profits	2,405.5	1,511.5	871.5
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation	(266.6)	(148.5)	(86.3)
One-time payment in connection with amendment to the Antibody License and Collaboration Agreement	(56.9)	—	—
Regeneron's share of profits in connection with commercialization of antibodies	$ 2,082.0	$ 1,363.0	$ 785.2
Regeneron's share of collaboration profits as a percentage of Dupixent, Praluent, and Kevzara net product sales	23%	21%	18%

[(a)] Global net product sales of Dupixent and Kevzara are recorded by Sanofi. The quarter ended March 31, 2020 was the last quarter for which Sanofi and the Company shared profits and losses in connection with Sanofi's global net sales and the related commercialization of Praluent (see further details below); therefore, the quarter ended March 31, 2020 was the last quarter for which net product sales of Praluent were included in the table above.

As described in Part I, Item 1. "Business - Collaboration, License, and Other Agreements - Sanofi - Antibody", effective April 1, 2020, the Company became solely responsible for the development and commercialization of Praluent in the United States. Under the new agreement, Sanofi is solely responsible for the development and commercialization of Praluent outside of the United States, and pays the Company a 5% royalty on Sanofi's net product sales of Praluent outside the United States.

During the year ended December 31, 2022, we earned two $50.0 million sales-based milestones from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding $2.0 billion and $2.5 billion, respectively, on a rolling twelve-month basis. During the year ended December 31, 2021, we earned a $50.0 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding $1.5 billion on a rolling twelve-month basis. We are entitled to receive the final sales milestone payment of $50.0 million that would be earned when such sales outside the United States exceed $3.0 billion on a rolling twelve-month basis.

The increase in reimbursements for manufacturing of commercial supplies in 2022, compared to 2021, was primarily due to higher Dupixent sales, as revenue for such cost reimbursements is recognized when the product is sold by Sanofi to third-party customers.

Bayer Collaboration Revenue

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**2020**
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	$ 1,317.4	$ 1,349.2	$ 1,107.9
Reimbursement for manufacturing of ex-U.S. commercial supplies[(a)]	91.4	60.1	78.2
One-time payment in connection with change in Japan arrangement	21.9	—	—
Total Bayer collaboration revenue	$ 1,430.7	$ 1,409.3	$ 1,186.1

[(a)] Corresponding costs incurred by the Company in connection with such production is recorded within Cost of collaboration and contract manufacturing

Bayer records net product sales of EYLEA outside the United States. The amount of the share of profits we earned in connection with commercialization of EYLEA outside the United States was adversely impacted in 2022 by the U.S. dollar strengthening against foreign currencies, including the Japanese yen and the euro.

Regeneron's share of profits in connection with commercialization of EYLEA outside the United States is summarized below:

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**2020**
EYLEA net product sales outside the United States	$ 3,382.8	$ 3,450.9*	$ 2,820.7*
Regeneron's share of collaboration profit from sales outside the United States	$ 1,375.1	$ 1,408.3	$ 1,165.8
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation	(57.7)	(59.1)	(57.9)
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	$ 1,317.4	$ 1,349.2	$ 1,107.9
Regeneron's share of profits as a percentage of EYLEA net product sales outside the United States	39%	39%	39%

* Effective January 1, 2022, the Company and Bayer commenced sharing equally in profits and losses based on sales from Bayer to its distributor in Japan. Previously, the Company received from Bayer a tiered percentage of sales based on sales by Bayer's distributor in Japan. Consequently, the prior year net product sales amount has been revised for comparability purposes.

Roche Collaboration Revenue

As described in Part I, Item 1. "Business - Agreements Related to COVID-19 - Roche", Roche distributes and records net product sales of Ronapreve outside the United States, and the parties share gross profits from worldwide sales of REGEN-COV and Ronapreve, depending on the amount of manufactured product supplied by each party to the market. Each quarter, a single payment is due from one party to the other to true-up the global gross profits between the parties. If Regeneron is to receive a true-up payment from Roche, such amount will be recorded to collaboration revenue. If Regeneron is to make a true-up payment to Roche, such amount will be recorded to Cost of goods sold.

During the years ended December 31, 2022 and 2021, the Company recognized $627.3 million and $361.8 million, respectively, of global gross profit payments from Roche within collaboration revenue.

Other Revenue

Other revenue increased in 2022, compared to 2021, primarily due to higher reimbursements for the manufacture of commercial supplies for Sanofi related to Praluent outside the United States.

Expenses

	Year Ended December 31,			Change	
(In millions, except headcount data)	**2022**	**2021**	**2020**	**2022 vs. 2021**	**2021 vs. 2020**
Research and development[(a)]	$ 3,592.5	$ 2,860.1	$ 2,647.0	$ 732.4	$ 213.1
Acquired in-process research and development	255.1	48.0	88.0	207.1	(40.0)
Selling, general, and administrative[(a)]	2,115.9	1,824.9	1,346.0	291.0	478.9
Cost of goods sold	800.0	1,773.1	491.9	(973.1)	1,281.2
Cost of collaboration and contract manufacturing[(b)]	760.4	664.4	628.0	96.0	36.4
Other operating (income) expense, net	(89.9)	(45.6)	(280.4)	(44.3)	234.8
Total operating expenses	$ 7,434.0	$ 7,124.9	$ 4,920.5	$ 309.1	$ 2,204.4
Average headcount	11,115	9,884	8,495	1,231	1,389

(a) Includes costs incurred net of any cost reimbursements from collaborators who are not deemed to be our customers

(b) Cost of collaboration and contract manufacturing includes costs we incur in connection with producing commercial drug supplies for collaborators and others.

Operating expenses in 2022, 2021, and 2020 included a total of $725.0 million, $601.7 million, and $432.0 million, respectively, of stock-based compensation expense related to equity awards granted under our long-term incentive plans. As of December 31, 2022, unrecognized stock-based compensation expense related to unvested stock options and unvested restricted stock (including performance-based restricted stock units) was $572.0 million and $1.064 billion, respectively. We expect to recognize this stock-based compensation expense related to stock options and restricted stock over weighted-average periods of 1.8 years and 2.6 years, respectively.

Research and Development Expenses

The following table summarizes our estimates of direct research and development expenses by clinical development program and other significant categories of research and development expenses. Direct research and development expenses are comprised primarily of costs paid to third parties for clinical and product development activities, including costs related to preclinical research activities, clinical trials, and the portion of research and development expenses incurred by our collaborators that we are obligated to reimburse. Indirect research and development expenses have not been allocated directly to each program, and primarily consist of costs to compensate personnel, overhead and infrastructure costs to maintain our facilities, and other costs related to activities that benefit multiple projects. Clinical manufacturing costs primarily consist of costs to manufacture bulk drug product for clinical development purposes as well as related external drug filling, packaging, and labeling costs. Clinical manufacturing costs also includes pre-launch commercial supplies which did not meet the criteria to be capitalized as inventory (see "Critical Accounting Policies and Use of Estimates - Inventories" above). The table below also includes reimbursements of research and development expenses by collaborators, as when we are entitled to reimbursement of all or a portion of such expenses that we incur under a collaboration, we record those reimbursable amounts in the period in which such costs are incurred.

	Year Ended December 31,			$ Change	
(In millions)	**2022**	**2021***	**2020***	**2022 vs. 2021**	**2021 vs. 2020**
Direct research and development expenses:					
Dupixent (dupilumab)	$ 156.5	$ 146.4	$ 129.7	$ 10.1	$ 16.7
Libtayo (cemiplimab)	138.0	146.2	155.3	(8.2)	(9.1)
EYLEA and aflibercept 8 mg	81.2	102.2	72.2	(21.0)	30.0
Pozelimab	72.4	28.3	16.0	44.1	12.3
Odronextamab	66.0	34.9	35.0	31.1	(0.1)
Linvoseltamab	45.5	18.7	11.4	26.8	7.3
Fianlimab	43.4	8.7	9.1	34.7	(0.4)
REGEN-COV	32.8	309.8	290.7	(277.0)	19.1
Other product candidates in clinical development and other research programs	407.1	401.0	587.8	6.1	(186.8)
Total direct research and development expenses	1,042.9	1,196.2	1,307.2	(153.3)	(111.0)
Indirect research and development expenses:					
Payroll and benefits	1,195.5	981.4	816.6	214.1	164.8
Lab supplies and other research and development costs	181.0	142.0	138.3	39.0	3.7
Occupancy and other operating costs	508.5	414.9	335.7	93.6	79.2
Total indirect research and development expenses	1,885.0	1,538.3	1,290.6	346.7	247.7
Clinical manufacturing costs	938.3	621.7	686.1	316.6	(64.4)
Reimbursement of research and development expenses by collaborators	(273.7)	(496.1)	(636.9)	222.4	140.8
Total research and development expenses	$ 3,592.5	$ 2,860.1	$ 2,647.0	$ 732.4	$ 213.1

* Certain prior year amounts have been reclassified to conform to the current year's presentation

Total research and development expenses increased in 2022, compared to 2021, partially due to the impact of the amendments to the Sanofi collaboration agreements described above in Part I, Item 1. "Business - Collaboration, License, and Other Agreements - Sanofi," as (i) Sanofi is no longer reimbursing us for 50% of Libtayo development costs, and (ii) effective July 1, 2022, we recognize our 50% share of research and development expenses in connection with the Sanofi Antibody Collaboration.

Research and development expenses included stock-based compensation expense of $406.8 million and $316.6 million in 2022 and 2021, respectively.

Reimbursement of research and development expenses by collaborators included reimbursements from Roche related to REGEN-COV of $128.1 million for the year ended December 31, 2021. For the year ended December 31, 2022, such reimbursements from Roche related to REGEN-COV were not material.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Part I, Item 1A. "Risk Factors". There is also variability in the duration and costs necessary to develop a pharmaceutical product, potential opportunities and/or uncertainties related to future indications to be studied, and the estimated cost and scope of the projects. The lengthy process of seeking FDA and other applicable approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business. We are unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows.

Acquired In-process Research and Development ("IPR&D")

Acquired IPR&D in 2022 included a $195.0 million charge related to our acquisition of Checkmate, a $30.0 million up-front payment in connection with our collaboration agreement with CytomX Therapeutics, Inc., and a $20.0 million opt-in payment in connection with a product candidate under our collaboration agreement with Adicet Bio, Inc. Acquired IPR&D in 2021 included $34.0 million in aggregate up-front payments in connection with our collaboration agreement with Nykode Therapeutics and in 2020 included $85.0 million in aggregate up-front payments in connection with our collaboration agreement with Intellia.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased in 2022, compared to 2021, primarily due to higher headcount and headcount-related costs, an increase in commercialization-related expenses for Libtayo (as effective July 1, 2022, the Company became solely responsible for the commercialization of Libtayo worldwide), and higher contributions to an independent not-for-profit patient assistance organization, partly offset by costs in 2021 for educational campaigns related to COVID-19 that did not recur during 2022. Selling, general, and administrative expenses also included $256.4 million and $213.3 million of stock-based compensation expense in 2022 and 2021, respectively.

Cost of Goods Sold

Cost of goods sold decreased in 2022, compared to 2021, primarily due to the Company recognizing REGEN-COV net product sales (and corresponding cost of goods sold) in the United States during 2021 and a 2021 payment of $259.6 million owed in connection with global gross profits under our Roche collaboration agreement; such transactions did not recur in 2022. Cost of goods sold also decreased during 2022 since effective July 1, 2022, as a result of the A&R IO LCA described in Part I, Item 1. "Business - Collaboration, License, and Other Agreements - Sanofi - Immuno-Oncology", we are no longer obligated to pay Sanofi for their share of Libtayo U.S. gross profits (during the six months ended June 30, 2022, Cost of goods sold included $70.1 million related to our obligation for Sanofi's share of Libtayo U.S. gross profits compared to $133.0 million for full year 2021).

Cost of goods sold in 2022 also decreased, compared to 2021, due to lower inventory write-offs and reserves. Inventory write-offs and reserves were $258.7 million in 2022 (including $157.4 million in the fourth quarter of 2022) compared to $457.1 million in 2021 (including $269.2 million in the fourth quarter of 2021). These inventory write-offs and reserves were primarily related to REGEN-COV. Refer to Part I, Item 1. "Business - Additional Information - Clinical Development Programs - REGEN-COV (casirivimab and imdevimab)" for further information related to regulatory developments for REGEN-COV which negatively impacted the estimated realizable value of inventory on hand.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing increased in 2022, compared to 2021, primarily due to the recognition of costs in connection with manufacturing additional commercial supplies for Sanofi related to Praluent outside the United States and Dupixent, and manufacturing costs associated with EYLEA outside the United States.

Other Operating (Income) Expense

Other operating (income) expense, net, includes recognition of a portion of amounts previously deferred in connection with up-front and development milestone payments, as applicable, received in connection with Sanofi IO, Teva, and MTPC collaborative arrangements.

During 2022, the Company discontinued further clinical development of fasinumab, and, as a result, recorded $44.4 million (as an increase to other operating income) related to our Teva and MTPC collaborative arrangements as we deemed our obligation to provide development services in connection with these collaborative arrangements to be complete.

As the A&R IO LCA became effective July 1, 2022, the three months ended June 30, 2022 was the last period in which such amounts were recognized in connection with our Sanofi immuno-oncology collaborative arrangement. During 2021, we updated our estimate of the total research and development costs expected to be incurred (which resulted in a change to the estimate of the stage of completion) in connection with the Sanofi IO Collaboration, and, as a result, recorded a cumulative catch-up adjustment of $66.9 million as a reduction to other operating income.

Other Income (Expense)

Other income (expense) consists of the following:

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**2020**
Unrealized (losses) gains on equity securities, net	$ (39.8)	$ 386.1	$ 196.0
Interest income	160.1	45.8	75.4
Other	59.0	4.4	19.3
Other income (expense), net	179.3	436.3	290.7
Interest expense	(59.4)	(57.3)	(56.9)
Total other income (expense)	$ 119.9	$ 379.0	$ 233.8

Income Taxes

	Year Ended December 31,		
(In millions, except effective tax rate)	**2022**	**2021**	**2020**
Income tax expense	$ 520.4	$ 1,250.5	$ 297.2
Effective tax rate	10.7%	13.4%	7.8%

The effective tax rate for 2022, compared to 2021, included a favorable benefit from the proportion of income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate (including the impact from REGEN-COV income earned in the United States during 2021).

Liquidity and Capital Resources

Our financial condition is summarized as follows:

	As of December 31,		
(In millions)	**2022**	**2021**	**$ Change**
Financial assets:			
Cash and cash equivalents	$ 3,105.9	$ 2,885.6	$ 220.3
Marketable securities - current	4,636.4	2,809.1	1,827.3
Marketable securities - noncurrent	6,591.8	6,838.0	(246.2)
	$ 14,334.1	$ 12,532.7	$ 1,801.4
Working capital:			
Current assets	$ 15,884.1	$ 14,014.9	$ 1,869.2
Current liabilities	3,141.3	3,932.5 *	(791.2)
	$ 12,742.8	$ 10,082.4	$ 2,660.4
Borrowings and finance lease liabilities:			
Long-term debt	$ 1,981.4	$ 1,980.0	$ 1.4
Finance lease liabilities	$ 720.0	$ 719.7 *	$ 0.3

* The $719.7 million related to finance lease liabilities was classified within current liabilities as of December 31, 2021. See "Tarrytown, New York Leases" section below for details.

As of December 31, 2022, we also had borrowing availability of $750.0 million under a revolving credit facility (see further description under "*Credit Facility*" below).

Sources and Uses of Cash for the Years Ended December 31, 2022, 2021, and 2020

	As of December 31,			$ Change	
(In millions)	**2022**	**2021**	**2020**	**2022 vs. 2021**	**2021 vs. 2020**
Cash flows provided by operating activities	$ 5,014.9	$ 7,081.3	$ 2,618.1	$ (2,066.4)	$ 4,463.2
Cash flows used in investing activities	$ (3,784.6)	$ (5,384.7)	$ (70.6)	$ 1,600.1	$ (5,314.1)
Cash flows used in financing activities	$ (1,009.0)	$ (1,005.8)	$ (1,970.5)	$ (3.2)	$ 964.7

Cash Flows from Operating Activities

2022

As of December 31, 2022, Accounts receivable had decreased by $707.8 million, compared to December 31, 2021, driven by the Company's collection of amounts due from the U.S. government in connection with REGEN-COV sales in the fourth quarter of 2021. Other non-cash items, net, in 2022 included inventory write-offs and reserves. As of December 31, 2022, deferred tax assets increased by $746.4 million, compared to December 31, 2021, primarily related to the impact of the Tax Cuts and Jobs Act of 2017, which requires, for tax purposes, the capitalization and amortization of research and development expenses effective for years beginning after December 31, 2021.

2021

As of December 31, 2021, Accounts receivable had increased by $1.927 billion, compared to December 31, 2020, primarily due to REGEN-COV sales in connection with our September 2021 agreement to supply drug product to the U.S. government. Other non-cash items, net, in 2021 included inventory write-offs and reserves. Accounts payable, accrued expenses, and other liabilities as of December 31, 2021 included a $259.6 million fourth quarter 2021 payment owed in connection with global gross profits under our Roche collaboration agreement.

2020

As of December 31, 2020, Accounts receivable had increased by $1.356 billion, compared to December 31, 2019, partly as a result of extending payment terms to EYLEA customers due to the COVID-19 pandemic. Inventories increased as of December 31, 2020, compared to December 31, 2019, partially as a result of purchasing additional raw materials in anticipation of potential disruptions to our supply chain due to the COVID-19 pandemic.

Cash Flows from Investing Activities

Capital expenditures in 2022 included costs associated with the expansion of our manufacturing facilities in Rensselaer, New York (including the ongoing construction of a fill/finish facility and related equipment) and Limerick, Ireland, as well as costs incurred in connection with the expansion of the Tarrytown, New York campus. We expect to incur capital expenditures of $825 million to $950 million in 2023 primarily in connection with the continued expansion of our research, preclinical manufacturing, and support facilities at our Tarrytown, New York campus and our manufacturing facilities (including the fill/finish facility). We expect continued significant capital expenditures over the next several years in connection with the planned expansion of our Tarrytown, New York campus.

Payments for Libtayo intangible asset of $1.027 billion in 2022 were related to our acquisition of the exclusive right to develop, commercialize, and manufacture Libtayo worldwide.

Asset acquisition, net of cash acquired, of $230.3 million in 2022 was related to our acquisition of Checkmate.

Cash Flows from Financing Activities

Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were $1.520 billion during 2022, compared to $1.672 billion during 2021 and $2.575 billion during 2020. For additional information related to cash flows from financing activities, see "Share Repurchase Programs", "Sanofi Funding of Certain Development Costs", "Secondary Offering and Purchase of Regeneron Common Stock Held by Sanofi", and "Issuance of Senior Notes" sections below.

Credit Facility

In December 2018, we entered into an agreement with a syndicate of lenders (the "2018 Credit Agreement") which provided for a $750.0 million senior unsecured five-year revolving credit facility. The 2018 Credit Agreement, which was set to mature in December 2023, included an option for us to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to $250.0 million, subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions.

In December 2022, we entered into an agreement with a syndicate of lenders (the "2022 Credit Agreement") which provides for a $750.0 million senior unsecured five-year revolving credit facility (the "2022 Credit Facility") and replaces the 2018 Credit Agreement, which was contemporaneously terminated. The 2022 Credit Agreement includes an option for the Company to elect to increase the commitments under the 2022 Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to $500.0 million, subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. The 2022 Credit Agreement also provides a $50.0 million sublimit for letters of credit. As set forth in the 2022 Credit Agreement, we have the option to amend the 2022 Credit Agreement to establish environmental, social, and governance targets which will be used to adjust pricing under the 2022 Credit Facility, subject to parameters to be provided in the 2022 Credit Agreement.

Proceeds of the loans under the 2022 Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. Regeneron Pharmaceuticals, Inc. has guaranteed all obligations under the 2022 Credit Facility. The 2022 Credit Agreement includes an option for us to elect to extend the maturity date of the 2022 Credit Facility beyond December 2027, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the 2022 Credit Facility may be prepaid, and the commitments under the 2022 Credit Facility may be terminated, at any time without premium or penalty.

We had no borrowings outstanding under the 2022 Credit Facility as of December 31, 2022.

The 2022 Credit Agreement contains operating covenants and a maximum total leverage ratio financial covenant. We were in compliance with all covenants of the 2022 Credit Agreement as of December 31, 2022.

Share Repurchase Programs

In November 2019, our board of directors authorized a share repurchase program to repurchase up to $1.0 billion of our Common Stock. The share repurchase program permitted the Company to make repurchases through a variety of methods, including open-

market transactions (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, accelerated share repurchases, block trades, and other transactions in compliance with Rule 10b-18 of the Exchange Act. As of December 31, 2020, the Company had repurchased the entire $1.0 billion of its Common Stock that it was authorized to repurchase under the program.

In January 2021, our board of directors authorized a share repurchase program to repurchase up to $1.5 billion of our Common Stock. The share repurchase program was approved under terms substantially similar to the November 2019 share repurchase program. As of December 31, 2021, the Company had repurchased the entire $1.5 billion of its Common Stock that it was authorized to repurchase under the program.

In November 2021, our board of directors authorized a share repurchase program to repurchase up to $3.0 billion of our Common Stock. The share repurchase program was approved under terms substantially similar to the share repurchase programs described above. The program has no time limit and can be discontinued at any time. As of December 31, 2022, $745.2 million remained available for share repurchases under the November 2021 program.

The table below summarizes the shares of our Common Stock we repurchased under the programs described above and the cost of the shares, which were recorded as Treasury Stock.

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**2020**
Number of shares	3.3	3.0	1.6
Total cost of shares	$ 2,099.8	$ 1,655.0	$ 746.0

In January 2023, our board of directors authorized a new share repurchase program to repurchase up to an additional $3.0 billion of our Common Stock. The share repurchase program was approved under terms substantially similar to the share repurchase programs described above. The program has no time limit and can be discontinued at any time.

Share repurchases may be made from time to time at management's discretion, and the timing and amount of any such repurchases will be determined based on share price, market conditions, legal requirements, and other relevant factors. There can be no assurance as to the timing or number of shares of any repurchases in the future.

Sanofi Funding of Certain Development Costs

Pursuant to a 2018 agreement, we agreed to allow Sanofi to satisfy in whole or in part its funding obligations with respect to Libtayo development and/or certain activities relating to dupilumab and itepekimab incurred in periods through September 30, 2020 by selling shares of our Common Stock owned by Sanofi. During 2020, Sanofi elected to sell, and we elected to purchase, shares of our Common Stock to satisfy Sanofi's funding obligation related to such activities. Consequently, we recorded the cost of the shares received, or $135.0 million, as Treasury Stock during 2020.

Secondary Offering and Purchase of Regeneron Common Stock Held by Sanofi

In May 2020, a secondary offering of 13,014,646 shares of our Common Stock (the "Secondary Offering") held by Sanofi was completed. In connection with the Secondary Offering, we also purchased 9,806,805 shares of our Common Stock directly from Sanofi for an aggregate purchase amount of $5.0 billion (the "Stock Purchase").

We funded the Stock Purchase with a combination of cash on hand, proceeds from the sale of marketable securities, and proceeds from loans under a $1.5 billion senior unsecured bridge loan facility (the "Bridge Facility") which was entered into in May 2020. The Bridge Facility was repaid in August 2020 following the issuance and sale of the Company's senior unsecured notes (as described below).

Issuance of Senior Notes

In August 2020, we issued and sold $1.250 billion aggregate principal amount of senior unsecured notes due 2030 (the "2030 Notes") and $750 million aggregate principal amount of senior unsecured notes due 2050 (the "2050 Notes" and, together with the 2030 Notes, the "Notes"). Net proceeds from the issuance and sale of the Notes (after deducting underwriting discounts and offering expenses) were used in part to repay in full the Bridge Facility described above, including accrued interest and related fees and expenses in connection therewith.

The 2030 Notes accrue interest at the rate of 1.750% per year and will mature on September 15, 2030. The 2050 Notes accrue interest at the rate of 2.800% per year and will mature on September 15, 2050. Interest on each series of Notes is payable semi-annually in arrears on March 15 and September 15 of each year until their respective maturity dates.

The Notes may be redeemed at the Company's option at any time at 100% of the principal amount plus accrued and unpaid interest, and, until a specified period before maturity, a specified make-whole amount. The Notes contain a change-of-control provision that, under certain circumstances, may require the Company to offer to repurchase the Notes at a price equal to 101% of the principal amount plus accrued and unpaid interest.

The Notes also contain certain limitations on the Company's ability to incur liens and enter into sale and leaseback transactions, as well as customary events of default.

Tarrytown, New York Leases

We lease laboratory and office facilities in Tarrytown, New York (the "Facility"). In 2016, we entered into a Purchase Agreement with the then lessor, pursuant to which we agreed to purchase the Facility for a purchase price of $720.0 million. In March 2017, we entered into a Participation Agreement with BA Leasing BSC, LCC, an affiliate of Banc of America Leasing & Capital, LLC ("BAL"), as lessor, and a syndicate of lenders (collectively with BAL, the "Lease Participants"), which provided for lease financing in connection with the acquisition by BAL of the Facility and our lease of the Facility from BAL. In March 2017, we assigned our right to take title to the Facility under the Purchase Agreement to BAL, and the Lease Participants advanced $720.0 million, which was used by BAL to finance the purchase price for the Facility. Concurrent with entering into the Participation Agreement, we also entered into a lease agreement for the Facility with BAL for a five-year term that was set to expire in March 2022.

In March 2022, we entered into a Second Amended and Restated Lease and Remedies Agreement (the "Restated Lease") with BAL, as lessor (the "Lessor"), which amends, restates, and extends our lease of the Facility. In March 2022, we also entered into a Second Amended and Restated Participation Agreement (the "Restated Participation Agreement") with Bank of America, N.A., as administrative agent, the Lessor, and a syndicate of financial institutions as rent assignees (collectively with the Lessor, the "Participants"), which amends and restates the original Participation Agreement entered into in March 2017.

The original Participation Agreement and certain related agreements were amended and restated in order to, among other things, (i) effect a five-year extension of the original March 2022 maturity date of the $720.0 million lease financing and the end of the term of our lease of the Facility from the Lessor to March 2027, at which time all amounts outstanding thereunder will become due and payable in full, and (ii) modify the rate of the interest or yield that is payable to the Participants. In accordance with the terms of the Restated Lease, we continue to pay all maintenance, insurance, taxes, and other costs arising out of the use of the Facility. We are also required to make monthly payments of basic rent during the term of the Restated Lease in an amount equal to a variable rate per annum, which was modified in connection with the Restated Lease, to be an adjusted one-month forward-looking term rate based on the Secured Overnight Financing Rate ("SOFR"), plus an applicable margin that varies with our debt rating and total leverage ratio.

The Restated Participation Agreement and Restated Lease include an option for us to elect to further extend the maturity date of the Restated Participation Agreement and the term of the Restated Lease for an additional five-year period, subject to the consent of all the Participants and certain other conditions. We also have the option prior to the end of the term of the Restated Lease to (a) purchase the Facility by paying an amount equal to the outstanding principal amount of the Participants' advances under the Restated Participation Agreement, all accrued and unpaid yield thereon, and all other outstanding amounts under the Restated Participation Agreement, Restated Lease, and certain related documents or (b) sell the Facility to a third party on behalf of the Lessor.

The Restated Lease is classified as a finance lease as we have the option to purchase the Facility under terms that make it reasonably certain to be exercised. The agreements governing the Restated Lease financing contain financial and operating covenants. Such financial covenants and certain of the operating covenants are substantially similar to the covenants set forth in our 2018 Credit Agreement. The Company was in compliance with all such covenants as of December 31, 2022.

Additional Funding Requirements

The amount required to fund operations will depend on various factors, including the potential regulatory approval and commercialization of our product candidates and the timing thereof and the extent and cost of our research and development programs. We believe that our existing capital resources, borrowing availability under the 2022 Credit Facility, funds generated by anticipated product sales, and funding for reimbursement of research and development costs that we are entitled to receive under our collaboration agreements, will enable us to meet our anticipated operating needs for the foreseeable future.

We expect continued increases in our expenditures, particularly in connection with our research and development activities (including preclinical and clinical programs). The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of

each trial, including the size of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and other expenses.

We also anticipate continuing to incur substantial commercialization costs for our marketed products. Commercialization costs over the next few years will depend on, among other things, the market potential for product candidates, whether commercialization costs are shared with a collaborator, and regulatory approval of additional product candidates.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will be substantial.

Liabilities for unrecognized tax benefits totaled $542.8 million as of December 31, 2022. Due to their nature, there is a high degree of uncertainty regarding the period and amounts of potential future cash settlement with tax authorities. See Note 15 to our Consolidated Financial Statements.

We enter into collaboration and licensing agreements that may require us to pay (i) amounts contingent upon the occurrence of various future events (e.g., upon the achievement of various development and commercial milestones), which, in the aggregate, could be significant, and/or (ii) royalties calculated based on a percentage of net product sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurring and for which the specific timing cannot be predicted. See Note 3 and Note 11 to our Consolidated Financial Statements.

Under our collaboration with Bayer for EYLEA outside the United States and our Antibody Collaboration with Sanofi, we and our collaborator share profits and losses in connection with commercialization of drug products. If the applicable collaboration is profitable, we have contingent contractual obligations to reimburse Bayer and Sanofi for a defined percentage (generally 50%) of agreed-upon development expenses funded by Bayer and Sanofi (i.e., "development balance"). These reimbursements are deducted each quarter, in accordance with a formula, from our share of the collaboration profits otherwise payable to us, unless, in the case of EYLEA, we elect to reimburse these expenses at a faster rate. As of December 31, 2022, our contingent reimbursement obligation to Bayer for EYLEA was approximately $273 million and our contingent reimbursement obligation to Sanofi in connection with the companies' Antibody Collaboration was approximately $2.864 billion. Therefore, we expect that, for the foreseeable future, a portion of our share of profits from sales under our collaborations with Bayer and Sanofi will be used to reimburse our collaborators for these obligations.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that are currently material or reasonably likely to be material to our consolidated financial position or results of operations.

Future Impact of Recently Issued Accounting Standards

As of December 31, 2022, the future adoption of recently issued accounting standards is not expected to have a material impact on the Company's financial position or results of operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our investments in marketable securities, which consist primarily of corporate bonds and U.S. treasury securities. We do not believe we are materially exposed to changes in interest rates related to our investments, and we do not currently use interest rate derivative instruments to manage exposure to interest rate changes of our investments. We estimate that a 100 basis point, or 1%, unfavorable change in interest rates would have resulted in approximately a $102.7 million and $120.0 million decrease in the fair value of our investment portfolio as of December 31, 2022 and 2021, respectively.

We have exposure to market risk for changes in interest rates, including the interest rate risk relating to our variable rate Tarrytown, New York lease (as described in Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - *Tarrytown, New York Leases*"). Our interest rate exposure is primarily offset by our investments in marketable securities. We continue to monitor our interest rate risk and may utilize derivative instruments and/or other strategies in the future to further mitigate our interest rate exposure.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. In 2022, 2021, and 2020, we did not record any charges for credit-related impairments of our available-for-sale debt securities.

We are subject to credit risk associated with the receivables due from our collaborators, including Bayer and Sanofi. We are also subject to credit risk in connection with trade accounts receivable due from our customers from our product sales. We have contractual payment terms with each of our collaborators and customers. We also monitor financial performance and credit worthiness so that we can properly assess and respond to any changes in collaborator and/or customer credit profiles. In 2022, 2021 and 2020, we did not recognize any charges for write-offs and allowances of accounts receivable related to credit risk for our collaborators or customers. As of December 31, 2022, two customers accounted on a combined basis for 86% of our net trade accounts receivables.

Foreign Exchange Risk

As discussed further above, our collaborators market certain products outside the United States, and we share in profits and losses with these collaborators from commercialization of products. In addition, pursuant to the applicable terms of the agreements with our collaborators, we also share in certain worldwide development expenses incurred by our collaborators.

We also incur worldwide development expenses for clinical products we are developing independently, incur expenses outside of the United States in connection with our international operations, and, effective July 1, 2022, market Libtayo outside of the United States as a result of obtaining worldwide rights to Libtayo under an A&R IO LCA with Sanofi.

Therefore, significant changes in foreign exchange rates of the countries outside the United States where our products are sold, where development expenses are incurred by us or our collaborators, or where we incur operating expenses can impact our operating results and financial condition. As sales outside the United States continue to grow, and as we expand our international operations, we will continue to assess potential steps, including foreign currency hedging and other strategies, to mitigate our foreign exchange risk.

Market Price Risk

We are exposed to price risk on equity securities included in our investment portfolio. Our marketable securities include equity investments in publicly traded stock of companies, including common stock of companies with which we have entered into collaboration arrangements. Changes in the fair value of our equity investments are included in Other income (expense), net on the Consolidated Statements of Income. We recorded $39.8 million of net unrealized losses and $386.1 million of net unrealized gains on equity securities in Other income (expense), net in 2022 and 2021, respectively.

Item 8. Financial Statements and Supplementary Data

The information required by this Item is set forth beginning on page F-1 of this report and is incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our principal executive officer and principal financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosures.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) or 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022 using the framework in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2022. The effectiveness of the Company's internal control over financial reporting as of December 31, 2022 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears under Part IV, Item 15.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) or 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item (other than the information set forth in the next paragraph in this Item 10) will be included in our definitive proxy statement with respect to our 2023 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to our officers, directors, and employees. The full text of our code of business conduct and ethics can be found on our website (http://www.regeneron.com) under the "Governance" heading on the "Investors & Media" page. We may satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or a waiver from, a provision of our code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer, or controller, or persons performing similar functions, by posting such information on our website where it is accessible through the same link noted above.

Item 11. Executive Compensation

The information called for by this item will be included in our definitive proxy statement with respect to our 2023 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information called for by this item will be included in our definitive proxy statement with respect to our 2023 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information called for by this item will be included in our definitive proxy statement with respect to our 2023 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information called for by this item will be included in our definitive proxy statement with respect to our 2023 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) 1. Financial Statements

The consolidated financial statements filed as part of this report are listed on the Index to Financial Statements on page F-1.

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and, therefore, have been omitted.

3. Exhibits

Exhibit Number	Description
3.1	Restated Certificate of Incorporation, as amended. (Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. (the "Registrant"), for the quarter ended June 30, 2015, filed August 4, 2015.)
3.2	Amended and Restated By-Laws. (Incorporated by reference from the Form 8-K for the Registrant filed December 21, 2016.)
4.1	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2019, filed February 7, 2020.)
4.2	Indenture, dated August 12, 2020, between the Registrant and U.S. Bank National Association. (Incorporated by reference from the Form 8-K for the Registrant, filed August 12, 2020.)
4.3	First Supplemental Indenture, dated August 12, 2020, between the Registrant and U.S. Bank National Association. (Incorporated by reference from the Form 8-K for the Registrant, filed August 12, 2020.)
4.4	Form of 1.750% Senior Note due 2030 (included in Exhibit 4.3).
4.5	Form of 2.800% Senior Note due 2050 (included in Exhibit 4.3).
10.1 +	Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan. (Incorporated by reference from the Registration Statement on Form S-8 for the Registrant, filed June 13, 2011.)
10.1.1 +	Form of option agreement and related notice of grant for use in connection with the grant of time based vesting stock options to the Registrant's non-employee directors and executive officers under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2009, filed April 30, 2009.)
10.1.2 +	Form of option agreement and related notice of grant for use in connection with the grant of time based vesting stock options to the Registrant's non-employee directors under the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan (revised). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2011, filed February 21, 2012.)
10.1.3 +	Amendment No. 1 to the Regeneron Pharmaceuticals, Inc. Second Amended and Restated 2000 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2013, filed February 13, 2014.)
10.2 +	Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Registration Statement on Form S-8 for the Registrant, filed June 12, 2017.)
10.2.1 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed June 18, 2014.)
10.2.2 +	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed June 18, 2014.)

10.2.3 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's non-employee directors under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed June 18, 2014.)
10.2.4 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to P. Roy Vagelos, M.D. under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2015, filed February 11, 2016.)
10.2.5 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised). (Incorporated by reference from the Form 8-K for the Registrant, filed November 19, 2015.)
10.2.6 +	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised). (Incorporated by reference from the Form 8-K for the Registrant, filed November 19, 2015.)
10.2.7 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's non-employee directors under the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2015, filed February 11, 2016.)
10.2.8 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's executive officers under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2017, filed February 8, 2018.)
10.2.9 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to P. Roy Vagelos, M.D. under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2017, filed February 8, 2018.)
10.2.10 +	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2017, filed February 8, 2018.)
10.2.11 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's non-employee directors under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2017, filed February 8, 2018.)
10.2.12 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's executive officers under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised 2018). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2018, filed February 7, 2019.)
10.2.13 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to P. Roy Vagelos, M.D. under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised 2018). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2018, filed February 7, 2019.)
10.2.14 +	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised 2018). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2018, filed February 7, 2019.)
10.2.15 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's non-employee directors under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised 2018). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2018, filed February 7, 2019.)

10.2.16 +	Form of restricted stock unit award agreement and related notice of grant for use in connection with the grant of restricted stock units to the Registrant's non-employee directors under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2018, filed February 7, 2019.)
10.2.17 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's executive officers under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised 2019). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2019, filed February 7, 2020.)
10.2.18 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to P. Roy Vagelos, M.D. under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised 2019). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2019, filed February 7, 2020.)
10.2.19 +	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised 2019). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2019, filed February 7, 2020.)
10.2.20 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's non-employee directors under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised 2019). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2019, filed February 7, 2020.)
10.2.21 +	Form of restricted stock unit award agreement and related notice of grant for use in connection with the grant of restricted stock units to the Registrant's non-employee directors under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (revised 2019). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2019, filed February 7, 2020.)
10.2.22 +	Form of performance restricted stock unit award agreement and related notice of grant for use in connection with the grant of performance restricted stock units to Leonard S. Schleifer, M.D., Ph.D., George D. Yancopoulos, M.D., Ph.D., and P. Roy Vagelos, M.D. under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2019, filed February 7, 2020.)
10.3 +	Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Registration Statement on Form S-8 for the Registrant, filed June 16, 2020.)
10.3.1 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's executive officers under the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2020, filed February 8, 2021.)
10.3.2 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to P. Roy Vagelos, M.D. under the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2020, filed February 8, 2021.)
10.3.3 +	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers under the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2020, filed February 8, 2021.)
10.3.4 +	Form of restricted stock unit award agreement and related notice of grant for use in connection with the grant of restricted stock units to P. Roy Vagelos, M.D. under the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2020, filed February 8, 2021.)
10.3.5 +	Form of stock option agreement and related notice of grant for use in connection with the grant of non-qualified stock options to the Registrant's non-employee directors under the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2020, filed February 8, 2021.)

10.3.6 +	Form of restricted stock unit award agreement and related notice of grant for use in connection with the grant of restricted stock units to the Registrant's non-employee directors under the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2020, filed February 8, 2021.)
10.3.7 +	Form of performance restricted stock unit award agreement and related notice of grant for use in connection with the grant of performance restricted stock units to Leonard S. Schleifer, M.D., Ph.D. and George D. Yancopoulos, M.D., Ph.D. under the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2020, filed February 8, 2021.)
10.4 +	Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Registrant and Leonard S. Schleifer, M.D., Ph.D. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2008, filed February 26, 2009.)
10.5* +	Employment Agreement, dated as of December 31, 1998, between the Registrant and P. Roy Vagelos, M.D. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2004, filed March 11, 2005.)
10.6 +	Offer Letter for Robert E. Landry effective September 9, 2013. (Incorporated by reference from the Form 8-K for the Registrant, filed September 12, 2013.)
10.7 +	Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, amended and restated effective as of November 14, 2008. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2008, filed February 26, 2009.)
10.8 +	Regeneron Pharmaceuticals, Inc. Cash Incentive Bonus Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed June 17, 2015.)
10.9*	IL-1 Antibody Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 8, 2009. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2009, filed August 4, 2009.)
10.10*	License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and the Registrant. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2006, filed November 6, 2006.)
10.10.1*	Restated Amendment Agreement, dated December 30, 2014 and entered into effective as of May 7, 2012, by and between Bayer HealthCare LLC and the Registrant. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2014, filed February 12, 2015.)
10.10.2**	Second Amendment Agreement, dated December 19, 2019, by and between Bayer HealthCare LLC and the Registrant. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2019, filed February 7, 2020.)
10.11*	Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009, by and among Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and the Registrant. (Incorporated by reference from the Form 10-K/A for the Registrant, for the year ended December 31, 2009, filed June 2, 2010.)
10.11.1*	First Amendment to Amended and Restated License and Collaboration Agreement by and between the Registrant and Aventis Pharmaceuticals Inc., dated May 1, 2013. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2013, filed August 6, 2013.)
10.11.2*	Amendment No. 2 to Amended and Restated License and Collaboration Agreement, dated July 27, 2015 and entered into effective as of July 1, 2015, by and between the Registrant and Sanofi Biotechnology SAS, as successor-in-interest to Aventis Pharmaceuticals, Inc. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2015, filed November 4, 2015.)
10.11.3**	Third Amendment to Amended and Restated License and Collaboration Agreement, dated as of April 5, 2020, and effective as of April 1, 2020, by and between the Registrant, Sanofi Biotechnology SAS, and Sanofi. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2020, filed August 5, 2020.)
10.11.4**	Fourth Amendment to Amended and Restated License and Collaboration Agreement, dated as of October 6, 2021, by and between the Registrant, Sanofi Biotechnology SAS, and Sanofi. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2021, filed February 7, 2022.)

10.11.5**	Fifth Amendment to Amended and Restated License and Collaboration Agreement, dated as of June 1, 2022, by and between the Registrant, Sanofi Biotechnology SAS, and Sanofi. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2022, filed August 3, 2022.)
10.12**	Praluent Cross License & Commercialization Agreement, dated as of April 5, 2020, and effective as of April 1, 2020, by and between the Registrant and Sanofi Biotechnology SAS. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2020, filed August 5, 2020.)
10.13	Amended and Restated Investor Agreement, dated as of January 11, 2014, by and among Sanofi, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and the Registrant. (Incorporated by reference from the Form 8-K for the Registrant, filed January 13, 2014.)
10.13.1	Amendment to the Amended and Restated Investor Agreement, dated as of May 25, 2020, by and among the Registrant, Sanofi, Sanofi-Aventis US LLC, and Aventisub LLC. (Incorporated by reference from the Form 8-K for the Registrant, filed May 29, 2020.)
10.14***	Credit Agreement, dated as of December 19, 2022, by and among the Registrant, as a borrower and guarantor, certain direct subsidiaries of the Registrant, as the initial subsidiary borrowers, the lenders and issuing banks party thereto, and JPMorgan Chase Bank, N.A., as administrative agent, swingline lender, and an issuing bank. (Incorporated by reference from the Form 8-K for the Registrant, filed December 20, 2022.)
10.15**	Amended and Restated Immuno-oncology License and Collaboration Agreement, dated as of June 1, 2022, by and between the Registrant and Sanofi Biotechnology SAS. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2022, filed August 3, 2022.)
10.16*	ANG2 License and Collaboration Agreement, dated as of March 23, 2016, by and between Bayer HealthCare LLC and the Registrant. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2016, filed May 5, 2016.)
10.17*	Purchase Agreement, dated as of December 30, 2016, by and among BMR-Landmark at Eastview LLC and BMR-Landmark at Eastview IV LLC and the Registrant. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2016, filed February 9, 2017.)
10.18***	Second Amended and Restated Participation Agreement, dated as of March 2, 2022, by and among Old Saw Mill Holdings LLC, as lessee, Bank of America, N.A., as administrative agent, BA Leasing BSC, LLC, as lessor, and the rent assignees party thereto from time to time. (Incorporated by reference from the Form 8-K for the Registrant, filed March 8, 2022.)
10.19***	Second Amended and Restated Lease and Remedies Agreement, dated as of March 2, 2022, between Old Saw Mill Holdings LLC, as lessee, and BA Leasing BSC, LLC, as lessor. (Incorporated by reference from the Form 8-K for the Registrant, filed March 8, 2022.)
10.20***	Second Amended and Restated Guaranty, dated as of March 2, 2022, made by the Registrant, Regeneron Healthcare Solutions, Inc., and Regeneron Genetics Center LLC, as guarantors. (Incorporated by reference from the Form 8-K for the Registrant, filed March 8, 2022.)
10.21**	Master Agreement, dated as of April 8, 2019, by and between the Registrant and Alnylam Pharmaceuticals, Inc. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended June 30, 2019, filed August 6, 2019.)
10.21.1**	Form of Co-Co Collaboration Agreement (Exhibit B to Master Agreement contained in Exhibit 10.21).
10.21.2**	Form of License Agreement (Exhibit C to Master Agreement contained in Exhibit 10.21).
10.22**	License Agreement, dated as of August 18, 2020, by and among the Registrant, F. Hoffman-La Roche Ltd, and Genentech, Inc. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2020, filed November 5, 2020.)
21.1	Subsidiaries of the Registrant.
23.1	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on the signature page of this Annual Report on Form 10-K).
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350.

101	Interactive Data Files pursuant to Rule 405 of Regulation S-T formatted in Inline Extensible Business Reporting Language ("Inline XBRL"): (i) the Registrant's Consolidated Balance Sheets as of December 31, 2022 and 2021; (ii) the Registrant's Consolidated Statements of Operations and Comprehensive Income for the years ended December 31, 2022, 2021, and 2020; (iii) the Registrant's Consolidated Statements of Stockholders' Equity for the years ended December 31, 2022, 2021, and 2020; (iv) the Registrant's Consolidated Statements of Cash Flows for the years ended December 31, 2022, 2021, and 2020; and (v) the notes to the Registrant's Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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* Portions of this document have been omitted and filed separately with the Securities and Exchange Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

** Certain confidential portions of this Exhibit were omitted in accordance with Item 601(b)(10) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of all confidential portions of this Exhibit that were omitted to the Securities and Exchange Commission upon its request.

*** Certain of the exhibits and/or schedules to this Exhibit have been omitted in accordance with Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of all omitted exhibits and schedules of this Exhibit to the Securities and Exchange Commission upon its request.

+ Indicates a management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: February 6, 2023

By: /s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leonard S. Schleifer, President and Chief Executive Officer, and Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer, and each of them, his or her true and lawful attorney-in-fact and agent, with the full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities therewith, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact and agent, or either of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ LEONARD S. SCHLEIFER Leonard S. Schleifer, M.D., Ph.D.	*President, Chief Executive Officer, and Director (Principal Executive Officer)*	February 6, 2023
/s/ ROBERT E. LANDRY Robert E. Landry	*Executive Vice President, Finance and Chief Financial Officer (Principal Financial Officer)*	February 6, 2023
/s/ CHRISTOPHER R. FENIMORE Christopher R. Fenimore	*Senior Vice President, Controller (Principal Accounting Officer)*	February 6, 2023
/s/ GEORGE D. YANCOPOULOS George D. Yancopoulos, M.D., Ph.D.	*President, Chief Scientific Officer, and Director*	February 6, 2023
/s/ P. ROY VAGELOS P. Roy Vagelos, M.D.	*Chair of the Board of Directors*	February 6, 2023
/s/ BONNIE L. BASSLER Bonnie L. Bassler, Ph.D.	*Director*	February 6, 2023
/s/ MICHAEL S. BROWN Michael S. Brown, M.D.	*Director*	February 6, 2023
/s/ N. ANTHONY COLES N. Anthony Coles, M.D.	*Director*	February 6, 2023
/s/ JOSEPH L. GOLDSTEIN Joseph L. Goldstein, M.D.	*Director*	February 6, 2023
/s/ CHRISTINE A. POON Christine A. Poon	*Director*	February 6, 2023
/s/ ARTHUR F. RYAN Arthur F. Ryan	*Director*	February 6, 2023
/s/ GEORGE L. SING George L. Sing	*Director*	February 6, 2023
/s/ MARC TESSIER-LAVIGNE Marc Tessier-Lavigne, Ph.D.	*Director*	February 6, 2023
/s/ CRAIG B. THOMPSON Craig B. Thompson, M.D.	*Director*	February 6, 2023
/s/ HUDA Y. ZOGHBI Huda Y. Zoghbi, M.D.	*Director*	February 6, 2023

REGENERON PHARMACEUTICALS, INC.
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Regeneron Pharmaceuticals, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Regeneron Pharmaceuticals, Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive income, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2022, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for the Acquisition of the Worldwide Rights to Libtayo

As described in Notes 1, 3, and 8 to the consolidated financial statements, in July 2022, the Company obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide under an Amended and Restated Immuno-oncology License and Collaboration Agreement with Sanofi. The transaction was accounted for as an asset acquisition. Amounts paid in connection with obtaining the worldwide rights to Libtayo, which included an up-front payment of $900 million, offset by the remaining up-front payments of $241 million previously received under the Immuno-oncology License and Collaboration Agreement, were recorded as an intangible asset. The Company recorded additions to the Libtayo intangible asset primarily related to contingent consideration due to Sanofi in connection with obtaining the worldwide rights to Libtayo. As disclosed by management, due to the complexity of the terms of the amendments to the collaboration agreements in contemplation of the acquisition of the worldwide rights to Libtayo, significant judgment was applied by management in identifying the elements of the transaction and evaluating the timing and recognition of contingent consideration including the following: royalties, which are recorded in the period in which the underlying sales occur; sales-based milestones up to an aggregate of $100 million, which are recorded when the milestone is deemed probable by the Company of being achieved; a regulatory milestone of $100 million, which is recorded upon achievement; and a portion of the value associated with the increase in the reimbursement percentage pursuant to the amendment to the Company's Antibody License and Collaboration Agreement.

The principal considerations for our determination that performing procedures relating to the accounting for the acquisition of the worldwide rights to Libtayo is a critical audit matter are (i) the significant judgment by management in identifying the elements of the transaction and in evaluating the timing and recognition of contingent consideration, (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating audit evidence related to the accounting for the transaction and related disclosures, and (iii) the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls over management's accounting for the amendments to the collaboration agreements including controls over the identification of the elements of the transaction and evaluating the timing and recognition of contingent consideration. These procedures also included, among others (i) reviewing the Amended and Restated Immuno-oncology License and Collaboration Agreement and the amended Antibody License and Collaboration Agreement and other agreements related to the transaction; (ii) evaluating management's identification of the elements of the transaction; and (iii) evaluating the timing and recognition of contingent consideration. Professionals with specialized skill and knowledge were used to assist in evaluating the identification of the elements of the transaction.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 6, 2023

We have served as the Company’s auditor since 1989.

REGENERON PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In millions, except per share data)

	December 31,	
	2022	**2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,105.9	$ 2,885.6
Marketable securities	4,636.4	2,809.1
Accounts receivable, net	5,328.7	6,036.5
Inventories	2,401.9	1,951.3
Prepaid expenses and other current assets	411.2	332.4
Total current assets	15,884.1	14,014.9
Marketable securities	6,591.8	6,838.0
Property, plant, and equipment, net	3,763.0	3,482.2
Intangible assets, net	915.5	6.7
Deferred tax assets	1,723.7	876.9
Other noncurrent assets	336.4	216.1
Total assets	$ 29,214.5	$ 25,434.8
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 589.2	$ 564.0
Accrued expenses and other current liabilities	2,074.2	2,206.8
Finance lease liabilities	—	719.7
Deferred revenue	477.9	442.0
Total current liabilities	3,141.3	3,932.5
Long-term debt	1,981.4	1,980.0
Finance lease liabilities	720.0	—
Deferred revenue	69.8	73.3
Other noncurrent liabilities	638.0	680.2
Total liabilities	6,550.5	6,666.0
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred Stock, par value $.01 per share; 30.0 shares authorized; issued and outstanding - none	—	—
Class A Stock, convertible, par value $.001 per share; 40.0 shares authorized; shares issued and outstanding - 1.8 in 2022 and 2021	—	—
Common Stock, par value $.001 per share; 320.0 shares authorized; shares issued - 130.4 in 2022 and 126.2 in 2021	0.1	0.1
Additional paid-in capital	9,949.3	8,087.5
Retained earnings	23,306.7	18,968.3
Accumulated other comprehensive loss	(238.8)	(26.2)
Treasury Stock, at cost; 22.6 shares in 2022 and 19.4 shares in 2021	(10,353.3)	(8,260.9)
Total stockholders' equity	22,664.0	18,768.8
Total liabilities and stockholders' equity	$ 29,214.5	$ 25,434.8

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME
(In millions, except per share data)

	Year Ended December 31,		
	2022	**2021**	**2020**
Statements of Operations			
Revenues:			
Net product sales	$ 6,893.7	$ 12,117.2	$ 5,567.6
Sanofi collaboration revenue	2,855.7	1,902.2	1,186.4
Other collaboration revenue	2,058.4	1,771.1	1,186.1
Other revenue	365.1	281.2	557.0
	12,172.9	16,071.7	8,497.1
Expenses:			
Research and development	3,592.5	2,860.1	2,647.0
Acquired in-process research and development	255.1	48.0	88.0
Selling, general, and administrative	2,115.9	1,824.9	1,346.0
Cost of goods sold	800.0	1,773.1	491.9
Cost of collaboration and contract manufacturing	760.4	664.4	628.0
Other operating (income) expense, net	(89.9)	(45.6)	(280.4)
	7,434.0	7,124.9	4,920.5
Income from operations	4,738.9	8,946.8	3,576.6
Other income (expense):			
Other income (expense), net	179.3	436.3	290.7
Interest expense	(59.4)	(57.3)	(56.9)
	119.9	379.0	233.8
Income before income taxes	4,858.8	9,325.8	3,810.4
Income tax expense	520.4	1,250.5	297.2
Net income	$ 4,338.4	$ 8,075.3	$ 3,513.2
Net income per share - basic	$ 40.51	$ 76.40	$ 32.65
Net income per share - diluted	$ 38.22	$ 71.97	$ 30.52
Weighted average shares outstanding - basic	107.1	105.7	107.6
Weighted average shares outstanding - diluted	113.5	112.2	115.1
Statements of Comprehensive Income			
Net income	$ 4,338.4	$ 8,075.3	$ 3,513.2
Other comprehensive income (loss), net of tax:			
Unrealized (loss) gain on debt securities	(213.6)	(56.4)	9.1
Unrealized gain (loss) on cash flow hedges	1.0	0.9	(0.9)
Comprehensive income	$ 4,125.8	$ 8,019.8	$ 3,521.4

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2022, 2021, and 2020
(In millions)

	Class A Stock		Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2019	1.8	$ —	113.3	$ 0.1	$ 4,428.6	$ 7,379.8	$ 21.1	(4.9)	$ (739.9)	$ 11,089.7
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	9.6	—	2,576.4	—	—	—	—	2,576.4
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(1.4)	—	(768.9)	—	—	—	—	(768.9)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	37.2	—	—	0.1	7.5	44.7
Repurchases of Common Stock	—	—	—	—	—	—	—	(11.6)	(5,880.9)	(5,880.9)
Stock-based compensation charges	—	—	—	—	442.9	—	—	—	—	442.9
Net income	—	—	—	—	—	3,513.2	—	—	—	3,513.2
Other comprehensive income, net of tax	—	—	—	—	—	—	8.2	—	—	8.2
Balance, December 31, 2020	1.8	—	121.5	0.1	6,716.2	10,893.0	29.3	(16.4)	(6,613.3)	11,025.3
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	6.2	—	1,676.0	—	—	—	—	1,676.0
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(1.5)	—	(944.6)	—	—	—	—	(944.6)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	40.7	—	—	0.1	7.4	48.1
Repurchases of Common Stock	—	—	—	—	—	—	—	(3.1)	(1,655.0)	(1,655.0)
Stock-based compensation charges	—	—	—	—	599.2	—	—	—	—	599.2
Net income	—	—	—	—	—	8,075.3	—	—	—	8,075.3
Other comprehensive loss, net of tax	—	—	—	—	—	—	(55.5)	—	—	(55.5)
Balance, December 31, 2021	1.8	—	126.2	0.1	8,087.5	18,968.3	(26.2)	(19.4)	(8,260.9)	18,768.8

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY *(continued)*

	Class A Stock		Common Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Treasury Stock		Total Stockholders' Equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	4.8	—	1,517.4	—	—	—	—	1,517.4
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.6)	—	(445.7)	—	—	—	—	(445.7)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	52.3	—	—	0.1	7.4	59.7
Repurchases of Common Stock	—	—	—	—	—	—	—	(3.3)	(2,099.8)	(2,099.8)
Stock-based compensation charges	—	—	—	—	737.8	—	—	—	—	737.8
Net income	—	—	—	—	—	4,338.4	—	—	—	4,338.4
Other comprehensive loss, net of tax	—	—	—	—	—	—	(212.6)	—	—	(212.6)
Balance, December 31, 2022	1.8	$ —	130.4	$ 0.1	$ 9,949.3	$ 23,306.7	$ (238.8)	(22.6)	$(10,353.3)	$ 22,664.0

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In millions)

	Year Ended December 31,		
	2022	**2021**	**2020**
Cash flows from operating activities:			
Net income	$ 4,338.4	$ 8,075.3	$ 3,513.2
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	341.4	286.2	235.9
Stock-based compensation expense	725.0	601.7	432.0
Losses (gains) on marketable and other securities, net	36.8	(387.0)	(221.8)
Other non-cash items, net	368.0	568.7	86.8
Deferred income taxes	(746.4)	(147.1)	75.6
Acquired in-process research and development in connection with asset acquisition	195.0	—	—
Changes in assets and liabilities:			
Decrease (increase) in accounts receivable	707.8	(1,927.4)	(1,356.1)
Increase in inventories	(696.5)	(494.3)	(529.4)
(Increase) decrease in prepaid expenses and other assets	(148.6)	(240.7)	114.9
Increase (decrease) in deferred revenue	32.4	(120.2)	148.1
(Decrease) increase in accounts payable, accrued expenses, and other liabilities	(138.4)	866.1	118.9
Total adjustments	676.5	(994.0)	(895.1)
Net cash provided by operating activities	5,014.9	7,081.3	2,618.1
Cash flows from investing activities:			
Purchases of marketable and other securities	(7,487.9)	(7,048.1)	(3,241.0)
Sales or maturities of marketable and other securities	5,550.5	2,215.3	3,785.0
Capital expenditures	(590.1)	(551.9)	(614.6)
Payments for Libtayo intangible asset	(1,026.8)	—	—
Asset acquisition, net of cash acquired	(230.3)	—	—
Net cash used in investing activities	(3,784.6)	(5,384.7)	(70.6)
Cash flows from financing activities:			
Proceeds from issuance of Common Stock	1,519.5	1,672.3	2,575.2
Payments in connection with Common Stock tendered for employee tax obligations	(445.7)	(1,032.7)	(680.8)
Repurchases of Common Stock	(2,082.8)	(1,645.4)	(5,846.8)
Proceeds from issuance of long-term debt	—	—	1,981.9
Proceeds from bridge loan facility	—	—	1,500.0
Repayment of bridge loan facility	—	—	(1,500.0)
Net cash used in financing activities	(1,009.0)	(1,005.8)	(1,970.5)
Net increase in cash, cash equivalents, and restricted cash	221.3	690.8	577.0
Cash, cash equivalents, and restricted cash at beginning of period	2,898.1	2,207.3	1,630.3
Cash, cash equivalents, and restricted cash at end of period	$ 3,119.4	$ 2,898.1	$ 2,207.3
Supplemental disclosure of cash flow information			
Cash paid for interest (net of amounts capitalized)	$ 53.7	$ 55.8	$ 23.2
Cash paid for income taxes	$ 1,502.4	$ 1,218.4	$ 188.1

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Business Overview and Summary of Significant Accounting Policies

Organization and Business

Regeneron Pharmaceuticals, Inc. and its subsidiaries ("Regeneron," "Company," "we," "us," and "our") is a fully integrated biotechnology company that discovers, invents, develops, manufactures, and commercializes medicines for serious diseases. Our products and product candidates in development are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, pain, hematologic conditions, infectious diseases, and rare diseases. The Company currently has nine products that have received marketing approval by the U.S. Food and Drug Administration ("FDA"). In addition, REGEN-COV® was authorized under an Emergency Use Authorization ("EUA") from November 2020 until January 2022 when the EUA was revised to exclude its use in geographic regions where infection or exposure is likely due to a variant that is not susceptible to the treatment; with this EUA revision, REGEN-COV is not currently authorized for use in any U.S. states, territories, or jurisdictions. The Company is a party to collaboration agreements to develop and commercialize, as applicable, certain products and product candidates (see Note 3).

The Company operates in one business segment, which includes all activities related to the discovery, development, and commercialization of medicines for serious diseases. The Company's business is subject to certain risks including, but not limited to, uncertainties relating to conducting research activities, product development, obtaining regulatory approvals, competition, and obtaining and enforcing patents.

Basis of Presentation

The consolidated financial statements include the accounts of Regeneron and its wholly-owned subsidiaries. Intercompany balances and transactions are eliminated in consolidation.

Beginning with the first quarter of 2022, the Company added a new line item, Acquired in-process research and development, to its Consolidated Statements of Operations and Comprehensive Income. This line item includes in-process research and development acquired in connection with asset acquisitions as well as up-front/opt-in payments related to license and collaboration agreements. Amounts recorded in this line item during the year ended December 31, 2022 would have historically been recorded to Research and development expenses.

Certain reclassifications have been made to prior period amounts to conform with the current period's presentation, including in connection with the addition of Acquired in-process research and development described above.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Concentration of Credit Risk

Financial instruments which potentially expose the Company to concentrations of credit risk consist of cash, cash equivalents, certain investments, and accounts receivable. In accordance with the Company's policies, the Company mandates asset diversification and monitors exposure with its counterparties.

Concentrations of credit risk with respect to customer and collaborator accounts receivable are significant. As of December 31, 2022, two individual customers accounted for 86% of the Company's net trade accounts receivable balances. Three individual customers accounted for 91% (including 29% related to the U.S. government) of the Company's net trade accounts receivable balances as of December 31, 2021. The Company has contractual payment terms with each of its collaborators and customers, and the Company monitors their financial performance and credit worthiness so that it can properly assess and respond to any changes in their credit profile. As of December 31, 2022 and 2021, there were no write-offs and allowances of accounts receivable related to credit risk for the Company's collaborators or customers.

Significant Accounting Policies

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments with a maturity of three months or less when purchased to be cash equivalents. The carrying amount reported in the Consolidated Balance Sheet for cash and cash equivalents approximates its fair value.

Debt and Equity Securities

The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and diversification. The Company invests its cash primarily in debt securities. The Company considers its investments in debt securities to be "available-for-sale," as defined by authoritative guidance issued by the Financial Accounting Standards Board ("FASB"). These assets are carried at fair value and the unrealized gains and losses are included in accumulated other comprehensive income (loss). Realized gains and losses on available-for-sale debt securities are included in other income (expense), net. The Company reviews its portfolio of available-for-sale debt securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost have resulted from a credit-related loss or other factors. If the decline in fair value is due to credit-related factors, a loss is recognized in net income, whereas if the decline in fair value is not due to credit-related factors, the loss is recorded in other comprehensive income (loss).

The Company also has investments in equity securities that are carried at fair value with changes in fair value recognized within other income (expense), net. The Company has elected to measure certain equity investments it holds that do not have readily determinable fair values at cost less impairment, if any, and adjusts for observable price changes in orderly transactions for identical or similar investments of the same issuer within other income (expense), net.

Accounts Receivable

The Company's trade accounts receivable arise from product sales and represent amounts due from its customers. In addition, the Company records accounts receivable arising from its collaboration and licensing agreements. The Company monitors the financial performance and credit worthiness of its counterparties so that it can properly assess and respond to changes in their credit profile. The Company provides allowances against receivables for estimated losses, if any, that may result from a counterparty's inability to pay. Amounts determined to be uncollectible are written-off against the allowance.

Inventories

Inventories are stated at the lower of cost or net realizable value. The Company determines the cost of inventory using the first-in, first-out, or FIFO, method.

The Company capitalizes inventory costs associated with the Company's products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed. The determination to capitalize inventory costs is based on various factors, including status and expectations of the regulatory approval process, any known safety or efficacy concerns, potential labeling restrictions, and any other impediments to obtaining regulatory approval.

The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and writes down such inventories as appropriate. In addition, the Company's products are subject to strict quality control and monitoring which the Company performs throughout the manufacturing process. If certain batches or units of product no longer meet quality specifications or become obsolete due to expiration, the Company records a charge to write down such inventory to its estimated realizable value.

Property, Plant, and Equipment

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets. Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the remaining lease term. Costs of construction of certain long-lived assets include capitalized interest, which is amortized over the estimated useful life of the related asset. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts, and any gain or loss is recognized within income from operations. The estimated useful lives of property, plant, and equipment are as follows:

Building and improvements	10–50 years
Laboratory and other equipment	3–10 years
Furniture and fixtures	5 years

The Company periodically assesses the recoverability of long-lived assets, such as property, plant, and equipment, and evaluates such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Leases

The Company determines if an arrangement is a lease considering whether there is an identified asset and the contract conveys the right to control its use. Leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company's lease terms may include options to extend or terminate a lease when it is reasonably certain that it will exercise that option. The Company accounts for lease components (e.g., rental payments) separately from non-lease components (e.g., common area maintenance costs).

Right-of-use assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term, unless there is a transfer of title or purchase option the Company is reasonably certain to exercise. For leases where an implicit rate is not readily determinable, the Company uses its incremental borrowing rate based on information available at the lease commencement date to determine the present value of future lease payments. Lease expense for operating leases is recognized on a straight-line basis over the expected lease term.

Intangible Assets

The Company makes a determination of whether an asset or set of assets acquired constitute a business. If it is determined that substantially all of the fair value of gross assets acquired in a transaction are concentrated in a single identifiable asset, then the transaction is accounted for as an asset acquisition. Intangible assets acquired in connection with an asset acquisition are recorded at cost. Such amounts may include up-front payments and contingent consideration. With regard to contingent consideration, the Company recognizes regulatory milestones upon achievement, royalties in the period in which the underlying sales occur, and sales-based milestones when the milestone is deemed probable by the Company of being achieved.

Intangible assets are amortized to Cost of goods sold over the estimated useful lives of the assets based on the pattern in which the economic benefits of the intangible assets are consumed; if that pattern cannot be reliably determined, a straight-line basis is used. If contingent consideration is recognized subsequent to the acquisition date in an asset acquisition, the amount of such consideration is recorded as an addition to the cost basis of the intangible asset with a cumulative catch-up adjustment for amortization expense as if the additional amount of consideration had been accrued from the outset of the acquisition.

The Company's intangible assets are reviewed for recoverability whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If an indicator of impairment exists, the Company compares the projected undiscounted cash flows to be generated by the asset to the intangible asset's carrying amount. If the projected undiscounted cash flows of the intangible asset are less than the carrying amount, the intangible asset is written down to its fair value in the period in which the impairment occurs.

Revenue Recognition - Product Revenue

Revenue from product sales is recognized at a point in time when the Company's customer is deemed to have obtained control of the product, which generally occurs upon receipt or acceptance by its customer.

The amount of revenue the Company recognizes from product sales may vary due to rebates, chargebacks, and discounts provided under governmental and other programs, distribution-related fees, and other sales-related deductions. In order to determine the transaction price, the Company estimates, utilizing the expected value method, the amount of variable consideration to which the Company will be entitled. This estimate is based upon contracts with customers, healthcare providers, payors, and government agencies, statutorily-defined discounts applicable to government-funded programs, historical experience, estimated payor mix, and other relevant factors. The Company reviews its estimates of rebates, chargebacks, and other applicable provisions each period and records any necessary adjustments in the current period's net product sales.

- *Rebates:* The Company's rebates include amounts paid to managed care organizations, group purchasing organizations, state Medicaid programs, and other rebate programs. The Company estimates reductions to product sales for each type of rebate and records an allowance for rebates in the same period in which the related product sales are recognized. The Company's liability for rebates consists of estimates for claims related to the current and prior periods that have not been paid and estimates for claims that will be made related to inventory that exists in the distribution channel at the end of the period.

- *Chargebacks and Discounts:* The Company's reserves related to discounted pricing to eligible physicians, Veterans' Administration ("VA"), Public Health Services, and others (collectively "qualified healthcare providers") represent the Company's estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices the Company charges to its customers (i.e., distributors and specialty pharmacies). The Company's customers charge the Company for the difference between what they pay for the products and the discounted selling price to the qualified healthcare providers. The Company estimates reductions to product sales for each type of chargeback and records an allowance for chargebacks in the same period that the related product sales are recognized. The Company's reserve for chargebacks consists of amounts for which it expects to issue credit based on expected sales by its customers to qualified healthcare providers and chargebacks that customers have claimed but for which the Company has not yet issued credit.
- *Distribution-Related Fees:* The Company has written contracts with its customers that include terms for distribution-related fees. The Company estimates and records distribution and related fees due to its customers generally based on gross sales.
- *Other Sales-Related Deductions*: The Company's other sales-related deductions include co-pay assistance programs and product returns. The Company estimates and records other sales-related deductions generally based on gross sales, written contracts, and other relevant factors.

Consistent with industry practice, the Company generally offers its customers a limited right to return product purchased directly from the Company, which is principally based upon the product's expiration date. Product returned is generally not resalable given the nature of the Company's products and method of administration. The Company develops estimates for product returns based upon historical experience, shelf life of the product, and other relevant factors. The Company monitors product supply levels in the distribution channel, as well as sales by its customers, using product-specific data provided by its customers. If necessary, the Company's estimates of product returns may be adjusted in the future based on actual returns experience, known or expected changes in the marketplace, or other factors.

Collaborative Arrangements

The Company has entered into various collaborative arrangements to research, develop, manufacture, and commercialize products and/or product candidates. Although each of these arrangements is unique in nature, such arrangements involve a joint operating activity where both parties are active participants in the activities of the collaboration and exposed to significant risks and rewards dependent on the commercial success of the activities.

In arrangements where the Company does not deem its collaborator to be its customer, payments to and from its collaborator are presented in the Company's statement of operations based on the nature of our business operations, the nature of the arrangement, including the contractual terms, and the nature of the payments, as summarized in the table and further described below.

Nature/Type of Payment	Statement of Operations Presentation
Regeneron's share of profits or losses in connection with commercialization of products	Collaboration revenue
Reimbursement for manufacturing of commercial supplies	Collaboration revenue
Royalties and/or sales-based milestones earned	Collaboration revenue
Reimbursement of Regeneron's research and development expenses	Reduction to Research and development expenses
Regeneron's obligation for its share of collaborator's research and development expenses	Research and development expense
Up-front/opt-in and development milestone payments to collaborators	Acquired in-process research and development expense
Reimbursement of Regeneron's commercialization-related expenses	Reduction to Selling, general, and administrative expense
Regeneron's obligation for its share of collaborator's commercialization-related expenses	Selling, general, and administrative expense
Regeneron's obligation to pay collaborator for its share of gross profits when Regeneron is deemed to be the principal	Cost of goods sold
Up-front and development milestones earned (when there is a combined unit of account which includes a license and providing research and development services)	Other operating income

In agreements involving multiple goods or services promised to be transferred to the Company's collaborator, the Company must assess, at the inception of the contract, whether each promise represents a separate obligation (i.e., is "distinct"), or whether such

promises should be combined as a single unit of account. When the Company has a combined unit of account which includes a license and providing research and development services to its collaborator, recognition of up-front payments and development milestones earned from its collaborator is deferred (as a liability) and recognized over the development period (i.e., over time) typically using an input method on the basis of the Company's research and development costs incurred relative to the total expected cost which determines the extent of the Company's progress toward completion. The Company reviews its estimates each period and makes revisions to such estimates as necessary.

When the Company is entitled to reimbursement of all or a portion of the expenses (e.g., research and development expenses) that it incurs under a collaboration, it records those reimbursable amounts in the period in which such costs are incurred.

If the Company's collaborator performs research and development work or commercialization-related activities and the parties share the related costs, the Company also recognizes, as expense (e.g., research and development expense or selling, general, and administrative expense, as applicable) in the period when its collaborator incurs such expenses, the portion of the collaborator's expenses that the Company is obligated to reimburse. The Company's collaborators provide the Company with estimated expenses for the most recent fiscal quarter. The estimates are revised, if necessary, in subsequent periods if actual expenses differ from those estimates.

Under certain of the Company's collaboration agreements, product sales and cost of sales may be recorded by the Company's collaborators as they are deemed to be the principal in the transaction. In arrangements where the Company:

- supplies commercial product to its collaborator, the Company may be reimbursed for its manufacturing costs as commercial product is shipped to the collaborator (however, recognition of such cost reimbursements may be deferred until the product is sold by the Company's collaborator to third-party customers);
- shares in any profits or losses arising from the commercialization of such products, the Company records its share of the variable consideration, representing net product sales less cost of goods sold and shared commercialization and other expenses, in the period in which such underlying sales occur and costs are incurred by the collaborator; and
- receives royalties and/or sales-based milestone payments from its collaborator, the Company recognizes such amounts in the period earned.

The Company's collaborators provide it with estimates of product sales and the Company's share of profits or losses, as applicable, for each quarter. The estimates are revised, if necessary, in subsequent periods if the Company's actual share of profits or losses differ from those estimates.

Research and Development Expenses

Research and development expenses include costs attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, costs related to research collaboration and licensing agreements, clinical trial expenses, the cost of services provided by outside contractors, including services related to the Company's clinical trials, the full cost of manufacturing drug for use in research and development, amounts that the Company is obligated to reimburse to collaborators for research and development expenses that they incur, and the allocable portions of facility costs. Costs associated with research and development are expensed.

For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter and remain in the trial, and/or the period over which clinical investigators, contract research organizations ("CROs"), or other third-party service providers are expected to provide services. In the event of early termination of a clinical trial, the Company accrues and recognizes expenses in an amount based on its estimate of the remaining noncancelable obligations associated with the winding-down of the clinical trial, including any applicable penalties.

Stock-based Compensation

The Company recognizes stock-based compensation expense for equity grants under the Company's long-term incentive plans (including stock options, restricted stock awards, and restricted stock units (both time-based and performance-based)) to employees and non-employee members of the Company's board of directors (as applicable) based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In addition, the Company reassesses its forfeiture rate assumptions at least annually, considering both historical forfeiture experience and an estimate of future forfeitures for currently outstanding unvested awards.

The Company uses the Black-Scholes model to compute the estimated fair value of stock option awards. Additionally, the Company uses a Monte Carlo simulation to compute the estimated fair value of performance-based restricted stock units that are subject to vesting based on the Company's attainment of pre-established criteria that include a market condition.

For performance-based restricted stock units that contain a performance condition, the Company recognizes stock-based compensation expense if and when the Company determines that it is probable the performance condition will be achieved (based on the number of shares expected to be vested and issued). The Company reassesses the probability of achievement at each reporting period and adjusts compensation cost, as necessary. If there are any changes in the Company's probability assessment, the Company recognizes a cumulative catch-up adjustment in the period of the change in estimate, with the remaining unrecognized expense recognized prospectively over the remaining requisite service period. If the Company subsequently determines that the performance criteria are not met or are not expected to be met, any amounts previously recognized as compensation expense are reversed in the period when such determination is made.

Income Taxes

The provision for income taxes includes U.S. federal, state, local, and foreign taxes. Income taxes are accounted for under the liability method. Deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns, including deferred tax assets and liabilities for expected amounts of global intangible low-taxed income ("GILTI") inclusions, are recognized on the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which it is more likely than not that some portion or all of the deferred tax assets will not be realized.

The Company recognizes the financial statement effects of a tax position when management's assessment is that there is more than a 50% probability that the position will be sustained upon examination by a taxing authority based upon its technical merits. Uncertain tax positions are recorded based upon certain recognition and measurement criteria. The Company re-evaluates uncertain tax positions and considers various factors, including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, and changes in facts or circumstances related to a tax position. The Company adjusts the amount of the liability to reflect any subsequent changes in the relevant facts and circumstances surrounding the uncertain tax positions. The Company recognizes interest and penalties related to income tax matters in income tax expense.

Per Share Data

Basic net income per share is computed by dividing net income by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net income per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. Basic net income per share excludes restricted stock until vested. Diluted net income per share includes the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is dilutive. Common stock equivalents include outstanding stock options and unvested restricted stock under the Company's long-term incentive plans, which are included under the treasury stock method when dilutive.

2. Product Sales

Net product sales consist of the following:

(In millions)		Year Ended December 31, 2022	2021	2020
EYLEA®	U.S.	$ 6,264.6	$ 5,792.3	$ 4,947.2
Libtayo®[a]	U.S.	374.5	306.3	270.7
	ROW[b]	73.0	—	—
Praluent®[c]	U.S.	130.0	170.0	150.9
REGEN-COV®[d]	U.S.	—	5,828.0	185.7
Evkeeza®	U.S.	48.6	18.4	—
Inmazeb®	U.S.	3.0	—	—
ARCALYST®[e]	U.S.	—	2.2	13.1
		$ 6,893.7	$ 12,117.2	$ 5,567.6

[a] Prior to July 1, 2022, Regeneron recorded net product sales of Libtayo in the United States and Sanofi recorded net product sales of Libtayo outside the United States. Effective July 1, 2022, the Company records global net product sales of Libtayo. See Note 3 for further details.

[b] Rest of world ("ROW")

[c] Effective April 1, 2020, the Company became solely responsible for the development and commercialization of Praluent in the United States and records net product sales of Praluent in the United States. Previously, Sanofi recorded net product sales of Praluent in the United States. See Note 3 for further details.

[d] Net product sales of REGEN-COV in the United States relate to product sold in connection with the Company's agreements with the U.S. government. See Note 3 for further details.

[e] Effective April 1, 2021, Kiniksa records net product sales of ARCALYST in the United States. Previously, the Company recorded net product sales of ARCALYST in the United States.

As of December 31, 2022 and 2021, the Company had $3.586 billion and $5.059 billion, respectively, of trade accounts receivable that were recorded within Accounts receivable, net.

The Company had product sales to certain customers that accounted for more than 10% of total gross product revenue for each of the years ended December 31, 2022, 2021, and 2020. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Year Ended December 31, 2022	2021	2020
Besse Medical, a subsidiary of AmerisourceBergen Corporation	55 %	30 %	51 %
McKesson Corporation	28 %	18 %	32 %
U.S. government	*	43 %	*

* Sales to the U.S. government represented less than 10% of total gross product revenue during the period

Revenue from product sales is recorded net of applicable provisions for rebates, chargebacks, and discounts, distribution-related fees, and other sales-related deductions. Accruals for chargebacks and discounts are recorded as a direct reduction to accounts receivable. Accruals for rebates, distribution-related fees, and other sales-related deductions are recorded within accrued liabilities. The following table summarizes the provisions, and credits/payments, for sales-related deductions.

(In millions)	Rebates, Chargebacks, and Discounts	Distribution-Related Fees	Other Sales-Related Deductions	Total
Balance as of December 31, 2019	$ 80.3	$ 46.4	$ 29.4	$ 156.1
Provisions	762.9	279.9	94.1	1,136.9
Credits/payments	(641.0)	(249.1)	(78.7)	(968.8)
Balance as of December 31, 2020	202.2	77.2	44.8	324.2
Provisions	1,047.1	363.6	150.4	1,561.1
Credits/payments	(1,034.7)	(360.8)	(127.6)	(1,523.1)
Balance as of December 31, 2021	214.6	80.0	67.6	362.2
Provisions	1,537.3	431.1	141.1	2,109.5
Credits/payments	(1,398.0)	(399.7)	(127.2)	(1,924.9)
Balance as of December 31, 2022	$ 353.9	$ 111.4	$ 81.5	$ 546.8

3. Collaboration, License, and Other Agreements

a. Sanofi

Amounts recognized in the Company's Statements of Operations in connection with its collaborations with Sanofi are detailed below:

(In millions)	Statement of Operations Classification	Year Ended December 31, 2022	2021	2020
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	Sanofi collaboration revenue	$ 2,082.0 *	$ 1,363.0	$ 785.2
Sales-based milestones earned	Sanofi collaboration revenue	$ 100.0	$ 50.0	$ 50.0
Reimbursement for manufacturing of commercial supplies	Sanofi collaboration revenue	$ 633.7	$ 488.8	$ 368.0
Other	Sanofi collaboration revenue	$ 28.7	$ —	$ —
Reimbursements of R&D expenses, net of Regeneron's obligation for its share of Sanofi R&D expenses	Reduction of R&D expense	$ 43.0	$ 129.2	$ 149.1
Reimbursement of commercialization-related expenses	Reduction of SG&A expense	$ 437.4	$ 320.5	$ 359.4
Immuno-oncology**:				
Regeneron's share of profits (losses) in connection with commercialization of Libtayo outside the United States	Sanofi collaboration revenue	$ 6.7	$ (13.6)	$ (25.7)
Reimbursement for manufacturing of ex-U.S. commercial supplies	Sanofi collaboration revenue	$ 4.6	$ 14.0	$ 8.9
Reimbursement of R&D expenses	Reduction of R&D expense	$ 42.7	$ 85.1	$ 166.2
Reimbursement of commercialization-related expenses	Reduction of SG&A expense	$ 41.4	$ 89.6	$ 64.7
Regeneron's obligation for its share of Sanofi commercial expenses	SG&A expense	$ (19.9)	$ (36.3)	$ (22.4)
Regeneron's obligation for Sanofi's share of Libtayo U.S. gross profits	Cost of goods sold	$ (70.1)	$ (133.0)	$ (119.1)
Amounts recognized in connection with up-front payments received	Other operating income	$ 35.1	$ 6.1	$ 210.6

* Net of one-time payment of $56.9 million to Sanofi in connection with the amendment to the Antibody License and Collaboration Agreement

** As described within the "*Immuno-Oncology*" section below, effective July 1, 2022, the Company obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide

Antibody

The Company is party to a global, strategic collaboration with Sanofi to research, develop, and commercialize fully human monoclonal antibodies (the "Antibody Collaboration"), which currently consists of Dupixent® (dupilumab), Kevzara® (sarilumab), and itepekimab.

Under the terms of the Antibody License and Collaboration Agreement (the "LCA"), Sanofi is generally responsible for funding 80% to 100% of agreed-upon development costs. The Company is obligated to reimburse Sanofi for 30% to 50% of worldwide development expenses that were funded by Sanofi based on the Company's share of collaboration profits from commercialization of collaboration products. Under the terms of the LCA, the Company was required to apply 10% of its share of the profits from the Antibody Collaboration in any calendar quarter to reimburse Sanofi for these development costs. On July 1, 2022, an amendment to the LCA became effective, pursuant to which the percentage of the Company's share of profits used to reimburse Sanofi for such development costs increased from 10% to 20%. A portion of the value associated with the increase in reimbursement percentage was deemed to be contingent consideration attributable to the Company's acquisition of the Libtayo rights described within the "*Immuno-Oncology*" section below; this portion will be recorded as an increase to the Libtayo intangible asset over time as the Company repays such development costs to Sanofi. The Company's contingent reimbursement

obligation (development balance) to Sanofi under the Antibody Collaboration was approximately $2.864 billion as of December 31, 2022.

Sanofi leads commercialization activities for products under the Antibody Collaboration, subject to the Company's right to co-commercialize such products. The Company co-commercializes Dupixent in the United States and in certain countries outside the United States. The parties equally share profits and losses from sales within the United States. The parties share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (Regeneron) and ending at 55% (Sanofi)/45% (Regeneron), and losses outside the United States at 55% (Sanofi)/45% (Regeneron).

In addition to profit and loss sharing, the Company is entitled to receive sales milestone payments from Sanofi. In each of 2020 and 2021, the Company earned a $50.0 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding $1.0 billion and $1.5 billion, respectively, on a rolling twelve-month basis. In 2022, the Company earned two additional $50.0 million sales-based milestones from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding $2.0 billion and $2.5 billion, respectively, on a rolling twelve-month basis. The Company is entitled to receive the final sales milestone payment of $50.0 million when such sales outside the United States exceed $3.0 billion on a rolling twelve-month basis.

The Company's significant promised goods and services in connection with the Antibody Collaboration consist of providing research and development services, including the manufacturing of clinical supplies; and providing commercial-related services, including the manufacturing of commercial supplies. The Company recognizes amounts in connection with the Antibody Collaboration based on the amount it has the right to invoice and such amount corresponds directly with the Company's performance to date; therefore, the Company does not disclose the value of the transaction price (i.e., the amount of consideration the Company expects to be entitled to) allocated to its remaining unsatisfied obligations.

The following table summarizes contract balances in connection with the Company's Antibody Collaboration with Sanofi:

	As of December 31,	
(In millions)	**2022**	**2021**
Accounts receivable, net	$ 692.3	$ 504.8
Deferred revenue	$ 415.8	$ 368.7

In April 2020, the Company and Sanofi entered into an amendment to the LCA in connection with, among other things, the removal of Praluent from the LCA such that (i) effective April 1, 2020, the LCA no longer governs the development, manufacture, or commercialization of Praluent and (ii) the quarterly period ended March 31, 2020 was the last quarter for which Sanofi and the Company shared profits and losses for Praluent under the LCA. The parties also entered into a Praluent Cross License & Commercialization Agreement (the "Praluent Agreement") pursuant to which, effective April 1, 2020, the Company, at its sole cost, became solely responsible for the development and commercialization of Praluent in the United States, and Sanofi, at its sole cost, became solely responsible for the development and commercialization of Praluent outside of the United States. Under the Praluent Agreement, Sanofi pays the Company a 5% royalty on Sanofi’s net product sales of Praluent outside the United States until March 31, 2032. The Company does not owe Sanofi royalties on the Company’s net product sales of Praluent in the United States. Although each party is responsible for manufacturing Praluent for its respective territory, the parties have entered into definitive supply agreements under which, for a certain transitional period, the Company continues to supply drug substance to Sanofi and Sanofi continues to supply finished product to Regeneron. With respect to any intellectual property or product liability litigation relating to Praluent, the parties have agreed that, effective April 1, 2020, Regeneron and Sanofi each are solely responsible for any such litigation (including damages and other costs and expenses thereof) in the United States and outside the United States, respectively, arising out of Praluent sales or other activities on or after April 1, 2020 (subject to Sanofi's right to set off a portion of any third-party royalty payments resulting from certain patent litigation proceedings against up to 50% of any Praluent royalty payment owed to Regeneron). The parties each bear 50% of any damages arising out of Praluent sales or other activities prior to April 1, 2020. See Note 16 for discussion of legal proceedings related to Praluent.

Immuno-Oncology

The Company was previously a party to a collaboration with Sanofi for antibody-based cancer treatments in the field of immuno-oncology (the "IO Collaboration"). The IO Collaboration was governed by an Amended and Restated Immuno-oncology Discovery and Development Agreement ("Amended IO Discovery Agreement"), and an Immuno-oncology License and Collaboration Agreement ("IO License and Collaboration Agreement"). In connection with the execution of the original Immuno-oncology Discovery and Development Agreement in 2015 ("2015 IO Discovery Agreement"), which was subsequently replaced by the Amended IO Discovery Agreement (as discussed below), Sanofi made a $265.0 million non-refundable up-front payment to the Company. Pursuant to the 2015 IO Discovery Agreement, the Company was to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof-of-concept.

Effective December 31, 2018, the Company and Sanofi entered into the Amended IO Discovery Agreement, which narrowed the scope of the existing discovery and development activities conducted by the Company under the 2015 IO Discovery Agreement to developing therapeutic bispecific antibodies targeting (i) BCMA and CD3 and (ii) MUC16 and CD3 through clinical proof-of-concept. During the first quarter of 2021, Sanofi did not exercise its options to license rights to these product candidates; as a result, the Company retains the exclusive right to develop and commercialize such product candidates and Sanofi will receive a royalty on sales (if any). In addition, the Company has no further obligations to develop drug product candidates under the Amended IO Discovery Agreement.

In connection with the execution of the IO License and Collaboration Agreement in 2015, Sanofi made a $375.0 million non-refundable up-front payment to the Company. Under the terms of the IO License and Collaboration Agreement, the parties were co-developing and co-commercializing Libtayo. The parties shared equally, on an ongoing basis, development and commercialization expenses for Libtayo. The Company had principal control over the development of Libtayo and led commercialization activities in the United States, while Sanofi led commercialization activities outside of the United States. The parties shared equally in profits and losses in connection with the commercialization of Libtayo.

Effective July 1, 2022, the Company obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide under an Amended and Restated Immuno-oncology License and Collaboration Agreement with Sanofi (the "A&R IO LCA"). In connection with the A&R IO LCA, in 2022, the Company made a $900.0 million up-front payment to Sanofi, as well as a $100.0 million regulatory milestone payment. In addition, Sanofi earned a $65.0 million sales-based milestone upon the achievement of a specified amount of worldwide net product sales of Libtayo in 2022, and is eligible to receive an additional $35.0 million sales-based milestone upon the achievement of a specified amount of worldwide net product sales of Libtayo in 2023 (aggregate of $100.0 million in sales-based milestones eligible to be earned under the terms of the A&R IO LCA). The Company also pays Sanofi an 11% royalty on net product sales of Libtayo through March 31, 2034. The transaction was accounted for as an asset acquisition and amounts paid to Sanofi in connection with obtaining the worldwide rights to Libtayo, including the up-front payment and any contingent consideration, are recorded as an intangible asset. See Note 8 for additional information related to the intangible asset recorded in connection with the transaction.

In accordance with the Amended IO Discovery Agreement, the Company was obligated to reimburse Sanofi for half of the development costs it funded that were attributable to clinical development of product candidates from the Company's share of profits from commercialized IO Collaboration products. Under the A&R IO LCA, the amount of development costs incurred under the IO Collaboration for which the Company was obligated to reimburse Sanofi was $35.0 million as of the effective date of the A&R IO LCA, and the Company pays Sanofi a 0.5% royalty on net product sales of Libtayo until all such development costs have been reimbursed by Regeneron.

The following table summarizes contract balances in connection with the Company's IO Collaboration with Sanofi:

	As of December 31,	
(In millions)	**2022**	**2021**
Accounts receivable, net	$ —	$ (22.5)
Deferred revenue	$ —	$ 16.0
Other liabilities	$ —	$ 276.1

Other liabilities included up-front payments received from Sanofi for which recognition had been deferred. Such amounts were being recognized over the remaining period in which the Company was obligated to perform development activities. In connection with the A&R IO LCA described above, the remaining IO Collaboration Other liabilities balance of $241.0 million as of July 1, 2022 was recognized as a reduction to the intangible asset during the third quarter of 2022.

During 2021, the Company updated its estimate of the total research and development costs expected to be incurred (which resulted in a change to the estimate of the stage of completion) in connection with the IO Collaboration, and, as a result, recorded a cumulative catch-up adjustment of $66.9 million as a reduction to other operating income. During 2020, the Company updated its estimate of the total research and development costs expected to be incurred (which resulted in a change to the estimate of the stage of completion) in connection with the IO Collaboration, and, as a result, recorded a cumulative catch-up adjustment of $135.4 million as an increase to other operating income.

b. Bayer

The Company is party to a license and collaboration agreement with Bayer for the global development and commercialization of EYLEA (aflibercept) and aflibercept 8 mg outside the United States. Agreed-upon development expenses incurred by the Company and Bayer are generally shared equally. The Company is also obligated to use commercially reasonable efforts to supply clinical and commercial bulk product.

Within the United States, the Company is responsible for commercialization and retains profits from such sales. Bayer markets EYLEA outside the United States and the companies share equally in profits and losses from sales. In Japan, the Company was entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net product sales through 2021, and effective January 1, 2022, the companies share equally in profits and losses from sales in Japan. The Company is obligated to reimburse Bayer out of its share of the collaboration profits for 50% of the agreed-upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option. The Company's contingent reimbursement obligation to Bayer was approximately $273 million as of December 31, 2022.

Amounts recognized in the Company's Statements of Operations in connection with its Bayer collaboration are as follows:

(In millions)	Statement of Operations Classification	Year Ended December 31, 2022	2021	2020
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	Other collaboration revenue	$ 1,317.4	$ 1,349.2	$ 1,107.9
Reimbursement for manufacturing of ex-U.S. commercial supplies	Other collaboration revenue	$ 91.4	$ 60.1	$ 78.2
One-time payment in connection with change in Japan arrangement	Other collaboration revenue	$ 21.9	$ —	$ —
Reimbursement of R&D expenses	Reduction of R&D expense	$ 51.0	$ 46.1	$ 46.7
Regeneron's obligation for its share of Bayer R&D expenses	R&D expense	$ (34.3)	$ (40.9)	$ (35.8)

The following table summarizes contract balances in connection with the Company's Bayer collaboration:

(In millions)	As of December 31, 2022	2021
Accounts receivable, net	$ 348.2	$ 355.5
Deferred revenue	$ 131.9	$ 129.4

c. Intellia

In 2016, the Company entered into a license and collaboration agreement with Intellia Therapeutics, Inc. to advance CRISPR/Cas9 gene-editing technology for *in vivo* therapeutic development. The parties collaborate to conduct research for the discovery, development, and commercialization of new therapies, in addition to the research and technology development of the CRISPR/Cas9 platform.

Under the terms of the 2016 agreement, the parties agreed to a target selection process, whereby the Company may obtain exclusive rights in up to 10 targets to be chosen by the Company during the collaboration term, subject to various adjustments and limitations set forth in the agreement. Certain targets that either the Company or Intellia selects pursuant to the target selection process may be subject to a co-development and co-commercialization arrangement at the Company's option or Intellia's option, as applicable.

In 2020, the Company expanded its existing collaboration with Intellia to provide the Company with rights to develop products for additional *in vivo* CRISPR/Cas9-based therapeutic targets and for the parties to jointly develop potential products for the treatment of hemophilia A and B. In addition, the Company also received non-exclusive rights to independently develop and commercialize *ex vivo* gene edited products. In connection with the agreement, in 2020, the Company made a $70.0 million up-front payment and purchased shares of Intellia common stock for an aggregate purchase price of $30.0 million. The up-front payment and the amount paid in excess of the fair market value of the shares purchased, or $15.0 million, were recorded to Acquired in-process research and development expense.

d. U.S. Government

In 2020, the Company expanded its Other Transaction Agreement with the Biomedical Advanced Research Development Authority ("BARDA"), pursuant to which the U.S. Department of Health and Human Services ("HHS") was obligated to fund certain of the Company's costs incurred for research and development activities related to COVID-19 treatments. In 2020, the Company also entered into an agreement with entities acting at the direction of BARDA and the U.S. Department of Defense to manufacture and deliver filled and finished drug product of REGEN-COV to the U.S. government. The agreement, as subsequently amended, provided for payments to the Company of up to $465.9 million in the aggregate for bulk manufacturing of the drug substance, as well as fill/finish, storage, and other activities.

In January 2021, the Company entered into an agreement with the U.S. Department of Defense and HHS to manufacture and deliver additional filled and finished drug product of REGEN-COV to the U.S. government. Pursuant to the agreement, the U.S. government was obligated to purchase 1.25 million doses of drug product, which the Company delivered by June 30, 2021, resulting in payments to the Company of $2.625 billion.

In September 2021, the Company entered into an amendment to its January 2021 agreement to supply the U.S. government with an additional 1.4 million doses of REGEN-COV. Pursuant to the agreement, the U.S. government was obligated to purchase all filled and finished doses of such additional drug product delivered by January 31, 2022, resulting in payments to the Company of $2.940 billion in the aggregate. Roche supplied a portion of the doses to Regeneron to fulfill the Company's agreement with the U.S. government (see "Roche" below for further details regarding the Company's collaboration agreement with Roche).

As of December 31, 2021, the Company had completed its final deliveries of drug product under the agreements described above. See Note 2 for REGEN-COV net product sales recognized during the years ended December 31, 2021 and 2020 in connection with these agreements.

e. Roche

In 2020, the Company entered into a collaboration agreement (the "Roche Collaboration Agreement") with Roche to develop, manufacture, and distribute the casirivimab and imdevimab antibody cocktail (known as REGEN-COV in the United States and Ronapreve™ in other countries). Under the terms of the collaboration agreement, the Company leads global development activities for REGEN-COV, and the parties jointly fund certain studies. The Company has the right to distribute the product in the United States and Roche has the right to distribute the product outside of the United States. The parties share gross profits from worldwide sales based on a pre-specified formula, depending on the amount of manufactured product supplied by each party to the market. Each quarter, a single payment is due from one party to the other to true-up the global gross profits between the parties. If Regeneron is to receive a true-up payment from Roche, such amount will be recorded to Other collaboration revenue. If Regeneron is to make a true-up payment to Roche, such amount will be recorded to Cost of goods sold.

Amounts recognized in the Company's Statements of Operations in connection with the Roche Collaboration Agreement are as follows:

(In millions)	**Statement of Operations Classification**	**Year Ended December 31,**		
		2022	**2021**	**2020**
Global gross profit payment from Roche in connection with sales of REGEN-COV and Ronapreve	Other collaboration revenue	$ 627.3	$ 361.8	$ —
Reimbursement of R&D expenses	Reduction of R&D expense	$ 6.8	$ 128.1	$ 78.5
Global gross profit payment to Roche in connection with sales of REGEN-COV and Ronapreve	Cost of goods sold	$ —	$ 259.6	$ —

The following table summarizes contract balances in connection with the Roche Collaboration Agreement:

(In millions)	**As of December 31,**	
	2022	**2021**
Accounts receivable, net	$ 396.6	$ —
Accrued expenses and other current liabilities	$ —	$ 268.8

f. Alnylam

In 2018, the Company and Alnylam Pharmaceuticals, Inc. entered into a collaboration to discover RNA interference ("RNAi") therapeutics for nonalcoholic steatohepatitis ("NASH") and potentially other related diseases, as well as to research, co-develop and commercialize any therapeutic product candidates that emerge from these discovery efforts (including ALN-HSD, which is currently in clinical development). Under the terms of the collaboration agreement, the parties share development costs equally. During the fourth quarter of 2022, Alnylam elected to opt-out of further development activities related to ALN-HSD; as a result, the Company retains the exclusive right to develop and commercialize such product and Alnylam will receive a royalty on sales (if any).

In 2019, the Company and Alnylam entered into a global, strategic collaboration to discover, develop, and commercialize RNA interference therapeutics for a broad range of diseases by addressing therapeutic disease targets expressed in the eye and central nervous system ("CNS"), in addition to a select number of targets expressed in the liver. In connection with the collaboration, the Company made an up-front payment of $400.0 million to Alnylam, and also purchased shares of Alnylam common stock for $400.0 million. For each program, the Company provides Alnylam with a specified amount of funding at program initiation and at lead candidate designation, and Alnylam is eligible to receive up to an aggregate of $200.0 million in clinical proof-of-principle milestones for eye and CNS programs.

Under the collaboration, the parties plan to perform discovery research until designation of lead candidates. Following designation of a lead candidate, the parties may further advance such lead candidate under either a co-development/co-commercialization collaboration agreement ("Co-Co Collaboration Agreement") (under which the parties are advancing ALN-APP and ALN-PNP, which are currently in clinical development) or License Agreement structure. The initial target nomination and discovery period is five years (which may under certain situations automatically be extended for up to seven years in the aggregate) (the "Research Term"). In addition, the Company has an option to extend the Research Term for an additional five-year period for a research extension fee ranging from $200.0 million to $400.0 million; the actual amount of the fee will be determined based on the acceptance of one or more Investigational New Drug Applications ("INDs") (or their equivalent in certain other countries) for programs in the eye and CNS.

In addition, during 2019, the parties entered into a Co-Co Collaboration Agreement for cemdisiran, a small interfering RNA ("siRNA") therapeutic targeting the C5 component of the human complement pathway being developed by Alnylam, with Alnylam as the lead party, and a License Agreement for a combination consisting of cemdisiran and a fully human monoclonal antibody targeting C5 being developed by the Company (pozelimab), with the Company as the licensee. Under the C5 siRNA Co-Co Collaboration Agreement, the parties shared costs equally and under the License Agreement, the Company as the licensee is responsible for its own costs and expenses. The C5 siRNA License Agreement contains a flat low double-digit royalty payable to Alnylam on potential future net sales of the combination only subject to customary reductions, as well as up to $325.0 million in sales milestones.

During the fourth quarter of 2022, the Company elected to opt-out of further development activities pursuant to the Co-Co Collaboration Agreement for cemdisiran as a monotherapy; as a result, Alnylam retains the right to develop and commercialize such product and the Company will receive a royalty on sales (if any).

Amounts recognized in the Company's Statements of Operations in connection with the Alnylam agreements described above were not material for the years ended December 31, 2022, 2021, and 2020. In addition, contract balances in the Company's Balance Sheets were not material as of December 31, 2022 and 2021.

g. Checkmate

In May 2022, the Company completed its acquisition of Checkmate Pharmaceuticals, Inc. (“Checkmate”) for a total equity value of approximately $250 million. The Company made an assessment as to whether the set of assets acquired constituted a business and should be accounted for as a business combination. Given that substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset, vidutolimod, which is in clinical development for oncology, the transaction was accounted for as an asset acquisition. As a result of the acquisition, the Company recorded (i) a charge of $ 195.0 million to Acquired in-process research and development and (ii) net assets of $35.3 million, net of cash, related to the assets acquired (including deferred tax assets and investments) and liabilities assumed.

h. Teva

The Company and Teva are parties to a collaboration agreement (the "Teva Collaboration Agreement") to develop and commercialize fasinumab globally, excluding certain Asian countries that are subject to the Company's collaboration agreement with Mitsubishi Tanabe Pharma Corporation. Under the terms of the Teva Collaboration Agreement, the Company led global development activities and the parties share development costs equally.

In connection with the agreement, Teva made a $250.0 million non-refundable up-front payment in 2016, and as of December 31, 2022, the Company had received an aggregate $120.0 million of development milestones from Teva.

Amounts recognized in the Company's Statements of Operations in connection with the Teva Collaboration Agreement are as follows:

(In millions)	Statement of Operations Classification	Year Ended December 31, 2022	2021	2020
Amounts recognized in connection with up-front and development milestone payments received	Other operating income	$ 33.3	$ 26.2	$ 47.2

In addition, the Company recognized reimbursement of R&D expenses (as a reduction of R&D expense) of $42.4 million and $109.4 million for the years ended December 31, 2021 and 2020, respectively. Such amount was not material for the year ended December 31, 2022.

The following table summarizes contract balances in connection with the Teva Collaboration Agreement:

(In millions)	As of December 31, 2022	2021
Accounts receivable, net	$ 1.6	$ 11.0
Other liabilities	$ —	$ 39.7

Other liabilities included up-front and development milestone payments received from Teva for which recognition had been deferred. During 2022, the Company discontinued further clinical development of fasinumab and, as a result, recorded $31.9 million as an increase to Other operating income as the Company deemed its obligation to provide development services in connection with the Teva Collaboration Agreement to be complete.

i. Other

In addition to the collaboration agreements discussed above, the Company has various other collaboration agreements that are not individually significant to its operating results or financial condition at this time. Pursuant to the terms of those agreements, the Company may be required to pay, or it may receive, additional amounts contingent upon the occurrence of various future events (e.g., upon the achievement of various development and commercial milestones) which in the aggregate could be significant. The Company may also incur, or get reimbursed for, significant research and development costs. In addition, if any products related to these collaborations are approved for sale, the Company may be required to pay, or it may receive, royalties on future sales. The payment or receipt of these amounts, however, is contingent upon the occurrence of various future events.

4. Marketable Securities

Marketable securities as of December 31, 2022 and 2021 consist of both available-for-sale debt securities of investment grade issuers (see below and Note 5) as well as equity securities of publicly traded companies (see Note 5).

The following tables summarize the Company's investments in available-for-sale debt securities:

(In millions)	Amortized	Unrealized		Fair
As of December 31, 2022	**Cost Basis**	**Gains**	**Losses**	**Value**
Corporate bonds	$ 6,975.5	$ —	$ (291.1)	$ 6,684.4
U.S. government and government agency obligations	2,945.4	0.9	(6.9)	2,939.4
Sovereign bonds	67.1	—	(3.0)	64.1
Commercial paper	121.1	—	—	121.1
Certificates of deposit	182.1	—	(0.1)	182.0
Asset-backed securities	28.9	—	(1.7)	27.2
	$ 10,320.1	$ 0.9	$ (302.8)	$ 10,018.2
As of December 31, 2021				
Corporate bonds	$ 7,518.4	$ 10.2	$ (40.9)	$ 7,487.7
U.S. government and government agency obligations	109.0	0.3	(0.8)	108.5
Sovereign bonds	64.4	0.3	(0.3)	64.4
Commercial paper	439.7	—	(0.1)	439.6
Certificates of deposit	255.2	—	(0.1)	255.1
Asset-backed securities	42.0	—	(0.1)	41.9
	$ 8,428.7	$ 10.8	$ (42.3)	$ 8,397.2

The Company classifies its investments in available-for-sale debt securities based on their contractual maturity dates. The available-for-sale debt securities listed as of December 31, 2022 mature at various dates through April 2028. The fair values of available-for-sale debt securities by contractual maturity consist of the following:

	As of December 31,	
(In millions)	**2022**	**2021**
Maturities within one year	$ 4,636.4	$ 2,809.1
Maturities after one year through five years	5,381.4	5,588.1
Maturities after five years	0.4	—
	$ 10,018.2	$ 8,397.2

The following table shows the fair value of the Company's available-for-sale debt securities that have unrealized losses, aggregated by investment category and length of time that the individual securities have been in a continuous loss position.

(In millions)	Less than 12 Months		12 Months or Greater		Total	
As of December 31, 2022	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Corporate bonds	$ 2,445.4	$ (73.1)	$ 4,200.4	$ (218.0)	$ 6,645.8	$ (291.1)
U.S. government and government agency obligations	785.2	(2.0)	71.0	(4.9)	856.2	(6.9)
Sovereign bonds	18.6	(1.1)	45.6	(1.9)	64.2	(3.0)
Certificates of deposit	40.2	(0.1)	—	—	40.2	(0.1)
Asset-backed securities	11.5	(0.6)	15.2	(1.1)	26.7	(1.7)
	$ 3,300.9	$ (76.9)	$ 4,332.2	$ (225.9)	$ 7,633.1	$ (302.8)
As of December 31, 2021						
Corporate bonds	$ 5,889.3	$ (40.9)	$ —	$ —	$ 5,889.3	$ (40.9)
U.S. government and government agency obligations	90.0	(0.8)	—	—	90.0	(0.8)
Sovereign bonds	37.0	(0.3)	—	—	37.0	(0.3)
Commercial paper	295.7	(0.1)	—	—	295.7	(0.1)
Certificates of deposit	169.4	(0.1)	—	—	169.4	(0.1)
Asset-backed securities	34.9	(0.1)	—	—	34.9	(0.1)
	$ 6,516.3	$ (42.3)	$ —	$ —	$ 6,516.3	$ (42.3)

The unrealized losses on corporate bonds as of December 31, 2022 were primarily driven by increases in interest rates. The Company has reviewed its portfolio of available-for-sale debt securities and determined that the decline in fair value below cost did not result from credit-related factors. In addition, the Company does not intend to sell, and it is not more likely than not that the Company will be required to sell, such securities before recovery of their amortized cost bases.

With respect to marketable securities, for the years ended December 31, 2022, 2021, and 2020, amounts reclassified from Accumulated other comprehensive income (loss) into Other income (expense), net were related to realized gains and losses on sales of available-for-sale debt securities.

Realized gains and losses on sales of marketable securities were not material for the years ended December 31, 2022, 2021, and 2020. Interest income of $160.1 million, $45.8 million, and $75.4 million for the years ended December 31, 2022, 2021, and 2020, respectively, was recognized in Other income (expense), net.

5. Fair Value Measurements

The table below summarizes the Company's assets which are measured at fair value on a recurring basis. The following fair value hierarchy is used to classify assets, based on inputs to valuation techniques utilized to measure fair value:

- Level 1 - Quoted prices in active markets for identical assets
- Level 2 - Significant other observable inputs, such as quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, or model-based valuations in which significant inputs used are observable
- Level 3 - Significant other unobservable inputs

(In millions)		Fair Value Measurements at Reporting Date	
As of December 31, 2022	**Fair Value**	**Level 1**	**Level 2**
Available-for-sale debt securities:			
Corporate bonds	$ 6,684.4	$ —	$ 6,684.4
U.S. government and government agency obligations	2,939.4	—	2,939.4
Sovereign bonds	64.1	—	64.1
Commercial paper	121.1	—	121.1
Certificates of deposit	182.0	—	182.0
Asset-backed securities	27.2	—	27.2
Equity securities (unrestricted)	24.6	24.6	—
Equity securities (restricted)	1,185.4	1,185.4	—
	$ 11,228.2	$ 1,210.0	$ 10,018.2
As of December 31, 2021			
Available-for-sale debt securities:			
Corporate bonds	$ 7,487.7	$ —	$ 7,487.7
U.S. government and government agency obligations	108.5	—	108.5
Sovereign bonds	64.4	—	64.4
Commercial paper	439.6	—	439.6
Certificates of deposit	255.1	—	255.1
Asset-backed securities	41.9	—	41.9
Equity securities (unrestricted)	58.4	58.4	—
Equity securities (restricted)	1,191.5	1,191.5	—
	$ 9,647.1	$ 1,249.9	$ 8,397.2

The Company held certain restricted equity securities as of December 31, 2022 which are subject to transfer restrictions that expire at various dates through 2024.

During the year ended December 31, 2022, the Company recorded $39.8 million of net unrealized losses on equity securities in Other income (expense), net. During the years ended December 31, 2021 and 2020, the Company recorded $386.1 million, and $196.0 million, respectively, of net unrealized gains on equity securities in Other income (expense), net.

In addition to the investments summarized in the table above, as of December 31, 2022 and 2021, the Company had $48.3 million and $40.0 million, respectively, in equity investments that do not have a readily determinable fair value. These investments are recorded within Other noncurrent assets.

The fair value of the Company's long-term debt (see Note 10), which was determined based on Level 2 inputs, was estimated to be $1.443 billion and $1.887 billion as of December 31, 2022 and 2021, respectively.

6. Inventories

Inventories consist of the following:

	As of December 31,	
(In millions)	**2022**	**2021**
Raw materials	$ 818.4	$ 721.9
Work-in-process	963.1	707.2
Finished goods	98.6	73.7
Deferred costs	521.8	448.5
	$ 2,401.9	$ 1,951.3

Inventory balances in the table above are net of reserves of $720.7 million and $510.0 million as of December 31, 2022 and 2021, respectively. Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred. For the years ended December 31, 2022 and 2021, Cost of goods sold included inventory write-offs and reserves of $258.7 million and $457.1 million, respectively, primarily related to REGEN-COV. Inventory write-offs and reserves for the year ended December 31, 2020 were not material.

7. Property, Plant, and Equipment

Property, plant, and equipment consists of the following:

	As of December 31,	
(In millions)	**2022**	**2021**
Land	$ 264.5	$ 248.0
Building and improvements	2,270.0	2,088.5
Leasehold improvements	114.3	113.9
Construction in progress	980.5	767.7
Laboratory equipment	1,315.3	1,225.5
Computer equipment and software	337.4	291.5
Furniture, office equipment, and other	150.2	145.2
	5,432.2	4,880.3
Less, accumulated depreciation and amortization	(1,669.2)	(1,398.1)
	$ 3,763.0	$ 3,482.2

Property, plant, and equipment in the table above includes leased property under the Company's finance lease at its Tarrytown, New York facility. See Note 11.

Depreciation and amortization expense on property, plant, and equipment was $303.9 million, $281.1 million, and $230.8 million for the years ended December 31, 2022, 2021, and 2020, respectively.

As of December 31, 2022 and 2021, $2.960 billion and $2.684 billion, respectively, of the Company's net property, plant, and equipment was located in the United States and $803.0 million and $797.8 million, respectively, was located outside the United States (primarily in Ireland).

8. Intangible Assets

Intangible assets consist of the following:

		As of December 31,					
		2022			2021		
(In millions)	Estimated Useful Life	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquired product rights - Libtayo	13 years	$ 946.3	$ (35.7)	$ 910.6	$ —	$ —	$ —
Other intangibles	5–8 years	10.0	(5.1)	4.9	29.3	(22.6)	6.7
Intangible assets, net		$ 956.3	$ (40.8)	$ 915.5	$ 29.3	$ (22.6)	$ 6.7

As described in Note 3, the Company recorded an intangible asset in connection with obtaining the exclusive right to develop, commercialize, and manufacture Libtayo worldwide. The intangible asset recognized upon the effective date of the A&R IO LCA primarily consisted of the $900.0 million up-front payment, offset by the remaining IO Collaboration Other liabilities balance of $241.0 million. During the year ended December 31, 2022, the Company recorded additions to the Libtayo intangible asset primarily related to contingent consideration (including regulatory and sales-based milestones, as described in Note 3) and other amounts due to Sanofi in connection with obtaining the worldwide rights to Libtayo.

Amortization expense on intangible assets was $37.6 million for the year ended December 31, 2022. Amortization expense for the years ended December 31, 2021 and 2020 was not material.

As of December 31, 2022, assuming no changes in the gross carrying amount of intangible assets, amortization expense is estimated to be approximately $72 million for each of the years ending December 31, 2023 through December 31, 2027.

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	As of December 31,	
(In millions)	2022	2021
Accrued payroll and related costs	$ 497.3	$ 440.7
Accrued clinical expenses	295.0	295.8
Accrued sales-related costs	633.6	472.7
Income taxes payable	0.3	326.3
Amounts due to collaborators (see Note 3)	10.5	287.4
Other accrued expenses and liabilities	637.5	383.9
	$ 2,074.2	$ 2,206.8

10. Debt

Credit Facility

In December 2018, the Company entered into an agreement with a syndicate of lenders (the "2018 Credit Agreement") which provided for a $750.0 million senior unsecured five-year revolving credit facility. The 2018 Credit Agreement, which was to mature in December 2023, included an option for the Company to elect to increase the commitments under the Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to $250.0 million, subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions.

In December 2022, the Company entered into an agreement with a syndicate of lenders (the "2022 Credit Agreement") which provides for a $750.0 million senior unsecured five-year revolving credit facility (the "2022 Credit Facility") and replaces the 2018 Credit Agreement, which was contemporaneously terminated. The 2022 Credit Agreement includes an option for the Company to elect to increase the commitments under the 2022 Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to $500.0 million, subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. The 2022 Credit Agreement also provides a $50.0 million sublimit for letters of credit.

As set forth in the 2022 Credit Agreement, the Company has the option to amend the 2022 Credit Agreement to establish environmental, social, and governance targets which will be used to adjust pricing under the 2022 Credit Facility, subject to parameters to be provided in the 2022 Credit Agreement.

Proceeds of the loans under the 2022 Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. Regeneron Pharmaceuticals, Inc. has guaranteed all obligations under the 2022 Credit Facility. The 2022 Credit Agreement includes an option for the Company to elect to extend the maturity date of the 2022 Credit Facility beyond December 2027, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the 2022 Credit Facility may be prepaid, and the commitments under the 2022 Credit Facility may be terminated, at any time without premium or penalty.

The Company had no borrowings outstanding under the 2022 Credit Facility as of December 31, 2022.

The 2022 Credit Agreement contains operating covenants and a maximum total leverage ratio financial covenant. The Company was in compliance with all covenants of the 2022 Credit Agreement as of December 31, 2022.

Senior Notes

In August 2020, the Company issued and sold $1.250 billion aggregate principal amount of senior unsecured notes due 2030 and $750 million aggregate principal amount of senior unsecured notes due 2050 (collectively, the "Notes"). The underwriting discounts and offering expenses are being amortized as additional interest expense over the period from issuance through maturity.

Long-term debt in connection with the Notes, net of underwriting discounts and offering expenses, consists of the following:

	As of December 31,	
(In millions)	**2022**	**2021**
1.750% Senior Notes due September 2030	$ 1,241.0	$ 1,239.9
2.800% Senior Notes due September 2050	740.4	740.1
	$ 1,981.4	$ 1,980.0

Interest on each series of Notes is payable semi-annually in arrears on March 15 and September 15 of each year until their respective maturity dates. Interest expense related to the Notes was $44.3 million, $44.4 million, and $17.6 million for the years ended December 31, 2022, 2021, and 2020, respectively.

The Notes may be redeemed at the Company's option at any time at 100% of the principal amount plus accrued and unpaid interest, and, until a specified period before maturity, a specified make-whole amount. The Notes contain a change-of-control provision that, under certain circumstances, may require the Company to offer to repurchase the Notes at a price equal to 101% of the principal amount plus accrued and unpaid interest. The Notes also contain certain limitations on the Company's ability to incur liens and enter into sale and leaseback transactions, as well as customary events of default.

11. Commitments and Contingencies

See Note 16 for disclosures related to legal contingencies.

a. Leases

The Company conducts certain of its research, development, and administrative activities at leased facilities. The Company also leases vehicles and other assets.

Operating leases

Amounts recognized in the Company's Consolidated Balance Sheets and Statements of Operations included in this report associated with operating leases were not material. Operating lease right-of-use assets are included within Other noncurrent assets, and lease liabilities are included in Accrued expenses and other current liabilities and Other noncurrent liabilities.

Finance leases

In March 2017, the Company entered into a Participation Agreement with BA Leasing BSC, LLC, an affiliate of Banc of America Leasing & Capital LLC ("BAL"), as lessor, and a syndicate of lenders (collectively with BAL, the "Lease Participants"), which provided for $720.0 million of lease financing from the Lease Participants for the acquisition of laboratory and office facilities in Tarrytown, New York (the "Facility"). In March 2017, the Company also entered into a Lease and Remedies Agreement with BAL, pursuant to which the Company leased the Facility from BAL for a five-year term which ended in March 2022.

In March 2022, the Company entered into a Second Amended and Restated Lease and Remedies Agreement (the "Restated Lease") with BAL, as lessor (the "Lessor"), which amends, restates, and extends its lease of the Facility. In March 2022, the Company also entered into a Second Amended and Restated Participation Agreement (the "Restated Participation Agreement") with Bank of America, N.A., as administrative agent, the Lessor, and a syndicate of financial institutions as rent assignees (collectively with the Lessor, the "Participants"), which amends and restates the original Participation Agreement entered into in March 2017.

The original Participation Agreement and certain related agreements were amended and restated in order to, among other things, (i) effect a five-year extension of the original March 2022 maturity date of the $720.0 million lease financing and the end of the term of the Company's lease of the Facility from the Lessor to March 2027, at which time all amounts outstanding thereunder will become due and payable in full, and (ii) modify the rate of the interest or yield that is payable to the Participants. In accordance with the terms of the Restated Lease, the Company continues to pay all maintenance, insurance, taxes, and other costs arising out of the use of the Facility. The Company is also required to make monthly payments of basic rent during the term of the Restated Lease in an amount equal to a variable rate per annum, which was modified in connection with the Restated Lease, to be an adjusted one-month forward-looking term rate based on the Secured Overnight Financing Rate ("SOFR"), plus an applicable margin that varies with the Company's debt rating and total leverage ratio.

The Restated Participation Agreement and Restated Lease include an option for the Company to elect to further extend the maturity date of the Restated Participation Agreement and the term of the Restated Lease for an additional five-year period, subject to the consent of all the Participants and certain other conditions. The Company also has the option prior to the end of the term of the Restated Lease to (a) purchase the Facility by paying an amount equal to the outstanding principal amount of the Participants' advances under the Restated Participation Agreement, all accrued and unpaid yield thereon, and all other outstanding amounts under the Restated Participation Agreement, Restated Lease, and certain related documents or (b) sell the Facility to a third party on behalf of the Lessor.

Consistent with the original lease, the Restated Lease continues to be classified as a finance lease as the Company has the option to purchase the Facility under terms that make it reasonably certain to be exercised. The agreements governing the Restated Lease financing contain financial and operating covenants. Such financial covenants and certain of the operating covenants are substantially similar to the covenants set forth in the Company's $750.0 million 2018 Credit Agreement. The Company was in compliance with all such covenants as of December 31, 2022.

Amounts recognized in the Consolidated Balance Sheet related to the Lease are included in the table below. Other than the Lease described above, the Company had no leases accounted for as finance leases as of December 31, 2022 and 2021.

		As of December 31,	
(In millions)	**Classification**	**2022**	**2021**
Finance lease right-of-use assets	Property, plant, and equipment, net[(a)]	$ 620.3	$ 631.3
Finance lease liabilities	Finance lease liabilities	$ 720.0	$ 719.7

[(a)] Finance lease right-of-use assets were recorded net of accumulated amortization of $119.4 million and $104.9 million as of December 31, 2022 and 2021, respectively.

Finance lease costs consist of the following:

	Year Ended December 31,	
(In millions)	**2022**	**2021**
Amortization of right-of-use assets	$ 14.5	$ 14.4
Interest on lease liabilities	21.6	11.9
	$ 36.1	$ 26.3

Other information related to the Company's finance lease includes the following:

	As of December 31,	
	2022	**2021**
Remaining lease term (in years)	4.2	0.2
Discount rate	4.84%	1.68%

Supplemental information

The following is a maturity analysis of the Company's finance lease liability:

(In millions)	**As of December 31, 2022**
2023	$ 44.9
2024	38.6
2025	31.3
2026	30.7
2027	727.9
Total undiscounted lease payments	873.4
Imputed interest	(153.4)
Total lease liability	$ 720.0

b. Research Collaboration and Licensing Agreements

As part of the Company's research and development efforts, the Company enters into research collaboration and licensing agreements with other companies, universities, and other organizations. These agreements contain varying terms and provisions which include fees to be paid by the Company, services to be provided, and license rights to certain proprietary technology developed under the agreements. Some of these agreements may require the Company to pay additional amounts contingent upon the occurrence of various future events (e.g., upon the achievement of various development and commercial milestones). Additionally, the Company has in-licensed patent and/or technology pursuant to agreements which contain provisions that require the Company to pay royalties, as defined, at rates that range from 0.5% to 12.0%, in the event the Company sells or licenses any proprietary products developed under the respective agreements. The Company also has contingent reimbursement obligations to its collaborators Sanofi and Bayer out of the respective collaboration's profits, if they are sufficient for that purpose. See Note 3 for a more detailed description of collaboration, license, and other agreements.

As described in Note 3, as a result of obtaining worldwide rights to Libtayo, the Company pays Sanofi a royalty on net product sales of Libtayo. In addition, in 2018, the Company and Sanofi entered into a license agreement with Bristol-Myers Squibb Company, E. R. Squibb & Sons, L.L.C., and Ono Pharmaceutical Co., Ltd. to obtain a license under certain patents owned and/or exclusively licensed by one or more of those parties that includes the right to develop and sell Libtayo. Under the agreement, the Company is obligated to pay royalties of 8.0% on worldwide sales of Libtayo through December 31, 2023, and royalties of 2.5% from January 1, 2024 through December 31, 2026. Prior to July 1, 2022, royalties on such sales were shared equally by the Company and Sanofi.

For the years ended December 31, 2022, 2021, and 2020, the Company recorded royalty expense (net of reimbursements from collaborators, as applicable) in Cost of goods sold and Cost of collaboration and contract manufacturing of $84.5 million, $66.9 million, and $56.5 million, respectively, based on product sales under various licensing agreements.

12. Stockholders' Equity

The Company's Restated Certificate of Incorporation, as amended, provides for the issuance of up to 40 million shares of Class A Stock, par value $0.001 per share, and 320 million shares of Common Stock, par value $0.001 per share. Shares of Class A Stock are convertible, at any time, at the option of the holder into shares of Common Stock on a share-for-share basis. Holders of Class A Stock have rights and privileges identical to Common Stockholders except that each share of Class A is entitled to ten votes per share, while each share of Common Stock is entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. Under the Company's Restated Certificate of Incorporation, the Company's board of directors is authorized to issue up to 30 million shares of Preferred Stock, in series, with rights, privileges, and qualifications of each series determined by the board of directors.

Share Repurchase Programs

In November 2019, the Company's board of directors authorized a share repurchase program to repurchase up to $1.0 billion of the Company's Common Stock. The share repurchase program permitted the Company to make repurchases through a variety of methods, including open-market transactions (including pursuant to a trading plan adopted in accordance with Rule 10b5-1 of the Exchange Act), privately negotiated transactions, accelerated share repurchases, block trades, and other transactions in compliance with Rule 10b-18 of the Exchange Act. As of December 31, 2020, the Company had repurchased the entire $1.0 billion it was authorized to repurchase under the program.

In January 2021, the Company's board of directors authorized a share repurchase program to repurchase up to $1.5 billion of the Company's Common Stock. The share repurchase program was approved under terms substantially similar to the November 2019 share repurchase program described above. As of December 31, 2021, the Company had repurchased the entire $1.5 billion of its Common Stock that it was authorized to repurchase under the program.

In November 2021, the Company's board of directors authorized an additional share repurchase program to repurchase up to $3.0 billion of the Company's Common Stock. The share repurchase program was approved under terms substantially similar to the share repurchase programs described above. The program has no time limit and can be discontinued at any time. As of December 31, 2022, $745.2 million remained available for share repurchases under the November 2021 program.

The table below summarizes the shares of the Company's Common Stock it repurchased under the programs and the cost of the shares, which were recorded as Treasury Stock.

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**2020**
Number of shares	3.3	3.0	1.6
Total cost of shares	$ 2,099.8	$ 1,655.0	$ 746.0

In January 2023, the Company's board of directors authorized a new share repurchase program to repurchase up to an additional $3.0 billion of the Company's Common Stock. The share repurchase program was approved under terms substantially similar to the share repurchase programs described above. The program has no time limit and can be discontinued at any time.

Share repurchases may be made from time to time at management’s discretion, and the timing and amount of any such repurchases will be determined based on share price, market conditions, legal requirements, and other relevant factors.

Sanofi Funding of Certain Development Costs

In 2018, the Company and Sanofi entered into an agreement, which, among other things, granted Sanofi a limited waiver of Sanofi's lock-up obligations under the amended and restated investor agreement between the Company and Sanofi in order to allow Sanofi to satisfy its funding obligations with respect to Libtayo development costs and/or certain activities relating to dupilumab and itepekimab incurred in quarterly periods through September 30, 2020 by selling shares of the Company's Common Stock owned by Sanofi. During 2020, Sanofi elected to sell, and the Company elected to purchase, shares of our Common Stock to satisfy Sanofi's funding obligation related to such activities. Consequently, the Company recorded the cost of the shares received, or $135.0 million, as Treasury Stock during 2020.

Additional Stock Purchased from Sanofi

In May 2020, a secondary offering of 13,014,646 shares of the Company's Common Stock (the "Secondary Offering") held by Sanofi was completed. In connection with the Secondary Offering, the Company also purchased 9,806,805 shares directly from Sanofi for an aggregate purchase amount of $5.0 billion (the "Stock Purchase"). As a result of the Secondary Offering and the Stock Purchase, Sanofi disposed of all of its shares of the Company's Common Stock, other than 400,000 shares that it retained as of the closing of the Secondary Offering and the Stock Purchase (a portion of which Sanofi used for the funding of certain development costs described above).

In May 2020, the Company entered into an amendment to the amended and restated investor agreement, which provides, among other things, that following the Secondary Offering and Stock Purchase, the “standstill” provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of the Company, continue to apply pursuant to their terms.

Arrangements with Other Collaborators

In connection with the Company's license and collaboration agreement with Bayer for the joint development and commercialization outside the United States of antibody product candidates to Ang2, Bayer is bound by certain "standstill" provisions, which contractually prohibit Bayer from seeking to influence the control of the Company or acquiring more than 20% of the Company's outstanding shares of Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the fifth anniversary of the termination of the agreement (which will occur on November 1, 2023) or (ii) other specified events.

Further, pursuant to the 2016 Teva Collaboration Agreement, Teva and its affiliates are bound by certain "standstill" provisions, which contractually prohibit them from seeking to directly or indirectly exert control of the Company or acquiring more than 5% of the Company's Class A Stock and Common Stock (taken together). This prohibition will remain in place until the earliest of (i) the fifth anniversary of the expiration or earlier termination of the agreement or (ii) other specified events.

13. Long-Term Incentive Plans

The Company has used long-term incentive plans for the purpose of granting equity awards to employees of the Company, including officers, and non-employees, including non-employee members of the Company's board of directors (collectively, "Participants"). The Participants may receive awards as determined by a committee of independent members of the Company's board of directors or, to the extent authorized by such committee with respect to certain Participants, a duly authorized employee (collectively, the "Committee"). The incentive plan currently used by the Company is the Second Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (the "Second Amended and Restated 2014 Incentive Plan"). It was most recently adopted and approved by the Company's shareholders in 2020. As of the most recent shareholder approval date, the Second Amended and Restated 2014 Incentive Plan provided for the issuance of up to 22.3 million shares of Common Stock in respect of awards. In addition, upon expiration, forfeiture, surrender, exchange, cancellation, or termination of any award previously granted under the Amended and Restated Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (the "Amended and Restated 2014 Incentive Plan"), the Regeneron Pharmaceuticals, Inc. 2014 Long-Term Incentive Plan (the "Original 2014 Incentive Plan"), or the Second Amended and Restated 2000 Long-Term Incentive Plan (the "2000 Incentive Plan"), any shares subject to such award are added to the pool of shares available for grant under the Second Amended and Restated 2014 Incentive Plan.

The awards that may be made under the Second Amended and Restated 2014 Incentive Plan include: (a) incentive stock options and non-qualified stock options, (b) restricted stock awards, (c) shares of phantom stock (also referred to as restricted stock units, which may be time- or performance-based), and (d) other awards. Any award granted may (but is not required to) be subject to vesting based on the attainment by the Company of performance goals pre-established by the Committee.

Stock option awards grant Participants the right to purchase shares of Common Stock at prices determined by the Committee, with exercise prices that are equal to or greater than the average of the high and low market prices of the Company's Common Stock on the date of grant (the "Market Price"). Options vest over a period of time determined by the Committee, generally on a

pro rata basis over a four-year period. The Committee also determines the expiration date of each option. The maximum term of options that have been awarded under the 2000 Incentive Plan, the Original 2014 Incentive Plan, the Amended and Restated 2014 Incentive Plan, and the Second Amended and Restated 2014 Incentive Plan (collectively, the "Incentive Plans") is ten years.

Restricted stock awards grant Participants shares of restricted Common Stock or allow Participants to purchase such shares at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). Should employment terminate, as specified in the Incentive Plans, except as determined by the Committee in its discretion and subject to the applicable Incentive Plan documents, the ownership of any unvested restricted stock awards will be transferred to the Company.

Phantom stock awards provide the Participant the right to receive Common Stock or an amount of cash based on the value of the Common Stock at a future date. The award is subject to such restrictions, if any, as the Committee may impose at the date of grant or thereafter, including a specified period of employment or the achievement of performance goals. Time-based restricted stock units and performance-based restricted stock units are each a type of phantom stock award permitted under the Second Amended and Restated 2014 Incentive Plan.

The Incentive Plans contain provisions that allow for the Committee to provide for the immediate vesting of awards upon a change in control of the Company, as defined in the Incentive Plans.

As of December 31, 2022, there were 15.9 million shares available for future grants under the Second Amended and Restated 2014 Incentive Plan. No additional awards may be made under the 2000 Incentive Plan, the Original 2014 Incentive Plan, or the Amended and Restated 2014 Incentive Plan.

a. Stock Options

Transactions involving stock option awards during 2022 under the Company's Incentive Plans are summarized in the table below.

		Number of Shares *(In millions)*	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term *(In years)*	Intrinsic Value *(In millions)*
Outstanding as of December 31, 2021		18.0	$ 435.56		
2022:	Granted	2.0	$ 705.02		
	Forfeited	(0.4)	$ 500.26		
	Exercised	(4.0)	$ 382.66		
Outstanding as of December 31, 2022		15.6	$ 481.62	6.3	$ 3,685.9
Vested and expected to vest as of December 31, 2022		15.1	$ 476.15	6.2	$ 3,632.8
Exercisable as of December 31, 2022		10.1	$ 420.47	5.0	$ 2,991.9

The Company satisfies stock option exercises with newly issued shares of the Company's Common Stock. The total intrinsic value of stock options exercised during 2022, 2021, and 2020 was $1.214 billion, $1.707 billion, and $2.251 billion, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

The table below summarizes the weighted-average exercise prices and weighted-average grant-date fair values of options issued during the years ended December 31, 2022, 2021, and 2020.

	Number of Options Granted *(In millions)*	Weighted-Average Exercise Price	Weighted-Average Fair Value
2022:			
Exercise price equal to Market Price	2.0	$ 705.02	$ 220.88
2021:			
Exercise price equal to Market Price	2.3	$ 628.43	$ 174.20
2020:			
Exercise price equal to Market Price	2.9	$ 492.60	$ 126.50

For the years ended December 31, 2022, 2021, and 2020, the Company recognized $341.9 million, $328.7 million, and $329.5 million, respectively, of stock-based compensation expense related to stock option awards (net of amounts capitalized as inventory, which were not material for each of the three years). As of December 31, 2022, there was $572.0 million of stock-based compensation cost related to unvested stock options, net of estimated forfeitures, which had not yet been recognized. The Company expects to recognize this compensation cost over a weighted-average period of 1.8 years.

Fair Value Assumptions:

The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2022, 2021, and 2020.

	2022	2021	2020
Expected volatility	28 %	27 %	28 %
Expected lives from grant date	5.2 years	5.5 years	5.0 years
Expected dividend yield	0 %	0 %	0 %
Risk-free interest rate	3.50 %	1.22 %	0.47 %

Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's historical exercise experience with previously issued employee and board of directors' option grants. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives.

b. Restricted Stock Awards and Time-Based Restricted Stock Units

A summary of the Company's activity related to restricted stock awards and time-based restricted stock units (excluding performance-based restricted stock units, which are detailed further below) (collectively, "restricted stock") during 2022 is summarized below.

		Number of Shares/Units *(In millions)*	Weighted-Average Grant Date Fair Value
Unvested as of December 31, 2021		2.1	$ 499.85
2022:	Granted	0.9	$ 702.32
	Vested	(0.3)	$ 477.22
	Forfeited	(0.1)	$ 522.18
Unvested as of December 31, 2022		2.6	$ 571.19

For the years ended December 31, 2022, 2021, and 2020, the Company recognized $331.1 million, $221.0 million, and $102.5 million, respectively, of stock-based compensation expense related to restricted stock (net of amounts capitalized as inventory, which were not material for each of the three years). As of December 31, 2022, there was $907.7 million of stock-based

compensation cost related to unvested restricted stock which had not yet been recognized. The Company expects to recognize this compensation cost over a weighted-average period of 2.1 years.

c. Performance-based Restricted Stock Units

Performance-based restricted stock units ("PSUs") have been granted to certain members of senior management of the Company. PSUs may be earned based upon the attainment of pre-established performance criteria, which may include a market and/or performance condition. Depending on the terms of the PSUs and the outcome of the pre-established performance criteria, a recipient may ultimately earn the target number of PSUs granted or a specified multiple thereof at the end of a 4–6 year vesting period, as applicable.

The table below summarizes activity related to PSUs during 2022. The number of PSUs granted represents the maximum number of units that are eligible to be earned.

	Number of Shares/Units *(In millions)*	Weighted-Average Grant Date Fair Value
Unvested as of December 31, 2021	1.3	$ 209.06
2022: Granted	0.2	$ 485.61
Unvested as of December 31, 2022	1.5	$ 245.94

For each of the years ended December 31, 2022, and 2021, the Company recognized $52.0 million of stock-based compensation expense related to PSUs. The Company did not recognize stock-based compensation expense related to PSUs in 2020 (as PSUs granted in 2020 were granted on December 31, 2020 and are expensed over the vesting period). As of December 31, 2022, there was $156.1 million of stock-based compensation cost related to unvested PSUs which had not yet been recognized. The Company expects to recognize this compensation cost on a straight-line basis over a weighted average period of 3.3 years.

Fair Value Assumptions:

The following table summarizes the weighted average values of the assumptions used in computing the fair value of PSUs that were granted during 2022 and 2020. The Company did not grant PSUs during 2021.

	2022	2020
Expected volatility	32%	35%
Expected dividend yield	0%	0%
Risk-free interest rate	3.3%	0.4%

14. Employee Savings Plans

The Company maintains the Regeneron Pharmaceuticals, Inc. 401(k) Savings Plan, as amended and restated (the "Savings Plan"). The terms of the Savings Plan allow U.S. employees (as defined by the Savings Plan) to contribute to the Savings Plan a percentage of their compensation. In addition, the Company may make discretionary contributions, as defined, to the accounts of participants under the Savings Plan. The Company also maintains additional employee savings plans outside of the United States, which cover eligible employees.

Expenses recognized by the Company related to contributions to such plans were $67.6 million, $55.5 million, and $49.9 million for the years ended December 31, 2022, 2021, and 2020, respectively.

15. Income Taxes

The Company is subject to U.S. federal, state, and foreign income taxes. Components of income before income taxes consist of the following:

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**2020**
United States	$ 839.9	$ 5,944.7	$ 2,442.3
Foreign	4,018.9	3,381.1	1,368.1
	$ 4,858.8	$ 9,325.8	$ 3,810.4

Components of income tax expense consist of the following:

	Year Ended December 31,		
(In millions)	**2022**	**2021**	**2020**
Current:			
Federal	$ 968.5	$ 1,429.8	$ 199.0
State	7.4	6.2	1.2
Foreign	290.9	(38.4)	21.4
Total current tax expense	1,266.8	1,397.6	221.6
Deferred:			
Federal	(797.7)	(423.2)	109.0
State	(2.7)	(0.6)	(2.0)
Foreign	54.0	276.7	(31.4)
Total deferred tax (benefit) expense	(746.4)	(147.1)	75.6
	$ 520.4	$ 1,250.5	$ 297.2

A reconciliation of the U.S. statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,		
	2022	**2021**	**2020**
U.S. federal statutory tax rate	21.0 %	21.0 %	21.0 %
Taxation of non-U.S. operations	(5.5)	(2.8)	(1.8)
Stock-based compensation	(2.9)	(2.4)	(7.6)
Income tax credits	(2.0)	(1.0)	(2.8)
Foreign-derived intangible income deduction	(1.0)	(1.4)	—
Sale of non-inventory related assets between foreign subsidiaries	—	—	(0.8)
Other permanent differences	1.1	—	(0.2)
Effective income tax rate	10.7 %	13.4 %	7.8 %

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows:

	As of December 31,	
(In millions)	**2022**	**2021**
Deferred tax assets:		
Capitalized research and development expenses	$ 845.3	$ —
Deferred compensation	416.2	406.6
Accrued expenses	235.6	262.1
Fixed assets and intangible assets	227.6	257.5
Tax attribute carryforwards	41.3	6.1
Other	15.9	10.8
Deferred revenue	—	57.3
Total deferred tax assets	1,781.9	1,000.4
Deferred tax liabilities:		
Unrealized gains on investments	(58.2)	(123.5)
Net deferred tax assets	$ 1,723.7	$ 876.9

The Company's federal income tax returns for 2017 through 2021 remain open to examination by the IRS. The Company's 2017 and 2018 federal income tax returns are currently under audit by the IRS. In general, the Company's state income tax returns from 2018 to 2021 remain open to examination. The Company's income tax returns outside of the United States remain open to examination from 2018 to 2021. The United States and many states generally have statutes of limitation ranging from 3 to 5 years; however, those statutes could be extended due to the Company's tax credit carryforward position. In general, tax authorities have the ability to review income tax returns in which the statute of limitation has previously expired to adjust the tax credits generated in those years.

The amount of net unrecognized tax benefits that, if settled, would impact the effective tax rate is $373.7 million, $321.1 million, and $267.0 million as of December 31, 2022, 2021, and 2020, respectively. The following table reconciles the beginning and ending amounts of unrecognized tax benefits.

(In millions)	**2022**	**2021**	**2020**
Balance as of January 1	$ 410.9	$ 267.0	$ 210.8
Gross increases related to current year tax positions	136.9	182.3	76.6
Gross (decreases) increases related to prior year tax positions	(5.0)	2.9	7.2
Gross decreases due to settlements and lapse of statutes of limitations	—	(41.3)	(27.6)
Balance as of December 31	$ 542.8	$ 410.9	$ 267.0

In 2022, 2021, and 2020, the increases in unrecognized tax benefits primarily related to the Company's calculation of certain tax credits and other items related to the Company's international operations. The decrease in unrecognized tax benefits in 2021 was related to the closing of audits for the Company's federal income tax returns for 2015 and 2016. Interest expense related to unrecognized tax benefits was not material in 2022, 2021, and 2020. The Company does not believe that it is reasonably possible that the resolution of tax exposures within the next twelve months would have a material impact on the consolidated financial statements as of December 31, 2022.

In August 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law in the United States. The IRA created a new corporate alternative minimum tax of 15% on adjusted financial statement income and an excise tax of 1% of the value of certain stock repurchases. The provisions of the IRA will be effective for periods beginning after December 31, 2022. The enactment of the IRA did not result in any material adjustments to the Company's income tax provisions or net deferred tax assets as of December 31, 2022.

16. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. If the Company were unable to prevail in any such proceedings, its consolidated financial position, results of operations, and future cash flows may be materially impacted. Costs associated with the Company's involvement in legal proceedings are expensed as incurred. The Company recognizes accruals for loss contingencies associated with such proceedings when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. As of December 31, 2022 and 2021, the Company's accruals for loss contingencies were not material. There are certain loss contingencies that the Company deems reasonably possible for which the possible loss or range of possible loss is not estimable at this time.

Proceedings Relating to Praluent (alirocumab) Injection

As described below, the Company is currently a party to patent infringement actions initiated by Amgen Inc. (and/or its affiliated entities) against the Company and/or Sanofi (and/or the Company's and Sanofi's respective affiliated entities) in a number of jurisdictions relating to Praluent. In addition, as described below, the Company filed a lawsuit against Amgen alleging that Amgen engaged in an anticompetitive bundling scheme which was designed to exclude Praluent from the market in violation of federal and state laws.

United States

In the United States, Amgen has asserted claims of U.S. Patent Nos. 8,829,165 (the "'165 Patent") and 8,859,741 (the "'741 Patent"), and sought a permanent injunction to prevent the Company and the Sanofi defendants from commercial manufacturing, using, offering to sell, or selling within the United States (as well as importing into the United States) (collectively, "Commercializing") Praluent. Amgen also seeks a judgment of patent infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuits, and attorneys' fees. As previously reported, on February 11, 2021, the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") affirmed the lower court's decision that certain of Amgen's asserted patent claims are invalid based on lack of enablement. On April 14, 2021, Amgen filed a petition for a rehearing en banc with the Federal Circuit, which was denied on June 21, 2021. On November 4, 2022, the United States Supreme Court granted Amgen's petition for writ of certiorari. An oral hearing has been scheduled for March 27, 2023.

On May 27, 2022, the Company filed a lawsuit against Amgen in the United States District Court for the District of Delaware, alleging that, beginning in 2020, Amgen engaged in an anticompetitive bundling scheme which was designed to exclude Praluent from the market in violation of federal and state laws. The lawsuit seeks damages for harm caused by the alleged scheme, as well as injunctive relief restraining Amgen from continuing its alleged anticompetitive conduct. On August 1, 2022, Amgen filed a motion to dismiss the complaint. On August 11, 2022, Amgen filed a motion to stay these proceedings pending resolution of the patent litigation described in the preceding paragraph. An oral hearing on Amgen's motion to dismiss and motion to stay has been scheduled for January 6, 2023.

Europe

Amgen has asserted European Patent No. 2,215,124 (the "'124 Patent"), which pertains to PCSK9 monoclonal antibodies, in certain countries in Europe. In October 2020, the '124 Patent claims directed to compositions of matter and medical use relevant to Praluent were ruled invalid based on a lack of inventive step by the Technical Board of Appeal (the "TBA") of the European Patent Office (the "EPO"). Following the EPO's decision, each of the '124 Patent infringement proceedings initiated by Amgen against the Company and certain of Sanofi's affiliated entities in these countries was dismissed, including in Germany. The dismissal in Germany followed an earlier finding of infringement and granting of an injunction, both of which were subsequently overturned. As a result of the overturned injunction in Germany discussed in the preceding sentence, the Company and/or certain of Sanofi's affiliated entities are seeking damages caused by Amgen's enforcement of the injunction. As part of its opposition to these damages claims, on March 23, 2022, Amgen filed a counterclaim that asserted the German designation of European Patent No. 2,641,917 (the "'917 Patent") and seeks, among other things, a judgment of patent infringement, injunctive relief, and monetary damages. The '917 Patent is a divisional patent of the '124 Patent discussed above (i.e., a patent that shares the same priority date, disclosure, and patent term of the parent '124 Patent but contains claims to a different invention). The '917 Patent is also subject to opposition proceedings in the EPO, which were initiated by Sanofi on May 5, 2021. An oral hearing before the EPO has been scheduled for February 21, 2023.

Proceedings Relating to Dupixent (dupilumab) Injection

On September 30, 2016, Sanofi initiated a revocation proceeding in the United Kingdom to invalidate the U.K. counterpart of European Patent No. 2,292,665 (the "'665 Patent"), a patent owned by Immunex Corporation relating to antibodies that bind the human interleukin-4 receptor. At the joint request of the parties to the revocation proceeding, the U.K. Patents Court ordered on January 30, 2017 that the revocation action be stayed pending the final determination of the EPO opposition proceedings initiated

by the Company and Sanofi in relation to the '665 Patent. The oral hearing before the EPO on the oppositions occurred on November 20, 2017, at which the claims of the '665 Patent were found invalid and the patent was revoked. A final written decision of revocation of the '665 Patent was issued by the EPO on January 4, 2018. Immunex filed a notice of appeal of the EPO's decision on January 31, 2018, which appeal was withdrawn at an oral hearing before the TBA on March 10, 2022 following the TBA's ruling discussed below. On May 18, 2022, the revocation action in the U.K. Patents Court was dismissed following the EPO's revocation of the '665 Patent. On September 20, 2017 and September 21, 2017, respectively, the Company and Sanofi initiated opposition proceedings in the EPO against Immunex's European Patent No. 2,990,420 (the "'420 Patent"), a divisional patent of the '665 Patent (i.e., a patent that shares the same priority date, disclosure, and patent term of the parent '665 Patent but contains claims to a different invention). The oral hearing before the EPO on the oppositions occurred on February 14–15, 2019, at which the '420 Patent was revoked in its entirety. Immunex filed a notice of appeal of the EPO's decision on May 31, 2019. At an oral hearing before the TBA on March 10, 2022, the TBA maintained the invalidity and revocation of the '420 Patent. The original patent term of the Immunex patents expired in May 2021.

Proceedings Relating to EYLEA (aflibercept) Injection

Certain of the Company's patents pertaining to EYLEA are subject to post-grant proceedings before the United States Patent and Trademark Office ("USPTO"), EPO, or other comparable foreign authorities, including those described in greater detail below. In addition, the Company has filed patent infringement lawsuits in several jurisdictions alleging infringement of certain Company patents pertaining to EYLEA, including those described in greater detail below.

United States

On February 11, 2020, anonymous parties filed two requests for *ex parte* reexamination of the Company's U.S. Patent Nos. 10,406,226 and 10,464,992 (the "'992 Patent"), and the USPTO has granted both requests to initiate reexamination proceedings.

On May 5, 2021, Mylan Pharmaceuticals Inc. filed *inter partes* review ("IPR") petitions in the USPTO against the Company's U.S. Patent Nos. 9,254,338 (the "'338 Patent") and 9,669,069 (the "'069 Patent") seeking declarations of invalidity of the '338 Patent and the '069 Patent. On November 10, 2021, the USPTO issued a decision instituting both IPR proceedings. On December 9, 2021, Apotex Inc. and Celltrion, Inc. each filed two separate IPR petitions against the Company's '338 and '069 Patents requesting that their IPRs be instituted and joined with the IPR proceedings initiated by Mylan concerning the '338 and '069 Patents, which petitions were granted on February 9, 2022. An oral hearing was held on August 10, 2022. On November 9, 2022, the USPTO issued final written decisions finding that the claims of the '338 and '069 Patents are unpatentable and, therefore, invalid. On January 10, 2023, the Company filed notices of appeal of the USPTO written decisions concerning the '338 and '069 Patents with the Federal Circuit.

On September 7, 2021, Celltrion, Inc. filed a post-grant review ("PGR") petition in the USPTO against the Company's U.S. Patent No. 10,857,231 (the "'231 Patent") seeking a declaration of invalidity of the '231 Patent. On March 14, 2022, the Company filed a Notice of Disclaimer with the USPTO, disclaiming all claims of the '231 Patent. As a result, on March 15, 2022, the USPTO denied institution of Celltrion's PGR petition.

In 2022, Mylan filed IPR petitions against the Company's U.S. Patent Nos. 10,130,681 (the "'681 Patent") and 10,888,601 (the "'601 Patent") (each filed July 1, 2022) and 10,857,205 (filed October 28, 2022) seeking declarations of invalidity of each of these patents. On January 11, 2023, the USPTO instituted IPR proceedings concerning the '681 Patent and the '601 Patent. On January 6, 2023, Samsung Bioepis Co., Ltd. filed a separate IPR petition against the Company's '681 Patent seeking a declaration of invalidity of the '681 Patent.

On September 9, 2022, Apotex filed an IPR petition against the Company's U.S. Patent No. 11,253,572 (the "'572 Patent") seeking a declaration of invalidity of the '572 Patent.

On January 17, 2023, Celltrion, Inc. filed an IPR petition against the '992 Patent seeking a declaration of invalidity of the '992 Patent.

On August 2, 2022, the Company filed a patent infringement lawsuit against Mylan in the United States District Court for the Northern District of West Virginia alleging that Mylan's filing for a U.S. Food and Drug Administration approval of an aflibercept biosimilar infringes certain Company patents. A trial has been scheduled to begin on June 12, 2023.

Europe

On October 26 and October 27, 2021, anonymous parties initiated opposition proceedings in the EPO against the Company's European Patent No. 2,944,306 (the "'306 Patent") seeking revocation of the '306 Patent in its entirety.

Canada

On June 15, July 15, August 30, and October 4, 2022, the Company and Bayer Inc. filed patent infringement lawsuits against BGP Pharma ULC d.b.a Viatris Canada ("Viatris Canada") in the Federal Court of Canada seeking a declaration that the making, constructing, using, or selling of an aflibercept biosimilar would directly or indirectly infringe one or more claims of the Company's Canadian Patent Nos. 2,654,510 (the "'510 Patent) and 3,007,276 (the "'276 Patent") (in the lawsuit filed on June 15, 2022); the Company's Canadian Patent No. 2,965,495 (the "'495 Patent") (in the lawsuit filed on July 15, 2022); the Company's Canadian Patent No. 2,906,768 (the "'768 Patent") (in the lawsuit filed on August 30, 2022, which has been joined with the lawsuit filed on July 15, 2022); and the Company's Canadian Patent No. 3,129,193 (the "'193 Patent") (in the lawsuit filed on October 4, 2022). A trial for the lawsuit concerning the '510 Patent and the '276 Patent has been scheduled for March 2024; a trial for the lawsuit concerning the '193 Patent has been scheduled for May 2024; and a trial for the lawsuit concerning the '495 Patent and the '768 Patent has been scheduled for November/December 2024. The filing of the lawsuit concerning the '510 Patent and the '276 Patent resulted in a statutory 24-month stay of regulatory approval of Viatris Canada's aflibercept biosimilar in Canada unless the lawsuit is resolved earlier.

South Korea

On October 31, 2022 and December 13, 2022, Samsung Bioepis Co., Ltd. initiated invalidation proceedings before the Intellectual Property Trial and Appeal Board of the Korean Intellectual Property Office against the Company's Korean Patent Nos. 1131429 and 1406811, respectively, seeking revocation of each of such patents in its entirety.

Proceedings Relating to EYLEA (aflibercept) Injection Pre-filled Syringe

On June 19, 2020, Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, "Novartis") filed a complaint with the U.S. International Trade Commission (the "ITC") pursuant to Section 337 of the Tariff Act of 1930 requesting that the ITC institute an investigation relating to the importation into the United States and/or sale within the United States after importation of EYLEA pre-filled syringes ("PFS") and/or components thereof which allegedly infringe Novartis's U.S. Patent No. 9,220,631 (the "'631 Patent"). The ITC instituted the investigation on July 22, 2020 and a trial was scheduled for April 19–23, 2021. On March 26, 2021, the staff attorney appointed by the ITC's Office of Unfair Import Investigations ("OUII")—an independent government party to the case representing the public interest—determined that the '631 Patent is invalid on several grounds. On April 8, 2021, Novartis moved to terminate the ITC investigation in its entirety based on its withdrawal of the complaint; and, on May 3, 2021, the ITC terminated the investigation.

On June 19, 2020, Novartis also filed a patent infringement lawsuit (as amended on August 2, 2021) in the U.S. District Court for the Northern District of New York asserting claims of the '631 Patent and seeking preliminary and permanent injunctions to prevent the Company from continuing to infringe the '631 Patent. Novartis also seeks a judgment of patent infringement of the '631 Patent, monetary damages (together with interest), an order of willful infringement of the '631 Patent (which would allow the court in its discretion to award damages up to three times the amount assessed), costs and expenses of the lawsuits, and attorneys' fees. On November 7, 2022, the Company and Novartis entered into a stipulation staying the lawsuit in light of the decision in the IPR proceeding discussed below.

On July 16, 2020, the Company initiated two IPR petitions in the USPTO seeking a declaration of invalidity of the '631 Patent on two separate grounds. On January 15, 2021, the USPTO declined to institute an IPR proceeding on procedural grounds in light of the pending ITC investigation discussed above; the other IPR petition has been withdrawn. Following Novartis's motion to terminate the ITC investigation discussed above, on April 16, 2021 the Company filed a new IPR petition seeking a declaration of invalidity of the '631 Patent based on the same grounds that were the basis for the OUII staff attorney's determination discussed above. On October 26, 2021, the USPTO issued a decision instituting the IPR proceeding. An oral hearing was held on July 21, 2022. On October 25, 2022, the Patent Trial and Appeal Board ("PTAB") of the USPTO issued a final written decision invalidating all claims of the '631 Patent. On December 23, 2022, Novartis filed a notice of appeal of the PTAB's decision to the Federal Circuit.

On July 17, 2020, the Company filed an antitrust lawsuit against Novartis and Vetter Pharma International Gmbh ("Vetter") in the United States District Court for the Southern District of New York seeking a declaration that the '631 Patent is unenforceable and a judgment that the defendants' conduct violates Sections 1 and 2 of the Sherman Antitrust Act of 1890, as amended (the "Sherman Antitrust Act"). The Company is also seeking injunctive relief and treble damages. On September 4, 2020, Novartis filed, and Vetter moved to join, a motion to dismiss the complaint, to transfer the lawsuit to the Northern District of New York, or to stay the suit; and on October 19, 2020, Novartis filed, and Vetter moved to join, a second motion to dismiss the complaint on different grounds. On January 25, 2021, the Company filed an amended complaint seeking a judgment that Novartis's conduct violates Section 2 of the Sherman Antitrust Act based on additional grounds, as well as a judgment of tortious interference with contract. On February 22, 2021, Novartis filed, and Vetter moved to join, a motion to dismiss the amended complaint. On September 21, 2021, the court granted Novartis and Vetter's motion to transfer this lawsuit to the Northern District of New York.

As a result, this lawsuit was transferred to the same judge that had been assigned to the patent infringement lawsuit discussed above. On November 5, 2021, the Company filed a motion to stay these proceedings in light of the pending IPR proceeding discussed above. On January 31, 2022, the court denied the Company's motion to stay these proceedings and granted Novartis and Vetter's motion to dismiss the amended complaint. On June 10, 2022, the Company filed an appeal of the District Court's decision to dismiss the amended complaint with the U.S. Court of Appeals for the Second Circuit.

Proceedings Relating to REGEN-COV (casirivimab and imdevimab)

On October 5, 2020, Allele Biotechnology and Pharmaceuticals, Inc. ("Allele") filed a lawsuit (as amended on April 8, 2021 and December 12, 2022) against the Company in the United States District Court for the Southern District of New York, asserting infringement of U.S. Patent No. 10,221,221 (the "'221 Patent"). Allele seeks a judgment of patent infringement of the '221 Patent, an award of monetary damages (together with interest), an order of willful infringement of the '221 Patent (which would allow the court in its discretion to award damages up to three times the amount assessed), costs and expenses of the lawsuit, and attorneys' fees. On July 16, 2021, the Company filed a motion to dismiss the complaint, which motion was denied on March 2, 2022.

Department of Justice Matters

In January 2017, the Company received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents relating to its support of 501(c)(3) organizations that provide financial assistance to patients; documents concerning its provision of financial assistance to patients with respect to products sold or developed by Regeneron (including EYLEA, Praluent, ARCALYST, and ZALTRAP ®); and certain other related documents and communications. On June 24, 2020, the U.S. Attorney's Office for the District of Massachusetts filed a civil complaint in the U.S. District Court for the District of Massachusetts alleging violations of the federal Anti-Kickback Statute, and asserting causes of action under the federal False Claims Act and state law. On August 24, 2020, the Company filed a motion to dismiss the complaint in its entirety. On December 4, 2020, the court denied the motion to dismiss. On December 28, 2022, the U.S. Attorney's Office for the District of Massachusetts filed a motion for partial summary judgment. On January 31, 2023, the Company filed a motion for summary judgment.

In September 2019, the Company and Regeneron Healthcare Solutions, Inc., a wholly-owned subsidiary of the Company, each received a civil investigative demand ("CID") from the U.S. Department of Justice pursuant to the federal False Claims Act relating to remuneration paid to physicians in the form of consulting fees, advisory boards, speaker fees, and payment or reimbursement for travel and entertainment allegedly in violation of the federal Anti-Kickback Statute. The CIDs relate to EYLEA, Praluent, Dupixent, ZALTRAP, ARCALYST, and Kevzara and cover the period from January 2015 to the present. On June 3, 2021, the United States District Court for the Central District of California unsealed a *qui tam* complaint filed against the Company, Regeneron Healthcare Solutions, Inc., and Sanofi-Aventis U.S. LLC by two *qui tam* plaintiffs (known as relators) purportedly on behalf of the United States and various states (the "State Plaintiffs"), asserting causes of action under the federal False Claims Act and state law. Also on June 3, 2021, the United States and the State Plaintiffs notified the court of their decision to decline to intervene in the case. On October 29, 2021, the *qui tam* plaintiffs filed an amended complaint in this matter. On January 14, 2022, the Company filed a motion to dismiss the amended complaint in its entirety.

In June 2021, the Company received a CID from the U.S. Department of Justice pursuant to the federal False Claims Act. The CID states that the investigation concerns allegations that the Company (i) violated the False Claims Act by paying kickbacks to distributors and ophthalmology practices to induce purchase of EYLEA, including through discounts, rebates, credit card fees, free units of EYLEA, and inventory management systems; and (ii) inflated reimbursement rates for EYLEA by excluding applicable discounts, rebates, and benefits from the average sales price reported to CMS. The CID covers the period from January 2011 through June 2021. The Company is cooperating with this investigation.

California Department of Insurance Subpoena

In September 2022, the Company received a subpoena from the Insurance Commissioner for the State of California pursuant to the California Insurance Code. The subpoena seeks information relating to the marketing, sale, and distribution of EYLEA, including (i) discounts, rebates, credit card fees, and inventory management systems; (ii) Regeneron's relationships with distributors; (iii) price reporting; (iv) speaker programs; and (v) patient support programs. The subpoena covers the period from January 1, 2014 through August 1, 2021. The Company is cooperating with this investigation.

Proceedings Initiated by Other Payors Relating to Patient Assistance Organization Support

The Company is party to several lawsuits relating to the conduct alleged in the civil complaint filed by the U.S. Attorney's Office for the District of Massachusetts discussed under "Department of Justice Matters" above. These lawsuits were filed by UnitedHealthcare Insurance Company and United Healthcare Services, Inc. (collectively, "UHC") and Humana Inc. ("Humana") in the United States District Court for the Southern District of New York on December 17, 2020 and July 22, 2021, respectively; and by Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc.

(collectively, "BCBS"), Medical Mutual of Ohio ("MMO"), Horizon Healthcare Services, Inc. d/b/a Horizon Blue Cross Blue Shield of New Jersey ("Horizon"), and Local 464A United Food and Commercial Workers Union Welfare Service Benefit Fund ("Local 464A") in the U.S. District Court for the District of Massachusetts on December 20, 2021, February 23, 2022, April 4, 2022, and June 17, 2022, respectively. These lawsuits allege causes of action under state law and the federal Racketeer Influenced and Corrupt Organizations Act and seek monetary damages and equitable relief. The MMO and Local 464A lawsuits are putative class action lawsuits. On December 29, 2021, the lawsuits filed by UHC and Humana were stayed by the United States District Court for the Southern District of New York pending resolution of the proceedings before the U.S. District Court for the District of Massachusetts discussed under "Department of Justice Matters" above. On September 27, 2022, the lawsuits filed by BCBS, MMO, and Horizon were stayed by the U.S. District Court for the District of Massachusetts pending resolution of the proceedings before the same court discussed under "Department of Justice Matters" above; and, in light of these stays, the parties to the Local 464A action have also agreed to stay that matter.

Shareholder Demands

On or about September 30, 2020, March 30, 2022, and March 31, 2022, the Company's board of directors received three demand letters from purported shareholders of the Company. The demands allege that Regeneron and its shareholders have been damaged by the conduct alleged in the civil complaint filed by the U.S. Attorney's Office for the District of Massachusetts discussed under "Department of Justice Matters" above. The demand letters request that the Company's board of directors investigate alleged breaches of fiduciary duty by its officers and directors and other alleged violations of law and corporate governance practices and procedures; bring legal action against the persons responsible for causing the alleged damages; and implement and maintain an effective system of internal controls, compliance mechanisms, and corporate governance practices and procedures. The Company's board of directors, working with outside counsel, investigated and evaluated the allegations in the demand letters and has concluded that pursuing the claims alleged in the demands would not be in the Company's best interests at this time.

Proceedings Relating to Shareholder Derivative Complaint

On June 29, 2021, an alleged shareholder filed a shareholder derivative complaint in the New York Supreme Court, naming the current and certain former members of the Company's board of directors and certain current and former executive officers of the Company as defendants and Regeneron as a nominal defendant. The complaint asserts that the individual defendants breached their fiduciary duties in relation to the allegations in the civil complaint filed by the U.S. Attorney's Office for the District of Massachusetts discussed under "Department of Justice Matters" above. The complaint seeks an award of damages allegedly sustained by the Company; an order requiring Regeneron to take all necessary actions to reform and improve its corporate governance and internal procedures; disgorgement from the individual defendants of all profits and benefits obtained by them resulting from their sales of Regeneron stock; and costs and disbursements of the action, including attorneys' fees. On July 28, 2021, the defendants filed a notice of removal, removing the case from the New York Supreme Court to the U.S. District Court for the Southern District of New York. On September 23, 2021, the plaintiff moved to remand the case to the New York Supreme Court. Also on September 23, 2021, the individual defendants moved to dismiss the complaint in its entirety. On December 19, 2022, the U.S. District Court for the Southern District of New York denied the plaintiff's motion to remand the case and granted a motion to stay the case pending resolution of the proceedings before the U.S. District Court for the District of Massachusetts discussed under "Department of Justice Matters" above. As a result of the stay, the court also terminated the Company's motion to dismiss the complaint without prejudice to renew upon conclusion of the stay.

17. Net Income Per Share

The calculations of basic and diluted net income per share are as follows:

	Year Ended December 31,		
(In millions, except per share data)	**2022**	**2021**	**2020**
Net income - basic and diluted	$ 4,338.4	$ 8,075.3	$ 3,513.2
Weighted average shares - basic	107.1	105.7	107.6
Effect of dilutive securities:			
Stock options	4.9	5.4	7.0
Restricted stock awards and restricted stock units	1.5	1.1	0.5
Weighted average shares - diluted	113.5	112.2	115.1
Net income per share - basic	$ 40.51	$ 76.40	$ 32.65
Net income per share - diluted	$ 38.22	$ 71.97	$ 30.52

Shares which have been excluded from diluted per share amounts because their effect would have been antidilutive include the following:

	Year Ended December 31,		
(Shares in millions)	**2022**	**2021**	**2020**
Stock options	2.3	2.9	2.7

18. Statement of Cash Flows

The following provides a reconciliation of cash, cash equivalents, and restricted cash reported within the Consolidated Balance Sheet to the total of the same such amounts shown in the Consolidated Statement of Cash Flows:

	December 31,		
(In millions)	**2022**	**2021**	**2020**
Cash and cash equivalents	$ 3,105.9	$ 2,885.6	$ 2,193.7
Restricted cash included in Other noncurrent assets	13.5	12.5	13.6
Total cash, cash equivalents, and restricted cash shown in the Consolidated Statement of Cash Flows	$ 3,119.4	$ 2,898.1	$ 2,207.3

Restricted cash consists of amounts held by financial institutions pursuant to contractual arrangements.

Supplemental disclosure of non-cash investing and financing activities

	As of December 31,		
(In millions)	**2022**	**2021**	**2020**
Accrued capital expenditures	$ 70.8	$ 74.8	$ 83.6
Accrued payments for Libtayo intangible asset	$ 135.5	$ —	$ —