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 , 2024

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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 $ 113.8 billion, computed by reference to the closing sales price of the stock on NASDAQ on June 28, 2024, 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 23, 2025:

Class of Common Stock	Number of Shares
Class A Stock, $.001 par value	1,817,146
Common Stock, $.001 par value	107,507,536

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2025 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 87 to 91 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 nature, timing, and possible success and therapeutic applications of products marketed or otherwise commercialized by Regeneron and/or its collaborators or licensees (collectively, "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 those discussed or referenced in this report, 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 Regeneron's Product Candidates and new indications for Regeneron's Products, including without limitation those discussed or referenced in this report;*
- *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 (including biosimilar versions of Regeneron's Products);*
- *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;*
- *changes in laws, regulations, and policies affecting the healthcare industry;*
- *the costs of developing, producing, and selling products or unanticipated expenses;*
- *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;*
- *the impact of public health outbreaks, epidemics, or pandemics on our business; and*
- *risks associated with 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), 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), 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, neurological diseases, hematologic conditions, infectious diseases, and rare diseases.

Our core business strategy is to maintain a strong foundation in scientific research and drug development using our proprietary technologies, and to build on that foundation with our clinical development, manufacturing, and commercial capabilities. Our objective is to continue to advance as 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)	**2024**	**2023**	**2022**
Revenues	$ 14,202.0	$ 13,117.2	$ 12,172.9
Net income	$ 4,412.6	$ 3,953.6	$ 4,338.4
Net income per share - diluted	$ 38.34	$ 34.77	$ 38.22

For purposes of this report, references to our products encompass products 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. Certain products have also received marketing approval in countries outside the United States, European Union ("EU"), or Japan.

		Territory		
Product	**Disease**	**U.S.**	**EU**	**Japan**
EYLEA HD® (aflibercept) Injection 8 mg[(a)]	Wet age-related macular degeneration ("wAMD")	a	a	a
	Diabetic macular edema ("DME")	a	a	a
	Diabetic retinopathy ("DR")	a		
EYLEA® (aflibercept) Injection[(a)]	wAMD	a	a	a
	DME	a	a	a
	DR	a		
	Macular edema following retinal vein occlusion ("RVO"), which includes macular edema following central retinal vein occlusion ("CRVO") and macular edema following branch retinal vein occlusion ("BRVO")	a	a	a
	Myopic choroidal neovascularization ("mCNV")		a	a
	Neovascular glaucoma ("NVG")			a
	Retinopathy of prematurity ("ROP")	a	a	a
Dupixent® (dupilumab) Injection[(b)]	Atopic dermatitis (in adults, adolescents, and pediatrics aged 6 months and older)	a	a	a
	Asthma (in adults and adolescents)	a	a	a

Product *(continued)*	Disease	Territory		
		U.S.	EU	Japan
Dupixent (dupilumab) Injection[b] *(continued)*	Asthma (in pediatrics 6–11 years of age)	a	a	
	Chronic rhinosinusitis with nasal polyposis ("CRSwNP") (in adults)	a	a	a
	CRSwNP (in adolescents)	a		
	Chronic obstructive pulmonary disease ("COPD")	a	a	
	Eosinophilic esophagitis ("EoE") (in adults, adolescents, and pediatrics aged 1 year and older)	a	a	
	Prurigo nodularis	a	a	a
	Chronic spontaneous urticaria ("CSU") (in adults and adolescents)			a
Libtayo® (cemiplimab) Injection	Metastatic or locally advanced first-line non-small cell lung cancer ("NSCLC")	a	a	
	Metastatic or locally advanced first-line NSCLC (in combination with chemotherapy)	a	a	
	Metastatic or locally advanced basal cell carcinoma ("BCC")	a	a	
	Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	a	a	
	Metastatic or recurrent second-line cervical cancer		a	a
Praluent® (alirocumab) Injection[c]	LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD")	a	a	
	HeFH in pediatrics and adolescents (8–17 years of age)	a	a	
	Cardiovascular risk reduction in patients with established cardiovascular disease	a	a	
	Homozygous familial hypercholesterolemia ("HoFH")	a		
Kevzara® (sarilumab) Injection[b]	Rheumatoid arthritis ("RA")	a	a	a
	Polymyalgia rheumatica ("PMR")	a	a	
	Polyarticular juvenile idiopathic arthritis ("pJIA")	a	a	
REGEN-COV®[d]	COVID-19		a	a
Evkeeza® (evinacumab) Injection[e]	HoFH (in adults, adolescents, and pediatrics)	a	a	a
Ordspono™ (odronextamab)	Follicular lymphoma ("FL")		a	
	Diffuse large B-cell lymphoma ("DLBCL")		a	
Inmazeb® (atoltivimab, maftivimab, and odesivimab) Injection	Infection caused by *Zaire ebolavirus*	a		
Veopoz® (pozelimab) Injection	CD55-deficient protein-losing enteropathy ("CHAPLE") (in adults, adolescents, and pediatrics aged 1 year and older)	a		

Product *(continued)*	Disease	Territory		
		U.S.	EU	Japan
ARCALYST® (rilonacept) Injection[f]	Cryopyrin-associated periodic syndromes ("CAPS"), including familial cold auto-inflammatory syndrome ("FCAS") and Muckle-Wells syndrome ("MWS") (in adults and adolescents)	a		
	Deficiency of interleukin-1 receptor antagonist ("DIRA") (in adults, adolescents, and pediatrics)	a		
	Recurrent pericarditis (in adults and adolescents)	a		
ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion[g]	Metastatic colorectal cancer ("mCRC")	a	a	a

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. Aflibercept 8 mg is known as EYLEA HD in the United States and EYLEA 8 mg in other countries.

[b] In collaboration with Sanofi

[c] The Company is solely responsible for the development and commercialization of Praluent in the United States and Sanofi is responsible for the development and commercialization of Praluent outside the United States.

[d] In collaboration with Roche. Product is known as REGEN-COV in the United States and Ronapreve™ in other countries.

[e] The Company is solely responsible for the development and commercialization of Evkeeza in the United States and Ultragenyx is responsible for the development and commercialization of Evkeeza outside the United States.

[f] Kiniksa is solely responsible for the development and commercialization of ARCALYST.

[g] Sanofi is solely responsible for the development and commercialization of ZALTRAP.

The table below includes net product sales of Regeneron-discovered products. Such net product sales are recorded by us or others, as further described in the footnotes to the table. We believe the information in the table is useful to investors as it demonstrates our pipeline productivity and our ability to innovate, discover, and develop new products, and bring those products to market either alone or based on contractual arrangements with other parties, which has a direct impact on our results of operations and financial condition. The table also shows the degree to which we, a collaborator, and/or a licensee is currently commercializing the products discovered by Regeneron. In addition, this information allows management and investors to assess the commercial trends and developments impacting Regeneron-discovered products. In arrangements where our collaborator or licensee is currently commercializing such products and is recording net product sales as a result, the net product sales shown in the table also are an important metric for management's review and assessment of (i) the revenues we record for our share of profits and/or royalties from such sales and (ii) the impact of our obligation to supply commercial product to certain of these collaborators or licensees.

	Year Ended December 31,								
	2024			2023			2022		
(In millions)	U.S.	ROW[g]	Total	U.S.	ROW	Total	U.S.	ROW	Total
EYLEA HD and EYLEA[a]	$ 5,968.2	$ 3,576.8	$ 9,545.0	$ 5,885.4	$ 3,495.2	$ 9,380.6	$ 6,264.6	$ 3,382.8	$ 9,647.4
Dupixent[b]	$ 10,398.7	$ 3,749.3	$ 14,148.0	$ 8,855.6	$ 2,732.5	$ 11,588.1	$ 6,668.0	$ 2,013.2	$ 8,681.2
Libtayo[c]	$ 787.3	$ 429.5	$ 1,216.8	$ 538.8	$ 330.0	$ 868.8	$ 374.5	$ 203.5	$ 578.0
Praluent[d]	$ 241.7	$ 523.3	$ 765.0	$ 182.4	$ 456.5	$ 638.9	$ 130.0	$ 337.4	$ 467.4
Kevzara[b]	$ 270.2	$ 188.5	$ 458.7	$ 214.7	$ 171.2	$ 385.9	$ 199.7	$ 158.3	$ 358.0
REGEN-COV[e]	$ —	$ 3.5	$ 3.5	$ —	$ 618.8	$ 618.8	$ —	$ 1,769.6	$ 1,769.6
Other products[f]	$ 202.9	$ 86.5	$ 289.4	$ 150.5	$ 67.4	$ 217.9	$ 56.1	$ 69.1	$ 125.2

[a] We record net product sales of EYLEA HD and EYLEA in the United States, and Bayer records net product sales outside the United States. We record our share of profits in connection with sales outside the United States within Collaboration revenue; refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Revenues - Bayer Collaboration Revenue" for such amounts.

[b] Sanofi records global net product sales of Dupixent and Kevzara, and we record our share of profits in connection with global sales of such products within Collaboration revenue. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations - Revenues - Sanofi Collaboration Revenue" for such amounts.

[c] We record global net product sales of Libtayo and pay Sanofi a royalty on such sales. Prior to July 1, 2022, Sanofi recorded net product sales of Libtayo outside the United States. Included in this line item for the years ended December 31, 2023 and 2022 is approximately $6 million and $34 million, respectively, of net product sales recorded by Sanofi in connection with sales in certain markets outside the United States (Sanofi recorded net product sales in such markets during a transition period).

[d] We record net product sales of Praluent in the United States. Sanofi records net product sales of Praluent outside the United States and pays us a royalty on such sales, which is recorded within Other revenue.

[e] Roche records net product sales outside the United States and we record our share of gross profits from sales, which is recorded within Collaboration revenue. Refer to Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations -Results of Operations - Revenues - Roche Collaboration Revenue" for such amounts.

[f] Included in this line item are products which are sold by us 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 us. Not included in this line item are net product sales of ARCALYST, which are recorded by Kiniksa.

[g] Rest of world ("ROW")

Programs in Clinical Development

Product candidates in Phase 2 and Phase 3 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 2	Phase 3	Regulatory Review[h]	2024 and 2025 Events to Date	Select Upcoming Milestones
Ophthalmology					
EYLEA HD (aflibercept) 8 mg[a]		–RVO	–Two-year data for wAMD and DME (U.S.) –Pre-filled syringe (U.S.)	–Approved by European Commission ("EC") and Japan's Ministry of Health, Labour and Welfare ("MHLW") for wAMD and DME –Pre-filled syringe approved by European Medicines Agency ("EMA") –Presented positive three-year data from extension study of Phase 3 DME trial at American Academy of Ophthalmology ("AAO") Annual Meeting –Reported that Phase 3 QUASAR trial in RVO met its primary endpoint	–U.S. Food and Drug Administration ("FDA") decision on supplemental Biologics License Application ("sBLA") with two-year data for wAMD and DME (target action date of April 20, 2025) –FDA decision for pre-filled syringe (mid-2025) –Submit sBLA for RVO (first quarter 2025) –Submit sBLA for every 4-week dosing regimen (first quarter 2025)
Pozelimab[f] (REGN3918) *Antibody to C5*		–Geographic atrophy, cemdisiran combination[i]			
Immunology & Inflammation					
Dupixent (dupilumab)[b] *Antibody to IL-4R alpha subunit*	–Ulcerative colitis	–Asthma in pediatrics (2–5 years of age) –Bullous pemphigoid[c] –CSU –Chronic pruritus of unknown origin ("CPUO") –Lichen simplex chronicus	–COPD with type 2 inflammatory phenotype (Japan) –CSU in adults and adolescents (U.S. and EU) –Bullous pemphigoid (U.S.)	–Approved by FDA for CRSwNP in adolescents –Approved by FDA and EC for EoE in pediatrics (1–11 years of age) –EMA's Committee for Medicinal Products for Human Use ("CHMP") adopted positive opinion for EoE in pediatrics (1–11 years of age) –Results from Phase 3 trial in pediatrics (1–11 years of age) with EoE published in *New England Journal of Medicine* ("*NEJM*")	–MHLW decision on regulatory submission for COPD (first half 2025) –FDA decision on sBLA (target action date of April 18, 2025) and EC decision on regulatory submission (first half 2025) for CSU in adults and adolescents –FDA decision on sBLA for bullous pemphigoid (second half 2025) –Submit regulatory application in the EU for bullous pemphigoid (first half 2025)

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2024 and 2025 Events to Date	Select Upcoming Milestones
Dupixent (dupilumab)[b] *(continued)*				–Approved by MHLW for CSU in adults and adolescents –Reported that second Phase 3 trial in CSU in biologic-naïve patients met its primary and key secondary endpoints –Approved by FDA, EC, and National Medical Products Administration ("NMPA") in China for uncontrolled COPD and an eosinophilic phenotype –Reported that Phase 3 NOTUS trial in COPD with evidence of type 2 inflammation met its primary and key secondary endpoints; results presented at 2024 American Thoracic Society International Conference and published in *NEJM* –Reported that Phase 3 trial in bullous pemphigoid met its primary and all key secondary endpoints –Reported that first Phase 3 trial in CPUO did not achieve statistical significance in its primary itch responder endpoint	
Kevzara (sarilumab)[b] *Antibody to IL-6R*	–Systemic juvenile idiopathic arthritis ("sJIA") (pivotal study)			–Approved by FDA and EC for pJIA –Approved by EC for PMR	

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2024 and 2025 Events to Date	Select Upcoming Milestones
Itepekimab[b] (REGN3500) *Antibody to IL-33*	–Non-cystic fibrosis bronchiectasis ("NCFB") –Chronic rhinosinusitis without nasal polyposis ("CRSsNP")	–COPD[e]			–Report results from Phase 3 study in COPD (second half 2025) –Initiate additional Phase 3 studies (first half 2025)
REGN5713-5715 *Multi-antibody therapy to Bet v 1*		–Birch allergy			
REGN1908-1909[f] *Multi-antibody therapy to Fel d 1*		–Cat allergy			
Solid Organ Oncology					
Libtayo (cemiplimab)[g] *Antibody to PD-1*	–Neoadjuvant CSCC –First-line NSCLC, BNT116[i] combination –Neoadjuvant NSCLC –Neoadjuvant hepatocellular carcinoma ("HCC")	–Adjuvant CSCC –Early-stage CSCC (intralesional)	–First-line NSCLC, monotherapy and chemotherapy combination (Japan)	–Presented positive five-year survival data from Phase 3 NSCLC monotherapy trial at IASLC 2024 World Conference on Lung Cancer –Reported positive interim data from Phase 3 study in adjuvant CSCC	–MHLW decision on regulatory submission for NSCLC, monotherapy and chemotherapy combination (second half 2025) –Submit sBLA for adjuvant CSCC (first half 2025)
Fianlimab[f] (REGN3767) *Antibody to LAG-3*	–First-line advanced NSCLC (Phase 2/3) –Perioperative NSCLC –Perioperative melanoma	–First-line metastatic melanoma[e] –Adjuvant melanoma		–Presented positive two-year data from Phase 1 trial (in combination with Libtayo) in advanced melanoma at European Society for Medical Oncology ("ESMO") Annual Meeting	–Initiate Phase 2 study (in combination with Libtayo) in first-line metastatic head and neck squamous cell carcinoma (2025) –Report results from Phase 3 study versus pembrolizumab in first-line metastatic melanoma (second half 2025) –Report initial data from Phase 2/3 study in first-line advanced NSCLC (first half 2025)
Vidutolimod *Immune activator targeting TLR9*				–Company discontinued Phase 2 study due to drug supply	
Ubamatamab[f] (REGN4018) *Bispecific antibody targeting MUC16 and CD3*	–Platinum-resistant ovarian cancer				–Report additional data from study in platinum-resistant ovarian cancer (2025)

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2024 and 2025 Events to Date	Select Upcoming Milestones
Nezastomig (REGN5678) *Bispecific antibody targeting PSMA and CD28*	–Prostate cancer				–Report additional data from study in prostate cancer (2025)
REGN7075 *Bispecific antibody targeting EGFR and CD28*	–Solid tumors			–Presented positive results from dose escalation portion of Phase 1/2 trial (in combination with Libtayo) in advanced solid tumors at American Society of Clinical Oncology ("ASCO") 2024 Annual Meeting	–Report additional data from study in solid tumors (2025)
Davutamig (REGN5093) *Bispecific antibody targeting two distinct MET epitopes*	–MET-altered advanced NSCLC				
Hematology					
Pozelimab[f] (REGN3918) *Antibody to C5*		–Myasthenia gravis, cemdisiran combination[c][l] –Paroxysmal nocturnal hemoglobinuria ("PNH"), cemdisiran combination[c][l]		–Presented positive updated data from Phase 3 trial (in combination with cemdisiran) in PNH at American Society of Hematology ("ASH") Annual Meeting	–Report results from Phase 3 cemdisiran combination study in myasthenia gravis (second half 2025)
Ordspono (odronextamab) *Bispecific antibody targeting CD20 and CD3*	–B-cell non-Hodgkin lymphoma ("B-NHL") (pivotal study)	–FL[e] –DLBCL[e]	–FL (U.S.)	–FDA issued Complete Response Letters ("CRLs") for BLA for relapsed/refractory FL and DLBCL due to enrollment status of confirmatory Phase 3 trials; subsequently resubmitted BLA for FL –Approved by EC for relapsed/refractory FL and DLBCL –Presented new and updated data for several B-NHL subtypes across earlier lines of treatment at ASH Annual Meeting	–FDA decision on BLA for relapsed/refractory FL (second half 2025)

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2024 and 2025 Events to Date	Select Upcoming Milestones
Linvoseltamab[f] (REGN5458) *Bispecific antibody targeting BCMA and CD3*	–Multiple myeloma (pivotal study)[c][e] –Earlier (pre-malignant) multiple myeloma –Monoclonal gammopathy of undetermined significance ("MGUS") –Light chain amyloidosis ("ALA")	–Multiple myeloma[c][e]	–Relapsed/refractory multiple myeloma (U.S. and EU)	–Resubmitted BLA for relapsed/refractory multiple myeloma following resolution of third-party manufacturing issues –Presented 14-month median follow-up data from pivotal Phase 1/2 trial in multiple myeloma at European Hematology Association ("EHA") Congress 2024 and published these data in *Journal of Clinical Oncology*	–FDA decision on BLA (mid-2025) and EC decision on regulatory application (first half 2025) for relapsed/refractory multiple myeloma
Nexiguran ziclumeran (Nex-z, NTLA-2001)[j] *TTR gene knockout using CRISPR/Cas9*		–Transthyretin amyloidosis with cardiomyopathy ("ATTR-CM")[c] –Hereditary transthyretin amyloidosis with polyneuropathy ("ATTRv-PN")[c][m]			
REGN9933 *Antibody to Factor XI*	–Thrombosis			–Reported positive results from Phase 2 trial in thrombosis	–Initiate Phase 3 program (2025)
REGN7508 *Antibody to Factor XI*	–Thrombosis			–Reported positive results from Phase 2 trial in thrombosis	–Initiate Phase 3 program (2025)
REGN7257 *Antibody to IL2Rg*	–Aplastic anemia				
REGN7999 *Antibody to TMPRSS6*	–Iron overload in beta-thalassemia				
Internal Medicine/Genetic Medicines					
Garetosmab[f] (REGN2477) *Antibody to Activin A*		–Fibrodysplasia ossificans progressiva ("FOP")[c][d][e]			–Report results from Phase 3 study in FOP (second half 2025)
Trevogrumab[f] (REGN1033) *Antibody to myostatin (GDF8)*	–Obesity[n]			–Completed enrollment in Phase 2 study in obesity	–Report results from Phase 2 study in obesity (second half 2025)

Clinical Program *(continued)*	Phase 2	Phase 3	Regulatory Review[h]	2024 and 2025 Events to Date	Select Upcoming Milestones
Mibavademab[f][o] (REGN4461) *Agonist antibody to leptin receptor ("LEPR")*		–Generalized lipodystrophy[d][e]			
REGN5381 *Agonist antibody to NPR1*	–Heart failure				
REGN7544 *Antagonist antibody to NPR1*	–Postural orthostatic tachycardia syndrome ("POTS")				
Rapirosiran (ALN-HSD)[k] *RNAi therapeutic targeting HSD17B13*	–Metabolic dysfunction-associated steatohepatitis ("MASH")				
DB-OTO *AAV-based gene therapy*	–Hearing deficit due to variants of the otoferlin gene[c][m] (Phase 1/2)			–Presented updated data from Phase 1/2 trial at American Society of Gene and Cell Therapy ("ASGCT") annual conference	–Report additional data from Phase 1/2 study (mid-2025)

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

[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 captures submissions to U.S., EU, and Japan regulatory authorities

[i] BioNTech's BNT116 is an mRNA cancer vaccine.

[j] In collaboration with Intellia

[k] 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.

[l] Under the terms of our license agreement for cemdisiran, Alnylam is entitled to receive royalties on sales (if any), as well as sales milestones.

[m] FDA granted Regenerative Medicine Advanced Therapy ("RMAT") designation

[n] Studied in combination with semaglutide with and without garetosmab

[o] A Phase 2 study, sponsored by Eli Lilly, is also ongoing and testing the combination of tirzepatide and mibavademab compared with tirzepatide alone in patients with obesity.

Additional Information - Clinical Development Programs

Linvoseltamab

In August 2024, the FDA issued a CRL for the BLA for linvoseltamab in relapsed/refractory multiple myeloma that has progressed after at least three prior therapies. The sole approvability issue identified related to findings from a pre-approval inspection at a third-party fill/finish manufacturer. In January 2025, the Company resubmitted the BLA following resolution of third-party manufacturing issues, and an FDA decision on the BLA is anticipated by mid-2025.

Dupixent

In September 2024, the Company and Sanofi announced that the first Phase 3 trial (Study A) of Dupixent in adults with uncontrolled and severe CPUO did not achieve statistical significance in its primary itch responder endpoint (despite favorable numerical improvements), but showed nominally significant improvements in all other itch endpoints. The Dupixent Phase 3 program in CPUO consists of Study A and Study B. Study B recently initiated as a subsequent pivotal trial.

Select Early-Stage Clinical Development Updates

In 2024, a Phase 1 study of linvoseltamab, in combination with dupilumab, in severe food allergy was initiated.

In 2024, a Phase 1 combination cohort of nezastomig and REGN4336 (bispecific antibody targeting PSMA and CD3) in metastatic castration-resistant prostate cancer was initiated.

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

EYLEA HD (aflibercept) 8 mg

EYLEA HD is a soluble fusion protein that acts as a vascular endothelial growth factor ("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 to treat various retinal diseases, including wAMD, DME, and DR.

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 play a major role in atopic dermatitis, asthma, CRSwNP, COPD, EoE, prurigo nodularis, CSU, 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 an immune system 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.

REGN5713-5715

REGN5713-5715 is an investigational combination of two fully human monoclonal antibodies designed to treat allergic inflammatory conditions caused by the allergen Bet v 1, 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.

REGN1908-1909

REGN1908-1909 is an investigational combination of two fully human monoclonal antibodies that is designed to specifically bind and block the Fel d 1 allergen, thus preventing it from binding and triggering the endogenous antibodies that cause allergies (i.e., immunoglobulin E antibodies). Cat allergy is primarily caused by exposure to Fel d 1, the major allergen in cat dander produced by all cats.

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. Libtayo has also been approved by regulatory authorities in a number of cancer indications, including advanced NSCLC, BCC, CSCC, and cervical cancer.

Fianlimab

Fianlimab is an investigational, fully human monoclonal antibody targeting the immune checkpoint receptor LAG-3 on T-cells. In melanoma and NSCLC, 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.

Pozelimab

Pozelimab is a fully human monoclonal antibody designed to block complement factor C5 in order to treat diseases mediated by abnormal complement pathway activity, and is approved by the FDA for CHAPLE. Pozelimab is being studied in investigational combinations with an investigational small interfering RNA ("siRNA") therapy, cemdisiran, in PNH, myasthenia gravis, and geographic atrophy.

Ordspono (odronextamab)

Odronextamab is a bispecific monoclonal antibody designed to bridge CD20 on cancer cells with CD3-expressing T cells to facilitate local T-cell activation and cancer-cell killing. We are studying odronextamab 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. We are also studying linvoseltamab in precursor conditions to multiple myeloma, including high-risk MGUS and high-risk smoldering myeloma.

Nex-z

Nex-z is an investigational CRISPR-based therapy to be systemically delivered to edit genes inside the human body and is being studied as a treatment for ATTR amyloidosis. ATTR amyloidosis is a progressive and fatal disorder resulting from deposition of insoluble amyloid fibrils into multiple organs and tissues leading to systemic failure. Delivered with *in vivo* technology, nex-z offers the possibility of halting and reversing the disease by driving a deep, consistent, and potentially lifelong reduction in transthyretin ("TTR") protein after a single dose.

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.

Mibavademab

Mibavademab is an investigational, fully human monoclonal antibody that binds to and activates the leptin receptor, which modulates the control of food intake, energy expenditure, and glucose/lipid metabolism. We are studying mibavademab as a potential treatment for generalized lipodystrophy.

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 HD, 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. We also leverage *VelociSuite* to produce new classes of bispecific antibodies. Additionally, we use genetic medicine platforms as complementary approaches to these core technologies to potentially treat or cure diseases.

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 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 T-cell receptors ("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 can be utilized to produce 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 patient's 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 nearly 3 million samples sequenced to date.

In January 2025, it was announced that RGC was selected by UK Biobank consortium members to complete proteomic assay data generation for the recently announced UK Biobank Pharma Proteomics Project.

In January 2025, RGC entered into an agreement with Truveta Inc. pursuant to which RGC will sequence exomes and conduct genotyping and imputation of up to ten million de-identified consented volunteers using biospecimens provided by Truveta health system members across the United States.

In addition, central to the ongoing work of RGC is the portfolio of collaborations with over 150 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, and the University of Cambridge. 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, RGC has deployed bulk RNA sequencing, whole genome sequencing, and an O-LINK proteomic assay to complement whole exome sequencing and genotyping. In addition, RGC leverages organoid models, siRNA, and CRISPR knockout models to validate genetic associations that lead to new therapeutic targets. 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 RGC have led to the identification of more than 30 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 Pharmaceuticals, Inc. and Intellia Therapeutics, Inc.

Collaboration, License, and Other Agreements

Sanofi

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 Collaboration, 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; however, we are only required to apply 20% of our share of profits from the collaboration each calendar quarter to reimburse Sanofi for these development expenses. As of December 31, 2024, the total amount of our contingent reimbursement obligation (i.e., "development balance") to Sanofi in connection with such development expenses was approximately $1.635 billion.

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 from sales within the United States, and 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).

Bayer

We and Bayer are parties to a license and collaboration agreement for the global development and commercialization of EYLEA 8 mg and EYLEA outside the United States. Agreed-upon development expenses incurred by the Company and Bayer are generally shared equally. Bayer is responsible for commercialization activities outside the United States, and the companies share equally in profits from such 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.

Alnylam

In 2019, we and Alnylam entered into a 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. For each program, we provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation. During 2023, we paid a $100.0 million development milestone to Alnylam (in connection with a CNS program) and Alnylam is eligible to receive an additional $100.0 million clinical proof-of-principle milestone in connection with an eye program.

Under the terms of the collaboration, the parties 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") or a license agreement structure. The initial target nomination and discovery period of five years has been automatically extended until the earlier of seven years from the effective date of the collaboration or the achievement of certain milestones (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 of $300.0 million.

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.

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. 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.

We have entered into various license agreements with Alnylam, with us as the licensee, including for cemdisiran as a monotherapy and for a combination consisting of cemdisiran and pozelimab.

During the second quarter of 2024, we elected to no longer co-develop ALN-APP pursuant to a Co-Co Collaboration Agreement; as a result, Alnylam retains the right to develop and commercialize such product and we will receive a royalty on sales (if any).

Intellia

We and Intellia Therapeutics, Inc. are parties to a license and collaboration agreement to advance CRISPR/Cas9 gene-editing technology for *in vivo* therapeutic development. Nex-z, 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 addition, we also have non-exclusive rights to independently develop and commercialize *ex vivo* gene edited products.

In September 2023, we expanded the license and collaboration agreement to develop additional *in vivo* CRISPR-based gene editing therapies focused on neurological and muscular diseases. Intellia will lead the design of the editing methodology, we will lead the design of the targeted viral vector delivery approach, and the parties share costs equally. Each company will have the opportunity to lead potential development and commercialization of product candidates for one target, and the company that is not leading development and commercialization will have the option to enter into a co-development and co-commercialization agreement for the target.

In addition, in October 2023, we elected to extend the period for selecting targets under the license and collaboration agreement for an additional two years until April 2026; as a result, we made a $30.0 million extension payment to Intellia.

In March 2024, Intellia elected to opt-out of further development activities pursuant to the Factor IX co-development and co-commercialization agreement; as a result, we retain the right to develop and commercialize products directed to Factor IX (which is currently in Phase 1 clinical development), and Intellia will be entitled to receive milestone payments and royalties on sales (if any).

Decibel

In 2017, we entered into an agreement with Decibel Therapeutics, Inc. to discover and develop new potential therapeutics to protect, repair and restore hearing (including DB-OTO, which is currently in clinical development, and preclinical programs for GJB2-related and stereocilin-related hearing loss).

In 2023, we acquired Decibel by paying $101.3 million in cash (or $4.00 per share of Decibel common stock). In addition, Decibel shareholders received one non-tradeable contingent value right ("CVR") per share of Decibel common stock, entitling them to receive up to an additional $3.50 per share in cash upon achievement of certain development milestones for DB-OTO within specified time periods. During 2024, the first and second (final) development milestones contemplated by the CVRs were achieved. As a result, we have paid an aggregate amount of $97.1 million, which was the maximum amount that holders of the CVRs were entitled to receive (including the payment in respect of the second development milestone made in 2025).

2seventy bio

In 2018, we entered into a collaboration agreement with bluebird bio, Inc. (which subsequently spun out 2seventy bio, Inc. in 2021) to research, develop, and commercialize novel cell therapy approaches to address cancer.

In April 2024, we acquired full development and commercialization rights to 2seventy bio's oncology and autoimmune preclinical and clinical stage cell therapy pipeline. Under the terms of the agreement, we made a $5.0 million up-front payment, and have assumed ongoing program, infrastructure, and personnel costs related to the product candidates acquired. We are obligated to pay 2seventy bio a regulatory milestone upon the first major market approval of the first approved product; and, with respect to any approved product, a low single-digit percent royalty on sales. In addition, we separately entered into sublease agreements for a portion of 2seventy bio's facilities.

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 manufacturing, office, laboratory, and warehouse space. In addition, we have constructed a fill/finish facility in Rensselaer, New York that is undergoing process validation as required by regulatory authorities.

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. See Part I, Item 1A. "Risk Factors - Risks Related to Manufacturing and Supply" for further information.

Among the conditions for marketing approval of a new drug or biologic product 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 Cencora, Inc., and McKesson Corporation) that each accounted for more than 10% of total gross product revenue for the year ended December 31, 2024. On a combined basis, our product sales to these customers accounted for 74% of our total gross product revenue for the year ended December 31, 2024. 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 Dupixent in accordance with our Sanofi collaboration and with obtaining the rights, in 2022, to commercialize Libtayo outside the United States.

Competition

We face substantial competition from pharmaceutical and biotechnology 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, ease of administration, dosing frequency, 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 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 HD and EYLEA [b]	Pavblu® (aflibercept-ayyh) (biosimilar referencing EYLEA)	Amgen Inc.	wAMD, DME, macular edema following RVO (including CRVO and BRVO), and DR	United States
	Vabysmo™ (faricimab-svoa)	Genentech/Roche	wAMD, DME, and macular edema following RVO	United States, EU, Japan
	Avastin® (bevacizumab) (off-label and repackaged)	Genentech/Roche	wAMD, DME, and macular edema following RVO	United States, EU, Japan
	Lucentis® (ranibizumab injection)	Novartis AG and Genentech/Roche	wAMD, DME, macular edema following RVO (including CRVO and BRVO), DR, mCNV, and ROP	United States, EU, Japan
	Byooviz™ (ranibizumab-nuna) (biosimilar referencing Lucentis)	Samsung Bioepis Co., Ltd. and Biogen Inc.	wAMD, DME, macular edema following RVO (including CRVO and BRVO), DR, and mCNV	United States, EU
	Ximluci® (ranibizumab) (biosimilar referencing Lucentis)	Xbrane Biopharma AB and STADA Arzneimittel AG	wAMD, DME, macular edema following RVO (including CRVO and BRVO), DR, and CNV	EU

Marketed Product *(continued)*	Competitor Product	Competitor	Indication	Territory[a]
EYLEA HD and EYLEA *(continued)*	Cimerli™ (ranibizumab-eqrn) (biosimilar referencing Lucentis)	Formycon AG, Bioeq AG, Sandoz, and Teva Ltd.	wAMD, DME, macular edema following RVO (including CRVO and BRVO), DR, and mCNV	United States, EU
	Susvimo® (ranibizumab ocular implant)	Genentech/Roche	wAMD, DME	United States
	Beovu® (brolucizumab) Injection	Novartis AG	wAMD, DME	United States, EU, Japan
	Ozurdex® (dexamethasone intravitreal implant)	Allergan/AbbVie Inc.	DME, RVO	United States, EU
	Iluvien® (fluocinolone acetonide intravitreal implant)	Alimera Sciences, Inc.	DME	United States, EU
Dupixent	Ebglyss® (lebrikizumab)	Almirall S.A., Eli Lilly and Company	Moderate-to-severe atopic dermatitis	United States, EU, Japan
	Rinvoq® (upadacitinib)	AbbVie	Moderate-to-severe atopic dermatitis	United States, EU, Japan
	Nemluvio®/Mitchga® (nemolizumab)	Galderma; Maruho Co., Ltd./Chugai Pharmaceutical Co., Ltd.	Moderate-to-severe atopic dermatitis, pruritus associated with atopic dermatitis, prurigo nodularis	United States, Japan
	Adbry™/Adtralza® (tralokinumab)	LEO Pharma Inc.	Moderate-to-severe atopic dermatitis	United States, EU, Japan
	Cibinqo® (abrocitinib)	Pfizer	Moderate-to-severe atopic dermatitis	United States, EU, Japan
	Tezspire™ (tezepelumab-ekko)	AstraZeneca/Amgen	Asthma	United States, EU, Japan
	Fasenra® (benralizumab)	AstraZeneca	Asthma	United States, EU, Japan
	Nucala® (mepolizumab)	GlaxoSmithKline ("GSK")	Asthma, nasal polyps	United States, EU, Japan
	Xolair® (omalizumab)	Roche/Novartis	Asthma, nasal polyps, CSU	United States, EU, Japan
Libtayo	Keytruda® (pembrolizumab)	Merck & Co., Inc.	Various cancers	United States, EU, Japan
	Opdivo® (nivolumab)	Bristol-Myers Squibb	Various cancers	United States, EU, Japan
	Tecentriq® (atezolizumab)	Roche	Various cancers	United States, EU, Japan
	Imfinzi® (durvalumab)	AstraZeneca	Various cancers	United States, EU, Japan
	Bavencio® (avelumab)	Pfizer/Merck KGaA	Various cancers	United States, EU, Japan
	Jemperli® (dostarlimab)	GSK	Various cancers	United States, EU
	Unloxcyt™ (cosibelimab)	Checkpoint Therapeutics, Inc.	CSCC	United States

[a] This table focuses on products that have received marketing approval in one or more of the specified indications in the United States, EU, and/or Japan. Certain products listed in this table have also received marketing approval in countries outside the United States, EU, and Japan.

[b] In addition to the products listed in this table, certain other biosimilar products referencing EYLEA have received marketing approval in the United States, EU, and/or Japan but have not yet launched in such jurisdictions. The timing of any launch of these biosimilar products will depend on, among other factors, the outcome of the pending patent litigation proceedings described in Note 16 to our Consolidated Financial Statements and the expiration of the patents protecting EYLEA (including those set forth under "Patents, Trademarks, and Trade Secrets" below).

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 other 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 have become 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 other 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 other 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 remaining issued patents covering these technologies will expire between 2025 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. The noted expiration dates include any patent term adjustments, and 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. We also own various patents with claims relating to methods of making, formulating, and/or using the active molecules contained within our key products, but that do not cover indications, methods of use or processes currently approved by regulatory agencies or used by us and/or our collaborators. Such patents are not listed in the following table.

Product	Molecule	Territory	Patent No.	General Subject Matter Class	Expiration
EYLEA HD	aflibercept (8 mg)	US	11,066,458	Formulation	June 14, 2027
		US	11,084,865	Formulation	June 14, 2027
		US	11,103,552	Formulation	May 15, 2039
		US	10,828,345	Methods of Treatment	January 11, 2032
		US	12,168,036	Methods of Treatment	May 15, 2039
		JP	7,235,770	Formulation	May 10, 2039
EYLEA[a]	aflibercept (2 mg)	US	8,092,803	Formulation	June 21, 2027
		US	11,066,458	Formulation	June 14, 2027
		US	11,084,865	Formulation	June 14, 2027
		US	11,732,024	Formulation	June 14, 2027
		US	10,828,345	Methods of Treatment	January 11, 2032
		US	11,559,564	Methods of Treatment	January 11, 2032
		US	11,707,506	Methods of Treatment	January 11, 2032
		US	11,730,794	Methods of Treatment	January 11, 2032
		EP	1183353	Composition of Matter (Supplementary Protection Certificate)	(May 23, 2025)[b]/(November 23, 2025)[c]
		EP	2364691	Formulation	June 14, 2027
		EP	2944306	Formulation	June 14, 2027[b]
		EP	2944306	Formulation (Supplementary Protection Certificate)	(May 25, 2028)[b]
		JP	5,216,002	Formulation	February 27, 2028 – October 1, 2029[d]
Dupixent	dupilumab	US	7,608,693	Composition of Matter	March 28, 2031[e]
		US	8,735,095	Composition of Matter	October 2, 2027
		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	11,926,670	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	10,066,017	Methods of Treatment	January 21, 2036
		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	January 21, 2036

Product *(continued)*	Molecule	Territory	Patent No.	General Subject Matter Class	Expiration
Dupixent *(continued)*		US	11,167,004	Methods of Treatment	September 21, 2037
		US	11,034,768	Methods of Treatment	March 28, 2039
		US	11,292,847	Methods of Treatment	May 10, 2039
		US	11,845,800	Methods of Treatment	December 22, 2033
		US	12,090,201	Methods of Treatment	February 3, 2043
		EP	2356151	Composition of Matter	October 27, 2029[b]
		EP	2356151	Composition of Matter (Supplementary Protection Certificate)	(September 28, 2032)[b]/(March 28, 2033)[c]
		EP	3715372	Composition of Matter	October 27, 2029
		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	3019191	Methods of Treatment	July 10, 2034
		EP	3703818	Methods of Treatment	October 29, 2038
		EP	4011915	Methods of Treatment	August 20, 2033
		EP	3515465	Methods of Treatment	September 21, 2037
		EP	3889181	Methods of Treatment	September 4, 2033
		EP	3973987	Methods of Treatment	February 20, 2035
		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	5,844,772	Composition of Matter	October 27, 2029 – February 22, 2034
		JP	5,918,246	Formulation	October 5, 2031 – September 14, 2035[d]
		JP	6,231,605	Formulation	October 5, 2031 – March 3, 2034
		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	6,640,977	Methods of Treatment	June 20, 2034 – September 6, 2034
		JP	6,861,630	Methods of Treatment	November 13, 2035
		JP	6,893,265	Methods of Treatment	February 20, 2035
		JP	7,164,530	Methods of Treatment	September 21, 2037
		JP	7,216,122	Methods of Treatment	November 13, 2035
		JP	7,216,157	Methods of Treatment	August 20, 2033
		JP	7,256,231	Methods of Treatment	September 4, 2033
		JP	7,315,545	Methods of Treatment	October 29, 2038
		JP	7,343,547	Methods of Treatment	February 20, 2035
Libtayo	cemiplimab	US	9,987,500	Composition of Matter	September 18, 2035
		US	10,737,113	Composition of Matter	April 10, 2035
		US	11,603,407	Formulation	March 21, 2038

Product *(continued)*	Molecule	Territory	Patent No.	General Subject Matter Class	Expiration
Libtayo *(continued)*		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
		US	11,926,668	Methods of Treatment	February 20, 2038
		EP	3097119	Composition of Matter	January 23, 2035
		EP	3606504	Formulation	March 23, 2038
		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 – March 15, 2039[(d)]
		JP	6,711,883	Composition of Matter	January 23, 2035 – August 13, 2037[(d)]
		JP	7,174,009	Composition of Matter	January 23, 2035 – March 9, 2035[(d)]
		JP	7,229,171	Formulation	March 23, 2038
		JP	7,240,512	Methods of Treatment	May 25, 2041

[(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 and patent infringement proceedings relating to EYLEA.

[(b)] Supplementary protection certificates ("SPCs") are pending 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.

[(c)] SPC term extensions are pending or have been granted in various European countries based on the completion of a pediatric investigation program, extending the term of the SPC in those countries, where granted, an additional 6 months 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.

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, have in the past reduced and could reduce in the future the duration of market exclusivity for our products*"). 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 paid royalties of 8.0% on worldwide sales of Libtayo through December 31, 2023, and are obligated to pay 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 other 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 other 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 other 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, European Medicines Agency ("EMA"), and regulatory authorities of other countries. The structure and substance of the FDA and other countries' 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 recruiting 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, representative, 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. 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 will typically inspect such facilities for compliance with these requirements and regulations prior to approving a BLA. 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 countries outside the United States 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. 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.*"

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. FDA and comparable foreign regulatory authorities' regulations impose restrictions on manufacturers' communications regarding unapproved uses, but under certain conditions manufacturers 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 countries outside the United States 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 - *Changes to product reimbursement and coverage policies and practices 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 the average manufacturer price increases more than inflation (measured by reference to the Consumer Price Index - Urban). Effective January 1, 2024, the rebate is no longer capped at 100% of the average manufacturer price and, as a result, the rebate liability of manufacturers could increase.

If we become aware that our Medicaid 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. If we fail to pay the required rebate amount or report pricing data on a timely basis, we may be subject to civil monetary penalties and/or termination of our Medicaid Drug Rebate program agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. For additional information regarding risks related to our price reporting and rebate payment obligations, see Part I, Item 1A. "Risk Factors - Other Regulatory and Litigation Risks - *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*."

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 healthcare 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. 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% 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, the Inflation Reduction Act ("IRA") has established a Medicare Part B inflation rebate scheme under which, generally speaking, manufacturers 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 created a drug price negotiation program requiring the government to set prices for select high-expenditure drugs covered under Medicare Parts B and D. Starting in 2023 and 2026, the government is authorized to select Part D and Part B drugs, respectively, for inclusion in the drug price negotiation program, with established prices to go into effect for selected Part D drugs in 2026 and for selected Part B drugs in 2028, in each case absent certain disqualifying events. 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 - *Changes to product reimbursement and coverage policies and practices 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 federal Patient Protection and Affordable Care 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. If we are found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price, we could be subject to significant civil monetary penalties and/or such failure also could be grounds for HRSA to terminate our agreement to participate in the 340B program, in which case our covered outpatient drugs would no longer be eligible for federal payment under Medicaid or Medicare Part B. Moreover, HRSA has established an 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. HRSA has 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 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, the IRA has 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 or otherwise comply with obligations under the Medicare Part D inflation rebate scheme 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 healthcare "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*."

We are subject to privacy and data protection laws in the United States and abroad, including health privacy laws, data breach notification laws, consumer protection laws, data localization laws, biometric privacy laws, and genetic privacy laws.

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. At the federal level, most U.S. healthcare providers, including research institutions from which we or our collaborators obtain clinical trial data, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations (collectively, "HIPAA"). While Regeneron is not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we, our affiliates, or our agents knowingly receive protected health information in a manner that is not permitted under HIPAA. The Federal Trade Commission ("FTC") also sets expectations for taking appropriate steps to safeguard consumers' personal information and for providing a level of privacy or security commensurate to promises made to individuals. Failure to meet these FTC standards may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records. Enforcement by the FTC under the FTC Act and Health Breach Notification Rule can result in civil penalties or enforcement actions. In addition, at the state level, many state consumer privacy laws recently went into effect and many other consumer privacy laws are expected to go into effect in the near future. These laws include certain transparency and other requirements to protect personal data and grant residents with certain rights regarding their personal data. These laws and regulations are constantly evolving and may impose limitations on our business activities.

Outside the United States, our activities subject us to additional data protection authority oversight and require us to comply with stringent local and regional data privacy laws. Such laws include the EU's General Data Protection Regulations ("GDPR"), which has a wide range of compliance obligations relating to the processing and protection of personal data. Violations of the GDPR carry significant financial penalties for noncompliance. The GDPR also confers a private right of action on data subjects and

consumer associations to file complaints with data protection authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Many other jurisdictions outside the United States have adopted and continue to adopt varying privacy and data protection legislation, the continued emergence of which has increased the costs and complexity of compliance.

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, 2024, we had 15,106 full-time employees, consisting of 11,914 employed in the United States, 2,168 employed in Ireland, and 1,024 employed in other countries (primarily in the United Kingdom, Japan, and Germany). Of these employees, 2,562 were within our research and preclinical development organization, 2,151 were within our global clinical development and regulatory affairs organization, and 6,846 were within our industrial operations and product supply organization. Company-wide, nearly 1,700 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.

Culture and Development

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. Our strategy is rooted in the understanding that a better workplace drives better science and that better science drives a better world. We believe that by fostering an inclusive culture and bringing diverse voices and perspectives to the discourse, we improve our ability to fulfill our mission to repeatedly bring important medicines to patients with serious diseases. We empower employee-led cross-functional resource groups, functional/site-level councils, and other interest groups, who connect around a common passion to build a culture of inclusion and collaboration. In recent years, we have expanded our mentoring program and inclusive leadership workshops for senior leaders and new managers, focusing on our diverse talent base to increase leadership skills, connection, and visibility 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 early 2021, we launched a global strategy to advance diversity, focused on creating a better workplace, better science, and better world; and implemented a new governance model that includes councils comprised of senior leaders who provide oversight and guidance on our diversity efforts and support the execution of our 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 and/or an appropriate committee thereof receives a detailed update on our efforts at least once a year and continues to monitor our progress.

2024 Workforce Diversity Representation*	
Female Representation (Global)	50.0%
People of Color Representation (U.S. Only)**	31.6%

* Based on full-time employees as of December 31, 2024

** 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 35.5%.

Externally, we support diversity 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 ("STS"), we allocate $3.1 million annually to fund the Society for Science's science, technology, engineering, and math ("STEM") outreach and equity programs. We have also been the title sponsor of the Regeneron International Science and Engineering Fair ("ISEF") since 2019 and made an additional $34 million, 5-year commitment to this program in 2023. Also in 2023, the Together for CHANGE™ ("Changing Healthcare for People of African Ancestry through InterNational Genomics & Equity") initiative was launched by a coalition of Meharry Medical College, the Regeneron Genetics Center, AstraZeneca, Novo Nordisk, and Roche to improve health outcomes for people of African ancestry and enhance their representation in STEM careers. Among our other efforts, 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, policies, 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 2024, 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 town halls, 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 2024, over 7,800 employees volunteered approximately 45,400 hours,

including approximately 49% of our employees who volunteered nearly 27,400 hours to approximately 220 nonprofits during our *Day for Doing Good*. Additionally, through our Matching Gift Program, we matched approximately $2.3 million in employee contributions in 2024, supporting over 2,300 charities. In 2024, we were named to the Civic 50 of most community-minded companies in the United States for the eighth consecutive year.

The success of our employee engagement efforts is demonstrated by our employee retention rate of 94% in 2024, as well as the fact that 88% 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 14 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 stock-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 stock-based grants to all new hires, in addition to our comprehensive annual stock-based compensation program. Total employee compensation packages (which vary by country and region) include market-competitive pay (with the opportunity to receive above-market rewards), broad-based grants of stock-based awards, comprehensive healthcare benefits, parental leave, child and elder care support, retirement savings options, and matching contributions in connection with employee savings plans.

Corporate Information

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://investor.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.

Commercialization Risks

- We are substantially dependent on the success of EYLEA, EYLEA HD, and Dupixent.
- Sales of our products are dependent on the availability and extent of coverage and reimbursement from third-party payors, including private payors and government programs such as Medicare and Medicaid.
- Product reimbursement and coverage policies and practices 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 established or 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 and outside the United States.

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, have in the past reduced and could reduce in the future the duration of market exclusivity for our products.

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 has been and will continue to 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, regulations, and policies affecting the healthcare industry could adversely affect our business.
- Tax liabilities and risks associated with our operations outside 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, may 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 or failure to realize the expected benefits from such acquisitions could adversely affect our business, operating results, and financial condition.

Other Risks Related to Our Business and Our Common Stock

- Our business is dependent on our key personnel and will be harmed if we cannot recruit and retain key members of our senior management team, including 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.
- Public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) have adversely affected and may in the future adversely affect our business.
- 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 Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products

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

We are substantially dependent on the success of EYLEA and, since its August 2023 FDA approval, EYLEA HD. EYLEA net product sales have historically represented a substantial portion of our revenues, and we expect that there will continue to be a concentration of our net sales from the net product sales of EYLEA HD and EYLEA. For the years ended December 31, 2024 and 2023, our aggregate EYLEA HD and EYLEA net product sales in the United States represented 42% and 45% of our total revenues, respectively. For the year ended December 31, 2024, EYLEA HD U.S. net product sales represented 20% of our aggregate EYLEA HD and EYLEA U.S. net product sales. If we are successful in commercializing EYLEA HD, we expect that our dependence on EYLEA HD will grow relative to our historical dependence on EYLEA. If we experience difficulty with the commercialization of EYLEA HD or EYLEA in the United States or if Bayer experiences any difficulty with the

commercialization of EYLEA HD or EYLEA outside the United States, if EYLEA net product sales experience a sustained decline in or outside the United States without an offset from EYLEA HD net product sales, or if we and Bayer are unable to maintain or obtain marketing approvals of these products (as applicable), we may experience a reduction in revenue and may not be able to stay profitable at the levels we previously achieved or at all, and our business, prospects, operating results, and financial condition may be materially harmed.

Commercialization of EYLEA and EYLEA HD in the United States and elsewhere is subject to significant competition (as described further below under "*The commercial success of our products and product candidates is subject to significant competition* "), which we expect to continue to increase in the future. For the year ended December 31, 2024, EYLEA U.S. net product sales declined by 17% compared to the same period in 2023. Following the expiration of the U.S. regulatory exclusivity period for EYLEA (i.e., the period during which no biosimilar product can be approved by the FDA) in May 2024, several biosimilar versions of EYLEA have been approved by the FDA, and one such product has launched in the United States. EYLEA and/or EYLEA HD net product sales recorded by us are likely to be negatively impacted by biosimilar competition in the United States, which may have a material adverse impact on our results of operations. In addition, we expect that competition for EYLEA outside the United States will increase in the future when biosimilar versions of EYLEA (including those already approved but not yet launched) are brought to market in additional countries, which may negatively impact the amount of collaboration revenue we earn from Bayer. While we anticipate several important 2025 milestones relevant to further commercialization of EYLEA HD as shown in the table under Part I, Item 1. "Business - Programs in Clinical Development," there can be no assurance that any such milestones will be achieved or, if achieved, that they will enable us and Bayer to accelerate the ongoing launch and further commercialization of EYLEA HD. The degree to which EYLEA HD net product sales may offset further potential decrease in EYLEA net product sales, resulting from the factors discussed above or otherwise, is uncertain.

We also are substantially dependent on our share of profits from the commercialization of Dupixent under our Antibody Collaboration with Sanofi. For the years ended December 31, 2024 and 2023, Sanofi collaboration revenue (most of which is attributable to our share of profits from the commercialization of Dupixent) represented 32% and 29% of our total revenues, respectively. 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 may 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):

- 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; and, in the case of EYLEA and EYLEA HD, the existing and potential new branded and biosimilar competition (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 such products or to switch from a competitive product to one of our products;
- the safety and efficacy of our marketed products (particularly those launched recently, such as EYLEA HD) seen in a broader patient group (i.e., real-world use);
- the effect of existing and new healthcare laws and regulations currently being considered or implemented in the United States and globally, 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 (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 proceedings initiated or joined by the U.S. Department of Justice and 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, Japan, and other countries. 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. 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.*"), 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 coverage and reimbursement from third-party payors.

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 also dependent, in large part, on complex coverage and 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 healthcare systems, 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.

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 many countries outside the United States, 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 of these 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. In addition, in many countries outside the United States, we or our collaborators must participate in a tender process for public procurement of our products, and any failure to obtain acceptable pricing in the tender process could adversely affect our business. Our results of operations may suffer if we or our collaborators are unable to market our products in countries outside the United States or if coverage and reimbursement for our marketed products in such countries is limited or delayed. As discussed below under "*If we are unable to establish sufficient 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 will need to manage these and other commercialization-related risks in order for us to successfully maintain and/or further develop sufficient commercial capabilities outside the United States (including those necessary for our successful commercialization and co-commercialization of Libtayo and Dupixent, respectively).

Changes to product reimbursement and coverage policies and practices may materially harm our business, prospects, operating results, and financial condition.

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). Private payor healthcare and insurance providers, health maintenance organizations, and PBMs are increasingly requiring significant discounts and rebates from manufacturers as a condition to including products on formulary with favorable coverage and copayment/coinsurance. In addition, many payors continue to adopt benefit plan changes that shift a greater portion of prescription costs to patients, including more limited benefit plan designs, higher patient co-pay or co-insurance obligations, and limitations on patients' use of commercial manufacturer co-pay payment assistance programs (including through co-pay accumulator adjustment or maximization programs). Some states have also enacted or are considering legislation to control the prices and reimbursement of prescription drugs, including by establishing Prescription Drug Affordability Boards (or similar entities) to review high-cost drugs, setting upper payment limits, and/or implementing marketing cost disclosure and transparency measures. Additionally, 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 healthcare 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, regulations, 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, in 2022 the U.S. Congress passed the Inflation Reduction Act ("IRA"), which includes, among other items, provisions regarding the following:

- *Implementation of a Medicare Drug Price Negotiation Program* (the "Medicare Drug Price Negotiation Program"). The Medicare Drug Price Negotiation Program requires the government to set prices for select high-expenditure drugs covered under Medicare Parts B and D. Starting in 2023 and 2026, the government is authorized to select Part D and Part B drugs, respectively, for inclusion in the Medicare Drug Price Negotiation Program, with established prices to go into effect for selected Part D drugs in 2026 and for selected Part B drugs in 2028, in each case absent certain disqualifying events.
- *Medicare Inflation Based Rebates*. The IRA includes measures requiring manufacturers to pay rebates where increases to the average sales price or average manufacturer price of drugs covered under Medicare Parts B and D, respectively, exceed the rate of inflation.
- *Medicare Part D Program Redesign*. The IRA implements changes to the Medicare Part D benefits to limit patient out-of-pocket drug costs and shift program liabilities from patients to other stakeholders, including health plans, manufacturers, and the government.

The extent to which the policy changes described above will ultimately impact reimbursement levels of our marketed products, including those covered under Medicare Part B (such as EYLEA and EYLEA HD), or our product candidates that may be covered under Medicare Part B or Medicare Part D in the future, is currently unclear.

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, EYLEA HD, or our other marketed products. Economic pressure on state budgets may also have a similar impact.

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

Marketed Products

We face substantial competition from pharmaceutical and biotechnology 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 EYLEA HD. EYLEA and EYLEA HD face significant competition in the marketplace. For example, each of EYLEA and EYLEA HD competes in one or more of its approved indications with other VEGF inhibitors. These include Genentech/Roche's Vabysmo® (faricimab-svoa) and Susvimo® (ranibizumab ocular implant); Novartis and Genentech/Roche's Lucentis® (ranibizumab); Novartis' Beovu® (brolucizumab); and biosimilar versions of Lucentis commercialized in the United States by Biogen Inc. and Sandoz Group AG. In addition, biosimilar versions of EYLEA have been approved both in and outside the United States. These include Amgen's Pavblu™ (aflibercept-ayyh), which recently launched in the United States. We expect that biosimilar competition for EYLEA will increase in the future when additional biosimilar versions of EYLEA are launched in the United States and other countries, the timing of which will depend on, among other factors, the outcome of the pending patent litigation proceedings described in Note 16 to our Consolidated Financial Statements and the expiration of the patents protecting EYLEA (including those set forth under Part I - Item 1. "Business - Patents, Trademarks, and Trade Secrets"). 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 and EYLEA HD's respective indications, and we are aware of another company developing an ophthalmic formulation of such product that has been approved in the EU. In DME (and, in the case of EYLEA, also RVO), EYLEA and EYLEA HD also compete 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 and EYLEA HD's respective 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 other companies developing biosimilar versions of EYLEA, EYLEA HD, and/or 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.

EYLEA HD was approved by the FDA in August 2023 for the treatment of wAMD, DME, and DR and entered the highly competitive environment described above. Our success in commercializing EYLEA HD will depend on a number of factors, including the degree of success and relative timing of our commercial launch and uptake efforts as compared to those of relevant competition, the extent to which we and our collaborators are able to differentiate EYLEA HD from competitive products (such as on the basis of dosing frequency, the method of administration, or the breadth of indications in which the product is approved), the safety and efficacy of EYLEA HD seen in a broader patient group (i.e., real-world use), the extent of payor coverage and reimbursement, and the applicability of any restrictions imposed by payors, such as step therapy.

Dupixent. The market for Dupixent's current and potential future indications is also increasingly competitive. In atopic dermatitis, there are systemic JAK inhibitors and antibodies against IL-13 and IL-4Ra approved or in development for atopic dermatitis. There is also an antibody against IL-31R approved for atopic dermatitis and prurigo nodularis. In addition, a number of companies are developing antibodies against other targets, including OX40(L), that may compete with Dupixent in atopic dermatitis and other indications (including asthma and/or prurigo nodularis). 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, EoE, and COPD. There are several other potentially competitive products in development that may compete with Dupixent in asthma, COPD, and potential future indications, including antibodies against the IL-33 ligand or receptor. Dupixent also faces competition from inhaled products in asthma, COPD, 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® (pembrolizumab), Bristol-Myers Squibb's Opdivo® (nivolumab), Roche's Tecentriq® (atezolizumab), AstraZeneca's Imfinzi® (durvalumab), and Checkpoint Therapeutics' Unloxcyt™ (cosibelimab). While Libtayo is currently approved for intravenous administration only, certain of these products are also approved or in development for subcutaneous use.

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) treat the same conditions as 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. While we evaluate market opportunities for our product candidates, there can be no assurance that our estimates will accurately reflect the market opportunity at the time of launch or that our product candidates will meet internal or external expectations and be successful commercially due to existing or potential future competition or otherwise.

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 HD and EYLEA in the United States for its currently approved indications, we have no sales, marketing, commercial, or distribution capabilities for EYLEA HD or 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 HD and EYLEA 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 adversely 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 many 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 considerable part on Sanofi's sales and marketing organization in such jurisdictions. As described in Note 16 to our Consolidated Financial Statements, we have sued Sanofi and certain of its affiliated entities (the "Antibody Collaboration Litigation") alleging that the defendants breached certain provisions of the agreement governing the Antibody Collaboration (the "Collaboration Agreement"). These provisions concern Sanofi's obligation to provide Regeneron with full access to material information relating to the commercialization of Dupixent or other products commercialized pursuant to the Collaboration Agreement and Regeneron's audit rights under the Collaboration Agreement. It is not possible to determine what impact (if any) the Antibody Collaboration Litigation may have on the Antibody Collaboration and our business relationship with Sanofi, or whether we will be successful in the Antibody Collaboration Litigation.

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. While we have some commercial presence outside the United States, our commercial capabilities outside the United States are still limited and would need to be further developed or outsourced. Therefore, termination of the Bayer collaboration agreement or our Antibody Collaboration with Sanofi 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 HD and 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 HD and 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, may 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, tax rates, or national regulation of prices. Under our arrangement with Bayer, pricing and reimbursement for EYLEA HD and 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 marketed products and product candidates are typically delivered either by intravenous infusion or by intravitreal or subcutaneous injections. These methods of administration are generally disfavored by patients when compared to tablet or capsule delivery, which could adversely affect the commercial success of such marketed products or, if they receive marketing approval, product candidates.

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 (collectively, "distributor customers"), which generally sell the product directly to healthcare providers or other pharmacies (as applicable). For the years ended December 31, 2024 and 2023, our product sales to two distributor customers accounted on a combined basis for 74% and 76% of our total gross product revenue, respectively. We expect significant distributor 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 distributor customers 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 distributor customers are responsible for a significant portion of our net trade accounts receivable balances. The loss of any large distributor 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. Commercialization of any of our marketed products may

also be adversely impacted by vertical integration of private payor healthcare and insurance programs, health maintenance organizations, and PBMs, or further consolidation among the healthcare providers served or operated by our distributor customers if, for example, one or more consolidated groups of healthcare providers determines not to use (or decides to switch from) such marketed product in favor of a competing product. See also "*The commercial success of our products and product candidates is subject to significant competition* - Marketed Products" above.

If we are unable to establish sufficient 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.

While we have made progress with establishing commercial capabilities in certain jurisdictions outside the United States in connection with our acquisition of the exclusive right to develop, commercialize, and manufacture Libtayo worldwide pursuant to the 2022 Amended and Restated Immuno-oncology License and Collaboration Agreement with Sanofi (the "A&R IO LCA") and the exercise of our option under the Antibody Collaboration to co-commercialize Dupixent in certain jurisdictions outside the United States, our commercial capabilities and experience with commercializing products outside the United States (as well as obtaining and/or maintaining regulatory approvals and securing pricing and reimbursement for our products outside the United States) are still somewhat limited. There may be other circumstances in which we need to establish further 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 beyond what we have done so far, we must build or enhance 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 requisite commercial capabilities outside the United States 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

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

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. We must obtain and maintain similar regulatory approvals from comparable foreign regulatory authorities in order to sell drugs outside the United States. Obtaining FDA or comparable foreign regulatory authority 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, in the United States, 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 or additional analyses of data from existing studies and submit the data before it will reconsider our application. Depending on the extent of these or any other studies or analyses 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 or analyses, 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. For example, in October 2023, the FDA issued a CRL for the sBLA for Dupixent in CSU stating that additional efficacy data are required to support an approval. While we reported results from a confirmatory Phase 3 clinical trial of Dupixent in CSU (in biologic-naïve patients) in September 2024, there can be no assurance that such data will ultimately result in FDA or other regulatory approval. As another example of this type of risk, the FDA's request for additional analyses regarding sub-populations from the BOREAS and NOTUS pivotal studies delayed by three months the FDA's September 2024 approval of our sBLA for Dupixent as an add-on maintenance treatment of adults with inadequately controlled COPD and an eosinophilic phenotype.

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 countries outside the United States.

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. While the FDA has performance goals that provide for action on BLA submissions by certain deadlines, 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. The FDA's review of our regulatory submissions has in the past been delayed, and may be delayed in the future, due to the FDA's request for additional information or for other reasons, including those beyond our control.

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. FDA guidance relating to accelerated approval of oncology therapeutics indicates that a confirmatory trial for a particular oncology product candidate should be underway when the related BLA is submitted to the FDA and also states that the FDA may require that a confirmatory trial for a particular oncology product candidate be well underway, if not fully enrolled, by the time of the accelerated approval action. Application of this guidance and related rules to our product candidates may result in a delay of the FDA review and approval process despite any earlier beneficial regulatory designation such product candidates may have received. For example, in March 2024, the FDA issued CRLs concerning our BLA for odronextamab for the treatment of relapsed/refractory FL and DLBCL due to the enrollment status of confirmatory Phase 3 trials.

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, the manner in which such principles are implemented may not be specifically delineated, which can be challenging as the FDA and comparable foreign regulatory authorities increasingly scrutinize compliance with these requirements and regulations. As a result, 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 example, in August 2024, the FDA issued a CRL concerning the Company's BLA for linvoseltamab in relapsed/refractory multiple myeloma due to findings from a pre-approval inspection at a third-party fill/finish provider for another company's product candidate. While the linvoseltamab BLA has recently been resubmitted to the FDA, this has resulted in a delay of any potential FDA approval of this product candidate. 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 or other regulatory 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 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 countries outside the United States. 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 countries outside the United States. 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; for example, this is now the case for Libtayo in many jurisdictions outside the United States (including Europe and Japan) due to the transition under the A&R IO LCA discussed above. 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 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 countries outside the United States before we can market that product or any other product in those countries.

Furthermore, we are subject to extensive pharmacovigilance reporting and other pharmacovigilance requirements, which may differ in the numerous countries in which we conduct clinical trials or commercialize a product. 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 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 countries outside the United States 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, Ukraine, and/or Israel. While we currently do not expect the Russia-Ukraine or Hamas-Israel armed conflict or related developments to have a significant impact on our ability to obtain results from clinical trials conducted by us or our collaborators, further escalation (whether in these countries or 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 such countries 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. If concerns arise about the safety of a product candidate or non-compliance with the protocol or applicable regulatory requirements, the FDA or other regulatory authorities can delay or suspend a clinical trial by placing it on a full or partial "clinical hold" pending receipt of additional data or the satisfaction of other conditions. A clinical hold may require us to spend significant resources to address the underlying causes of the clinical hold and may result in a delay in the clinical program, which may be significant. In addition, if we are not able to successfully address such underlying causes or our response is not deemed adequate to lift the clinical hold, the clinical program may have to be terminated. Any such clinical program delays or terminations may adversely affect our business.

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. 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 or complex clinical programs (including those evaluating combination therapies), 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 EYLEA HD, there are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to further successfully commercialize EYLEA and to successfully commercialize EYLEA HD. 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, sterile and culture positive endophthalmitis, corneal decomposition, retinal detachment, retinal tear, and retinal vasculitis), 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. While the safety of EYLEA HD was similar to EYLEA in clinical trials, it is possible that the use of EYLEA HD outside the clinical trial setting may yield different

outcomes or patient experiences. In addition, commercialization of EYLEA and EYLEA HD or our other products and potential future commercialization of our 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 and EYLEA HD.

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 the safety data from these trials will be consistent with the known Dupixent and Libtayo safety profiles (as applicable) or 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.

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. In addition, the 8mg pre-filled syringe for EYLEA HD is approved in the EU and is currently under regulatory review in the United States. 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. 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. Our ability to protect our trade secrets may be impaired by a number of risks and uncertainties, including those discussed under "Other Regulatory and Litigation Risks - *Increasing use of social media and artificial intelligence-based platforms could give rise to liability, breaches of data security and privacy laws, or reputational damage*" and "Other Risks Related to Our Business - *Significant disruptions of information technology systems or breaches of data security could adversely affect our business*" below. 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 further 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, certain of our European patents, including those pertaining to EYLEA (as further described in Note 16 to our Consolidated Financial Statements included in this report) and Dupixent, are subject to opposition proceedings before the EPO and/or patent offices of various European countries. 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. We cannot be certain that our intellectual property rights related to any current or future product or product candidate or technology would not be eliminated, narrowed, or weakened by any such change 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 are not 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 are currently party to patent infringement and other proceedings relating to EYLEA, 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 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 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, under the Orphan Drug Act in the United States, if a product candidate with an orphan drug designation subsequently receives FDA approval for indication(s) within the scope of such designation, the product will be entitled to orphan drug exclusivity for such indication(s), barring the FDA from approving for seven years in such approved indication(s) another sponsor's application for a product candidate considered under the FDA regulations to be the same drug as the previously-approved drug with orphan drug exclusivity. This orphan drug exclusivity does not block approval of competing products intended for the orphan exclusivity-protected indication but containing a different active moiety or principal molecular structure, or containing the same active moiety or principal molecular structure but intended for a different indication. Similarly, 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. In both the United States and the EU, if a sponsor can demonstrate that a new product is safer, more effective, or otherwise clinically superior to the original orphan product, orphan exclusivity will not bar approval of the new product.

Loss or limitation of patent rights, and regulatory pathways for biosimilar competition, have in the past reduced and could reduce in the future 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 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. Biosimilar versions of EYLEA have been recently approved in the United States, EU, and other jurisdictions, with additional biosimilar versions of EYLEA and/or EYLEA HD in development, 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. As an EYLEA biosimilar has been launched in the United States following the expiration of the U.S. regulatory exclusivity period for EYLEA (i.e., the period during which no biosimilar product could be approved by the FDA) in May 2024, EYLEA no longer has U.S. market exclusivity. In addition, as EYLEA HD does not benefit from regulatory exclusivity in the United States, market exclusivity for EYLEA HD in the United States is based solely on our patent rights pertaining to this product (which are subject to the risks and uncertainties discussed 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.*"). Any future loss of market exclusivity for a product would likely negatively affect revenues from product sales of that product and thus our financial results and condition and could have a material negative impact on our business.

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 or if there is greater demand than currently expected for our marketed products. 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. 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 this or other public health outbreaks, epidemics, or pandemics may in the future further exacerbate, certain of these risks. For example, the impact of having to prioritize certain manufacturing-related resources for our COVID-19 monoclonal antibodies in recent years 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 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 currently 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 has been and will continue to 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 have constructed a fill/finish facility in Rensselaer, New York that is currently undergoing process validation as required by regulatory authorities (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 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 in a cost-effective manner 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. 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 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.

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), have led in the past and could lead in the future to product defects or manufacturing failures, resulting in lot failures, product recalls, product liability claims, and/or 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.

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 armed conflict between Russia and Ukraine or public health outbreaks, epidemics, or pandemics or other geopolitical developments). Regional or single-source dependencies may in some cases accentuate these risks. For example, the pharmaceutical industry generally, and in some instances our Company or our collaborators or other third parties on which we rely, depend on China-based suppliers or service providers for certain raw materials, products and services, or other activities. Our ability or the ability of our collaborators or such other third parties to continue to engage these China-based suppliers or service providers for certain preclinical research programs and clinical development programs could be restricted due to geopolitical developments between the United States and China, including as a result of the escalation of tariffs or other trade restrictions or if the previously proposed federal legislation known as the BIOSECURE Act or a similar law were to be enacted. 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 or advance our or our collaborators' preclinical research or clinical development programs, 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. Recently, the FDA issued CRLs to multiple companies (including us, as further discussed below) citing unresolved inspection findings at third-party manufacturers, which prevented the timely approval of such companies' marketing applications. 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, identify and onboard new service providers, 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. For example, in August 2024, the FDA issued a CRL concerning the Company's BLA for linvoseltamab in relapsed/refractory multiple myeloma due to findings from a pre-approval inspection at a third-party fill/finish provider for another company's product candidate. While the linvoseltamab BLA has recently been resubmitted to the FDA, this has resulted in a delay of any potential FDA approval of this product candidate. Refer to Part I, Item 1. "Business - Programs in Clinical Development - Additional Information - Clinical Development Programs" for more information. Significant noncompliance with the requirements discussed in this paragraph 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 have previously been subject to, and may in the future 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, certain 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 U.S. Department of Health and Human Services ("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 healthcare "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 healthcare 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, administrative fines and 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 proceedings initiated or joined by the U.S. Department of Justice and the U.S. Attorney's Office for the District of Massachusetts concerning certain 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. In addition, a number of 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 program (which is administered by HRSA), the VA FSS pricing program, the Tricare Retail Pharmacy Program, and other federal and state government pricing programs. Such programs often require us to provide discounts and/or pay rebates to certain government payors and/or private purchasers. See Part I, Item 1, "Business - Government Regulation - Pricing and Reimbursement" for additional information on 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. For example, 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 fail to pay the required rebate, 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 knowingly and intentionally 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 operating results. In September 2024, CMS modified the regulations governing the Medicaid Drug Rebate Program, which could further increase our costs and the complexity of compliance, impact rebate liabilities, and be time-consuming to implement. 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 operating results. Moreover, 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. Further, any 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.

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 expanded and continue to expand due to, in part, our efforts to establish further 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 healthcare 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. In recent years, 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 (including the imposition of monetary penalties), which could exceed our resources or insurance coverage. In addition, if we fail to obtain or maintain required permits and registrations, we may be subject to administrative fines and penalties or other regulatory actions, which could adversely affect our business.

Changes in laws, regulations, and policies 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 U.S. federal, state, and foreign laws and agency regulations and policies could have a materially negative impact on our business.

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. In addition, in April 2023, the European Commission

published a proposal to replace the current pharmaceutical legislative framework in the EU. While it is uncertain whether such proposal will be adopted in its current form, there may ultimately be a number of changes to the current regulatory framework in the EU, including a reduction of the data protection and market exclusivity periods provided thereby.

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 - *Changes to product reimbursement and coverage policies and practices 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 many countries outside the United States and have been significantly expanding the scope of these activities in existing and/or additional countries, including EU countries and Japan. For example, as discussed above, we now have commercial presence in certain jurisdictions outside the United States in connection with our acquisition of the exclusive right to develop, commercialize, and manufacture Libtayo worldwide pursuant to the A&R IO LCA; and we perform co-commercialization activities under the Antibody Collaboration related to Dupixent in certain jurisdictions outside the United States. Consequently, we are, and will continue to be, subject to risks related to operating in countries outside the United States, particularly those in which we have not previously established operations, 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, and the cost of compliance with such foreign laws and regulatory requirements;
- 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*"), as well as labor and employment laws and regulations;
- changes in the political or economic condition of a specific country or region, including as a result of the Russia-Ukraine or Hamas-Israel armed conflict;
- fluctuations in the value of foreign currency versus the U.S. dollar;
- tariffs (including tariffs that have been or may in the future be imposed by the United States or other countries), trade protection measures, import or export licensing requirements, trade embargoes, sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), other trade barriers (including further legislation or actions taken by the United States or other countries that restrict trade), and protectionist or retaliatory measures taken by the United States or other countries;
- 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, Japan, 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 foreign jurisdictions in which we operate. Significant judgment is required in determining our worldwide tax liabilities, and our effective tax rate is derived from the applicable statutory tax rates and relative earnings in each taxing jurisdiction. We record liabilities for uncertain tax positions that involve significant management judgment as to the application of law. 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. Consequently, tax assessments or judgments in excess of accrued amounts that we have estimated in preparing our financial statements may materially and adversely affect our reported effective tax rate or our cash flows. Further, other factors may adversely affect our effective tax rate, including changes in the mix of our

profitability from country to country, tax effects of stock-based compensation (which depend in part on the price of our stock and, therefore, are beyond our control), and changes in tax laws or regulations. For example, the OECD Pillar Two framework has influenced tax laws in countries in which we operate, including the implementation of minimum taxes. Changes to these or other laws and regulations or their interpretations could materially adversely impact our effective tax rate or cash flows.

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 privacy and data protection laws in and outside the United States, including health privacy laws, data breach notification laws, consumer protection laws, data localization laws, biometric privacy laws, and genetic privacy laws. Such laws may apply to our operations and/or those of our collaborators and business partners and may impose restrictions on our collection, use, and dissemination of individuals' health and other personal data, including data that we may receive throughout the clinical trial process, in the course of our research collaborations, from individuals who enroll in our patient assistance programs, from healthcare professionals that interact with us, or from our own employees. Laws and regulations in this area are constantly evolving and are often not interpreted consistently by regulatory authorities, institutional review boards/ethics committees, or clinical trial sites.

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. At the federal level, most U.S. healthcare providers, including research institutions from which we or our collaborators obtain clinical trial data, are subject to privacy and security regulations promulgated under HIPAA. While Regeneron is not directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we, our affiliates, or our agents knowingly receive protected health information in a manner that is not permitted under HIPAA. The FTC also sets expectations for taking appropriate steps to safeguard consumers' personal information and for providing a level of privacy or security commensurate to promises made to individuals. Failure to meet these FTC standards may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records. Enforcement by the FTC under the FTC Act and Health Breach Notification Rule can result in civil penalties or enforcement actions. In addition, at the state level, many state consumer privacy laws recently went into effect and many other consumer privacy laws are expected to go into effect in the near future. These laws include certain transparency and other requirements to protect personal data and grant residents with certain rights regarding their personal data. These laws and regulations are constantly evolving and may impose limitations on our business activities.

Outside the United States, we have operations and conduct business in several countries and have been significantly expanding the scope of these activities in those and/or additional countries, as discussed above under "*Risks associated with our operations outside the United States could adversely affect our business*." We also conduct clinical trials in these and many other countries around the world. These activities subject us to additional data protection authority oversight and require us to comply with stringent local and regional data privacy laws. Such laws include the GDPR, which has a wide range of compliance obligations relating to the processing and protection of personal data. Violations of the GDPR carry significant financial penalties for noncompliance. The GDPR also confers a private right of action on data subjects and consumer associations to file complaints with data protection authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Many other jurisdictions outside the United States have adopted and continue to adopt varying privacy and data protection legislation, the continued emergence of which has increased the costs and complexity of compliance.

If we or any of our 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 result in fines or other penalties or otherwise affect our or any such collaborators' ability to commercialize our products. Any threatened or actual government enforcement action could also generate adverse publicity and could result in additional regulatory oversight.

Increasing use of social media and artificial intelligence-based platforms could give rise to liability, breaches of data security and privacy laws, 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 participants, 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. Additionally, artificial intelligence ("AI")-based solutions, including generative AI, are increasingly being used in the biopharmaceutical industry (including by us). The use of AI solutions by our employees or third parties on which we rely may continue to increase and may lead to the impermissible use or public disclosure of confidential information (including personal data and proprietary information) in contravention of our internal policies, data protection laws, other applicable laws, or contractual requirements. In the United States and in many jurisdictions outside the United States, new regulations have recently passed or have been proposed to ensure the ethical use, privacy, and security of AI solutions and the data processed thereby. The misuse of AI solutions may give rise to liability, lead to the loss of trade secrets or other intellectual property, result in reputational harm, or lead to outcomes with unintended biases or other consequences. The misuse of AI solutions could also result in unauthorized access and use of personal data of our employees, clinical trial participants, collaborators, or other third parties. 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, may 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 and product candidates that we are co-developing with Sanofi under our Antibody Collaboration (currently consisting of Dupixent, Kevzara, and itepekimab), Sanofi initially funds a significant portion of development expenses incurred in connection with the development of these products and product candidates. 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 obligations thereunder, our business, prospects, operating results, and financial condition may be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our development efforts or cut back on such activities. If Sanofi does not perform its obligations with respect to the products and product candidates it is co-developing and/or co-commercializing with us, our ability to develop, manufacture, and commercialize these products and product candidates may be adversely affected. As described in Note 16 to our Consolidated Financial Statements, we have commenced the Antibody Collaboration Ligation against Sanofi and certain of its affiliated entities. It is not possible to determine what impact (if any) the Antibody Collaboration Litigation may have on the Antibody Collaboration and our business relationship with Sanofi, or whether we will be successful in the Antibody Collaboration Litigation. While we have some commercial presence outside the United States, our commercial capabilities outside the United States are still limited and would need to be further developed or outsourced 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 sufficient 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 may create substantial new and additional risks to the successful development and commercialization of the products and product candidates subject to such collaborations, particularly outside the United States.

If our collaboration with Bayer for EYLEA HD and 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 HD and EYLEA outside the United States would be materially harmed.

We rely heavily on Bayer with respect to the commercialization of EYLEA HD and EYLEA outside the United States. 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 HD and 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 HD and 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 HD and 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 sufficient 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 HD and EYLEA.

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 the armed conflict between Russia and 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. 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.*"

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 and September 2023, we completed our acquisition of Checkmate Pharmaceuticals, Inc. and Decibel Therapeutics, Inc., respectively; and in April 2024, we acquired full development and commercialization rights to 2seventy bio, Inc.'s oncology and autoimmune preclinical and clinical stage cell therapy pipeline. 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, controls, systems, practices, policies, and procedures of our Company and the acquired business 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, research and development, regulatory, 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, product development or regulatory setbacks (including those relating to

issues that may have arisen before we completed the transaction in question), 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 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 to consummate a particular transaction are successful, we may incur substantial charges for closure costs associated with elimination of duplicate operations and facilities, acquired in-process research and development charges, or intangible asset impairment charges. In either case, the incurrence of these charges could adversely affect our operating results for particular periods.

Other Risks Related to Our Business

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 and other key members of our senior management team. 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 Leonard S. Schleifer, M.D., Ph.D., our Board co-Chair, President and Chief Executive Officer, and George D. Yancopoulos, M.D., Ph.D., our Board co-Chair, 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, manufacturing, 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.

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. 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 and incidents. For example, in the past we have experienced, and expect to continue to experience, various types of cybersecurity incidents, including unauthorized access to our IT systems, data security breaches, malware incursions, denial-of-service attacks, phishing campaigns, and other similar disruptions. Similar incidents have been experienced and may in the future be experienced by certain third parties on which we rely. Although we believe, based on an assessment of the relevant facts available to us, that none of these incidents has had a material adverse impact on our operations, there can be no assurance that a future incident would not result in material harm to our business, prospects, operating results, and financial condition. There is also 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 or Hamas-Israel armed conflict.

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.

Public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) have adversely affected and may in the future adversely affect our business.

The COVID-19 pandemic previously adversely affected, and actual or threatened public health outbreaks, epidemics, or pandemics may in the future 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.

Such disruptions in our operations could materially adversely impact our business, prospects, operating results, and financial condition. To the extent a public health outbreak, epidemic, or 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.

Our indebtedness could adversely impact our business.

We have certain indebtedness and contingent liabilities, including milestone and royalty payment obligations. As of December 31, 2024, we had an aggregate of $2.704 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, Chinese yuan, and Australian dollar. If the U.S. dollar weakens against a specific foreign currency, assuming all other variables remained constant, 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, assuming all other variables remained constant, 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. For example, as previously reported, 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.

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, 2024, we had $2.488 billion in cash and cash equivalents and $15.424 billion in marketable securities (including $1.095 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 HD, EYLEA, Dupixent, and Libtayo, 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, and our overall operating results;
- if any of our product candidates 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 HD, EYLEA, Dupixent, and Libtayo;
- whether our net product sales and net profits underperform, meet, or exceed the expectations of investors or analysts;
- U.S. or other major market launch of a biosimilar version of one of our key marketed products (such as EYLEA or EYLEA HD);
- 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;
- 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 and developments relating to patent litigation and other proceedings and government investigations relating to our Company and operations;
- 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;
- 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, including as a result of changes in trade, economic, and other policies of the United States or other countries;
- impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on our business;
- our ability to repurchase our Common Stock under any share repurchase program on favorable terms or at all and our ability to continue to declare cash dividends on our Common Stock and Class A Stock;
- 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. Securities class action litigation is often initiated against companies following periods of volatility in their stock price. For example, a putative class action civil complaint was recently filed against the Company and certain current and former executive officers of the Company asserting violations of federal securities laws, as further described in Note 16 to our Consolidated Financial Statements. 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, 2024, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39.0% 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, 2024. 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 continue to repurchase shares of our Common Stock or continue to declare cash dividends.

In April 2024, our board of directors authorized a share repurchase program to repurchase up to $3.0 billion of our Common Stock (of which $1.917 billion remained available as of December 31, 2024); and, in February 2025, authorized an additional $3.0 billion for share repurchases. In February 2025, our board of directors also initiated a quarterly cash dividend program and declared a first quarter 2025 cash dividend on our Common Stock and Class A Stock. Any future share repurchases, share repurchase program authorizations, or dividend declarations 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. Our share repurchases and dividend payments may change from time to time, and we can provide no assurance that we will repurchase shares of our Common Stock at favorable prices, in particular amounts, or at all, or that we will maintain or increase our quarterly cash dividend payments or declare future cash dividends. A reduction in our share repurchases or reduction in, or elimination of, our quarterly cash dividend payments could have an adverse effect on our stock price.

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, 2024, 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, 2024:

- our current executive officers and directors beneficially owned 5.4% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options and release of all restricted stock units held by such persons which are exercisable or releasable within 60 days of December 31, 2024, and 17.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options and release of all restricted stock units held by such persons which are exercisable or releasable within 60 days of December 31, 2024; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39.0% 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, 2024. In addition, these five shareholders plus our Chief Executive Officer held approximately 46.2% 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, 2024.

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 current or former 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, which contractually prohibits Sanofi from seeking to directly or indirectly exert control of our Company or acquiring more than 30% of our Class A Stock and Common Stock, taken together.

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 1C. Cybersecurity

Risk Management and Strategy

We regularly assess risks from cybersecurity threats; monitor our information systems for potential vulnerabilities; and test those systems pursuant to our cybersecurity policies, processes, and practices, which are integrated into our overall risk management program. To protect our information systems from cybersecurity threats, we use various security tools that are designed to help identify, escalate, investigate, resolve, and recover from security incidents in a timely manner. Our Technology Risk Management Committee, which is comprised of representatives from our business operations and support functions (e.g., legal, finance, internal audit, commercial, privacy), assesses cybersecurity risks based on probability and potential impact to key business systems and processes. Cybersecurity risks that are considered high are incorporated into our overall risk management program. A mitigation plan is developed for each identified high risk, with progress on risk mitigation reported to the Technology Risk Management Committee and tracked as part of our overall risk management program, which is overseen by the Audit Committee of our board of directors.

We collaborate with third parties to assess the effectiveness of our cybersecurity prevention and response systems and processes. These include cybersecurity assessors, consultants, and other external cybersecurity experts to assist in the identification, verification, and validation of cybersecurity risks, as well as to support associated mitigation plans when necessary. We have also

developed a process to conduct due diligence on third parties with which we work to oversee and identify material risks from cybersecurity threats associated with our use of those third parties' services, including those that perform cybersecurity services.

To date, the Company is not aware of risks from cybersecurity threats, including those resulting from any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect our Company, including our business strategy, results of operations, or financial condition. Refer to the risk factor captioned "*Significant disruptions of information technology systems or breaches of data security could adversely affect our business*" in Part I, Item 1A. "Risk Factors" for additional information regarding cybersecurity risks and potential related impacts on our Company.

Governance

Our board of directors oversees our risk management process, including as it pertains to cybersecurity risks, directly and through its committees. The Audit Committee of the board oversees our risk management program, which focuses on the most significant risks we face in the short-, intermediate-, and long-term timeframe. Audit Committee meetings include discussions of specific risk areas throughout the year, including, among others, those relating to cybersecurity threats, and reports from the Chief Audit Executive on our enterprise risk profile on an annual basis. The Audit Committee reviews our cybersecurity risk profile with management on a periodic basis using key performance and/or risk indicators. These key performance indicators are metrics and measurements designed to assess the effectiveness of our cybersecurity program in the prevention, detection, mitigation, and remediation of cybersecurity incidents.

We take a risk-based approach to cybersecurity and have implemented cybersecurity policies throughout our operations that are designed to address cybersecurity threats and incidents. The Company's Chief Information Security Officer ("CISO"), in coordination with the Chief Information Officer and the Technology Risk Management Committee, is responsible for the establishment and maintenance of our cybersecurity program, as well as the assessment and management of cybersecurity risks . The current CISO has over 35 years of experience in technology and information security, including operating in the role of the CISO for several large companies in the pharmaceutical and healthcare industries, and possesses the requisite education, skills, experience, and industry certifications expected of an individual assigned to these duties. The CISO provides periodic updates on our cybersecurity risk profile to management's Technology Risk Management Committee and the Audit Committee of our board of directors.

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.

Location	Approximate Square Feet	Use	Leased/Owned
Tarrytown, New York	1,500,000	Corporate headquarters, laboratory, and office space	Leased[a]
Rensselaer, New York	1,600,000	Manufacturing, warehouse, laboratory, fill/finish[b], and office space	Owned
Limerick, Ireland	850,000	Manufacturing, warehouse, laboratory, and office space	Owned

[a] 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 Corporate Headquarters Lease*" for further details.

[b] Our fill/finish facility in Rensselaer, New York is currently undergoing process validation as required by regulatory authorities.

In addition to the properties summarized in the table above, we own an approximate 100-acre parcel of land adjacent to our Tarrytown, New York location, which we are in the process of developing, primarily to expand our research, preclinical manufacturing, and support facilities to accommodate our growth. In September 2024, we also acquired an approximate 1,000,000 square foot facility in Saratoga Springs, New York.

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

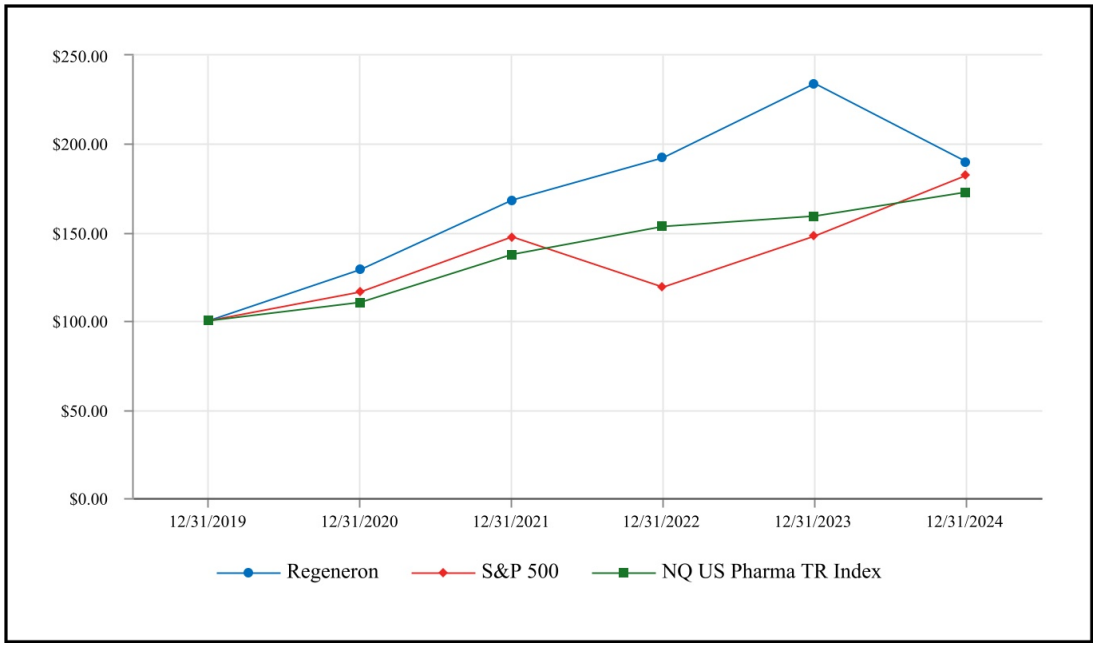
Our Common Stock, par value $.001 per share, is quoted on The NASDAQ Global Select Market under the symbol "REGN." Our Class A Stock, par value $.001 per share, is not publicly quoted or traded.

As of January 23, 2025, there were 149 shareholders of record of our Common Stock and 14 shareholders of record of our Class A Stock.

Prior to 2025, no dividends on our Common Stock or Class A Stock had been declared or paid. In February 2025, our board of directors approved the initiation of a quarterly cash dividend program and declared a cash dividend of $0.88 per share on our Common Stock and Class A Stock. The cash dividend will be payable on March 20, 2025 to shareholders of record as of February 20, 2025.

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, 2019 through December 31, 2024. The comparison assumes that $100 was invested on December 31, 2019 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.



	12/31/2019	12/31/2020	12/31/2021	12/31/2022	12/31/2023	12/31/2024
Regeneron	$ 100.00	$ 128.66	$ 168.19	$ 192.15	$ 233.91	$ 189.71
S&P 500	$ 100.00	$ 116.26	$ 147.52	$ 118.84	$ 147.64	$ 182.05
NQ US Pharma TR Index	$ 100.00	$ 110.52	$ 137.47	$ 153.08	$ 159.01	$ 172.62

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 in 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, 2024. 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)*
10/1/2024–10/31/2024	316,483	$ 982.90	316,431	$ 2,581.9
11/1/2024–11/30/2024	404,299	$ 782.08	395,051	$ 2,273.3
12/1/2024–12/31/2024	748,201	$ 744.67	483,956	$ 1,916.7
Total	1,468,983 [a]		1,195,438 [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 February 2025, our board of directors authorized a share repurchase program to repurchase up to an additional $3.0 billion of our Common Stock. See Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - 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, 2023 (filed with the SEC on February 5, 2024) for additional discussion of our financial condition and results of operations for the year ended December 31, 2022, as well as our financial condition and results of operations for the year ended December 31, 2023 compared to the year ended December 31, 2022.

Overview

Regeneron Pharmaceuticals, Inc. is a fully integrated biotechnology company that invents, develops, manufactures, and commercializes medicines for people with serious diseases. Our research and development efforts have led to numerous approved products that have received marketing approval and approximately 40 product candidates in clinical development (including a number of marketed products for which we are investigating additional indications), most of which were homegrown in our laboratories.

Our ability to generate profits and to generate positive cash flow from operations over the next several years depends significantly on the success in commercializing EYLEA HD, EYLEA, and Dupixent. We expect to continue to incur substantial expenses related to our research and development activities, and our research and development activities and related costs which are not reimbursed by collaborators 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. There is uncertainty surrounding 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 products 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.

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 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. 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;
- 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. The forfeiture rate estimate is calculated by considering both historical forfeiture experience and an estimate of expected future forfeitures for currently outstanding unvested awards. This estimate is reviewed at least annually and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. 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.

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 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.

We recognize the financial statement effects of a tax position when our 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, the effective settlement of matters subject to audit, information obtained during in-process audit activities, 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 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. 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.

Acquisitions

We make certain judgments to determine whether a transaction should be accounted for as a business combination or as an asset acquisition.

In a business combination, the acquisition method of accounting generally requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values. There can be significant judgment involved in determining the estimated fair values of such assets and liabilities. Amounts allocated to acquired in-process research and development are capitalized as indefinite-lived intangible assets. Any excess of the purchase price (consideration transferred) over the fair values of net assets acquired is recorded as goodwill. Contingent consideration obligations are recorded at fair value as of the acquisition date and remeasured each subsequent reporting period until the contingencies have been resolved. The fair value of contingent consideration liabilities is determined using inputs that may include the probability of achieving certain milestones and estimated discount rates.

If it is determined that the assets acquired do not meet the definition of a business, or if substantially all of the fair value of the assets acquired are concentrated in a single identifiable asset, then the transaction is accounted for as an asset acquisition rather than a business combination. In an asset acquisition, assets acquired are recorded at cost, goodwill is not recorded, and acquired in-process research and development with no alternative future use is charged to expense.

Intangible Assets

Intangible assets acquired in a business combination are recorded at fair value, while intangible assets acquired in connection with an asset acquisition are recorded at cost.

Payments to acquire intangible assets in an asset acquisition may include up-front payments and contingent consideration. With regard to contingent consideration in an asset acquisition, 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. 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.

Indefinite-lived intangible assets are subject to impairment testing until completion or abandonment of the associated research and development efforts. Definite-lived 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.

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.

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

(In millions, except per share data)	Year Ended December 31, 2024	2023	2022
Revenues	$ 14,202.0	$ 13,117.2	$ 12,172.9
Operating expenses	10,211.3	9,070.1	7,434.0
Income from operations	3,990.7	4,047.1	4,738.9
Other income (expense)	789.2	152.2	119.9
Income before income taxes	4,779.9	4,199.3	4,858.8
Income tax expense	367.3	245.7	520.4
Net income	$ 4,412.6	$ 3,953.6	$ 4,338.4
Net income per share - diluted	$ 38.34	$ 34.77	$ 38.22

Revenues

(In millions)	Year Ended December 31, 2024	2023	2022	$ Change 2024 vs. 2023	2023 vs. 2022
Net product sales:					
EYLEA HD - U.S.	$ 1,201.1	$ 165.8	$ —	$ 1,035.3	$ 165.8
EYLEA - U.S.	4,767.1	5,719.6	6,264.6	(952.5)	(545.0)
Total EYLEA HD and EYLEA - U.S.	5,968.2	5,885.4	6,264.6	82.8	(379.2)
Libtayo - U.S.	787.3	538.8	374.5	248.5	164.3
Libtayo - ROW[(a)]	429.5	324.3	73.0	105.2	251.3
Total Libtayo - Global	1,216.8	863.1	447.5	353.7	415.6
Praluent - U.S.	241.7	182.4	130.0	59.3	52.4
Evkeeza - U.S.	125.7	77.3	48.6	48.4	28.7
Inmazeb - U.S.	76.8	69.8	3.0	7.0	66.8
Total net product sales	$ 7,629.2	$ 7,078.0	$ 6,893.7	$ 551.2	$ 184.3
Collaboration revenue:					
Sanofi	$ 4,531.4	$ 3,799.5	$ 2,855.7	$ 731.9	$ 943.8
Bayer	1,499.0	1,487.5	1,430.7	11.5	56.8
Roche	1.4	211.0	627.3	(209.6)	(416.3)
Other	26.0	5.1	0.4	20.9	4.7
Other revenue	515.0	536.1	365.1	(21.1)	171.0
Total revenues	$ 14,202.0	$ 13,117.2	$ 12,172.9	$ 1,084.8	$ 944.3

[(a)] Effective July 1, 2022, we obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide under an Amended and Restated Immuno-oncology License and Collaboration Agreement with Sanofi ("A&R IO LCA") and, as a result, we began recording net product sales of Libtayo outside the United States as of such date.

Net Product Sales

Total EYLEA HD and EYLEA net product sales in the U.S. increased in 2024 compared to 2023. EYLEA HD was approved by the FDA in August 2023 and net product sales in 2024 were driven by the transition of patients from other anti-VEGF products, including EYLEA, as well as new patients naïve to anti-VEGF therapy. Net product sales of EYLEA HD and EYLEA in 2024 were adversely impacted by a lower net selling price compared to 2023.

Total EYLEA HD and EYLEA net product sales for the fourth quarter of 2024 were favorably impacted by approximately $85 million as a result of higher wholesaler inventory levels for EYLEA, partially offset by lower wholesaler inventory levels for EYLEA HD, at the end of the fourth quarter of 2024 compared to the end of the third quarter of 2024.

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, 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
Provisions	2,074.5	439.2	155.3	2,669.0
Credits/payments	(1,972.7)	(388.3)	(157.5)	(2,518.5)
Balance as of December 31, 2023	455.7	162.3	79.3	697.3
Provisions	2,447.3	462.7	143.0	3,053.0
Credits/payments	(2,363.9)	(497.2)	(128.8)	(2,989.9)
Balance as of December 31, 2024	$ 539.1	$ 127.8	$ 93.5	$ 760.4

Sanofi Collaboration Revenue

	Year Ended December 31,		
(In millions)	2024	2023	2022
Antibody:			
Regeneron's share of profits	$ 3,923.5	$ 3,136.5	$ 2,082.0
Sales-based milestones earned	—	50.0	100.0
Reimbursement for manufacturing of commercial supplies [(a)]	607.9	613.0	633.7
Other	—	—	28.7
Total Antibody	4,531.4	3,799.5	2,844.4
Total Immuno-oncology[(b)]	—	—	11.3
Total Sanofi collaboration revenue	$ 4,531.4	$ 3,799.5	$ 2,855.7

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

[(b)] As the A&R IO LCA became effective July 1, 2022, the six months ended June 30, 2022 was the last period in which Sanofi collaboration revenue was recognized in connection with the Immuno-oncology collaboration.

Antibody

Global net product sales of Dupixent and Kevzara are recorded by Sanofi, and we and Sanofi share profits on such sales.

Regeneron's share of profits in connection with the commercialization of Dupixent and Kevzara is summarized below:

	Year Ended December 31,		
(In millions)	**2024**	**2023**	**2022**
Dupixent and Kevzara net product sales	$ 14,606.7	$ 11,974.0	$ 9,039.2
Regeneron's share of collaboration profits in connection with commercialization of antibodies	4,527.2	3,596.3	2,405.5
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation[(a)]	(603.7)	(459.8)	(266.6)
One-time payment in connection with amendment to the Antibody License and Collaboration Agreement	—	—	(56.9)
Regeneron's share of profits	$ 3,923.5	$ 3,136.5	$ 2,082.0
Regeneron's share of profits as a percentage of Dupixent and Kevzara net product sales	27%	26%	23%

[(a)] See "Liquidity and Capital Resources - Additional Funding Requirements" below for additional details on our contingent reimbursement obligation.

The increase in our share of profits during the year ended December 31, 2024, compared to 2023, was driven by higher profits associated with Dupixent sales.

During the year ended December 31, 2023, we earned the final $50.0 million sales-based milestone from Sanofi upon aggregate annual sales of antibodies outside the United States exceeding $3.0 billion on a rolling twelve-month basis.

Bayer Collaboration Revenue

	Year Ended December 31,		
(In millions)	**2024**	**2023**	**2022**
Regeneron's share of profits	$ 1,403.3	$ 1,376.4	$ 1,317.4
Reimbursement for manufacturing of ex-U.S. commercial supplies [(a)]	95.7	111.1	91.4
One-time payment in connection with change in Japan arrangement [(b)]	—	—	21.9
Total Bayer collaboration revenue	$ 1,499.0	$ 1,487.5	$ 1,430.7

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

[(b)] Effective January 1, 2022, the Company and Bayer commenced sharing equally in profits 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.

Bayer records net product sales of EYLEA 8 mg and EYLEA outside the United States. Regeneron's share of profits in connection with commercialization of EYLEA 8 mg and EYLEA outside the United States is summarized below:

	Year Ended December 31,		
(In millions)	**2024**	**2023**	**2022**
EYLEA 8 mg and EYLEA net product sales outside the United States	$ 3,576.8	$ 3,495.2	$ 3,382.8
Regeneron's share of collaboration profit from sales outside the United States	$ 1,469.7	$ 1,436.1	$ 1,375.1
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation[(a)]	(66.4)	(59.7)	(57.7)
Regeneron's share of profits	$ 1,403.3	$ 1,376.4	$ 1,317.4
Regeneron's share of profits as a percentage of EYLEA 8 mg and EYLEA net product sales outside the United States	39%	39%	39%

[(a)] See "Liquidity and Capital Resources - Additional Funding Requirements" below for additional details on our contingent reimbursement obligation.

Roche Collaboration Revenue

(In millions)	Year Ended December 31, 2024	2023	2022
Regeneron's share of profits	$ 1.4	$ 224.3	$ 627.3
Other	—	(13.3)	—
Total Roche collaboration revenue	$ 1.4	$ 211.0	$ 627.3

Roche distributes and records net product sales of Ronapreve outside the United States, and the parties share gross profits from sales based on a pre-specified formula. Net product sales of Ronapreve outside the United States declined as a result of new variants of the SARS-CoV-2 virus emerging that are not susceptible to the treatment.

Other Revenue

Other revenue in 2024 and 2023 included $328.6 million and $247.6 million, respectively, of royalties and share of profits earned in connection with license agreements.

Operating Expenses

(In millions, except headcount data)	Year Ended December 31, 2024	2023	2022	Change 2024 vs. 2023	2023 vs. 2022
Research and development[(a)]	$ 5,132.0	$ 4,439.0	$ 3,592.5	$ 693.0	$ 846.5
Acquired in-process research and development	101.0	186.1	255.1	(85.1)	(69.0)
Selling, general, and administrative[(a)]	2,954.4	2,631.3	2,115.9	323.1	515.4
Cost of goods sold	1,087.3	932.1	800.0	155.2	132.1
Cost of collaboration and contract manufacturing[(b)]	883.2	883.7	760.4	(0.5)	123.3
Other operating expense (income), net	53.4	(2.1)	(89.9)	55.5	87.8
Total operating expenses	$ 10,211.3	$ 9,070.1	$ 7,434.0	$ 1,141.2	$ 1,636.1
Average headcount	14,383	12,698	11,115	1,685	1,583

[(a)] Includes costs incurred net of any cost reimbursements from collaborators

[(b)] Includes costs incurred in connection with manufacturing drug supplies for collaborators and others

Operating expenses in 2024 and 2023 included a total of $982.8 million and $885.0 million, respectively, of stock-based compensation expense related to equity awards granted under our long-term incentive plans. As of December 31, 2024, unrecognized stock-based compensation expense related to unvested stock options and unvested restricted stock (including performance-based restricted stock units) was $626.7 million and $1.271 billion, respectively. We expect to recognize this stock-based compensation expense related to stock options and restricted stock over a weighted-average period of 1.9 years.

Research and Development Expenses

The following table summarizes our 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 drug filling, packaging, and labeling costs. Clinical manufacturing costs also include pre-launch commercial supplies which did not meet the criteria to be capitalized as inventory (see "Critical Accounting 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)	**2024**	**2023***	**2022***	**2024 vs. 2023**	**2023 vs. 2022**
Direct research and development expenses:					
Fianlimab	$ 215.5	$ 112.2	$ 43.4	$ 103.3	$ 68.8
Linvoseltamab	141.9	78.7	45.5	63.2	33.2
Ordspono (odronextamab)	129.4	96.3	66.0	33.1	30.3
Dupixent (dupilumab)	128.8	168.0	156.5	(39.2)	11.5
EYLEA HD (aflibercept) 8 mg	98.3	96.2	67.9	2.1	28.3
Itepekimab	96.2	70.3	26.5	25.9	43.8
Pozelimab	79.4	60.2	72.4	19.2	(12.2)
Libtayo (cemiplimab)	79.1	105.3	138.0	(26.2)	(32.7)
Other product candidates in clinical development and other research programs	620.2	508.4	426.7	111.8	81.7
Total direct research and development expenses	1,588.8	1,295.6	1,042.9	293.2	252.7
Indirect research and development expenses:					
Payroll and benefits	1,681.7	1,537.0	1,195.5	144.7	341.5
Lab supplies and other research and development costs	241.5	210.6	181.0	30.9	29.6
Occupancy and other operating costs	614.9	518.2	508.5	96.7	9.7
Total indirect research and development expenses	2,538.1	2,265.8	1,885.0	272.3	380.8
Clinical manufacturing costs	1,195.9	1,053.9	938.3	142.0	115.6
Reimbursement of research and development expenses by collaborators	(190.8)	(176.3)	(273.7)	(14.5)	97.4
Total research and development expenses	$ 5,132.0	$ 4,439.0	$ 3,592.5	$ 693.0	$ 846.5

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

Research and development expenses included stock-based compensation expense of $543.8 million and $488.7 million in 2024 and 2023, respectively.

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 product candidate, 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") Expenses

Acquired IPR&D expense in 2024 included a $45.0 million development milestone in connection with our collaboration agreement with Sonoma Biotherapeutics, Inc.

Acquired IPR&D expense in 2023 included a $100.0 million development milestone in connection with our collaboration agreement with Alnylam Pharmaceuticals, Inc., a $45.0 million up-front payment in connection with our collaboration agreement with Sonoma, and a $30.0 million charge to extend the period for selecting targets under our collaboration agreement with Intellia Therapeutics, Inc.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased in 2024, compared to 2023, due to higher commercialization-related expenses to support our launch of EYLEA HD and higher headcount and headcount-related costs partly related to our international commercial expansion. Selling, general, and administrative expenses also included stock-based compensation expense of $355.0 million and $307.1 million in 2024 and 2023, respectively.

Cost of Goods Sold

Cost of goods sold increased in 2024, compared to 2023, primarily due to higher start-up costs for our Rensselaer, New York fill/finish facility.

Other Operating Expense (Income)

Other operating expense (income), net, in 2024 reflected a charge of $53.4 million related to the increase in the estimated fair value of the contingent consideration liability recognized in connection with our 2023 acquisition of Decibel Therapeutics, Inc.

Other Income (Expense)

Other income (expense) consists of the following:

	Year Ended December 31,		
(In millions)	**2024**	**2023**	**2022**
Unrealized gains (losses) on equity securities, net	$ 117.7	$ (237.8)	$ (39.8)
Interest income	711.4	495.9	160.1
Foreign currency (losses) gains, net	(0.5)	(12.9)	50.2
Other	15.8	(20.0)	8.8
Other income (expense), net	844.4	225.2	179.3
Interest expense	(55.2)	(73.0)	(59.4)
Total other income (expense)	$ 789.2	$ 152.2	$ 119.9

Income Taxes

	Year Ended December 31,		
(In millions, except effective tax rate)	**2024**	**2023**	**2022**
Income tax expense	$ 367.3	$ 245.7	$ 520.4
Effective tax rate	7.7%	5.9%	10.7%

Our effective tax rate for 2024 and 2023 was positively impacted, compared to the U.S. federal statutory rate, primarily by stock-based compensation, income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate, and federal tax credits for research activities.

Certain countries in which we have operations, including Ireland, have adopted legislation influenced by the Organization for Economic Co-operation and Development ("OECD") Global Anti-Base Erosion Model Rules ("Pillar Two") framework, including a minimum tax rate of 15%. The adoption of the Pillar Two framework did not have a material impact on our effective tax rate for the year ended December 31, 2024. It is uncertain whether the United States will enact legislation to adopt the Pillar Two framework. We continue to evaluate additional guidance released by the OECD, along with the pending legislative adoption by additional countries.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

	As of December 31,		
(In millions)	**2024**	**2023**	**$ Change**
Financial assets:			
Cash and cash equivalents	$ 2,488.2	$ 2,730.0	$ (241.8)
Marketable securities - current	6,524.3	8,114.8	(1,590.5)
Marketable securities - noncurrent	8,900.1	5,396.5	3,503.6
	$ 17,912.6	$ 16,241.3	$ 1,671.3
Working capital:			
Current assets	$ 18,660.9	$ 19,479.2	$ (818.3)
Current liabilities	3,944.3	3,423.4	520.9
	$ 14,716.6	$ 16,055.8	$ (1,339.2)
Borrowings and finance lease liabilities:			
Long-term debt	$ 1,984.4	$ 1,982.9	$ 1.5
Finance lease liabilities	$ 720.0	$ 720.0	$ —

As of December 31, 2024, 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, 2024, 2023, and 2022

	Year Ended December 31,			$ Change	
(In millions)	**2024**	**2023**	**2022**	**2024 vs. 2023**	**2023 vs. 2022**
Cash flows provided by operating activities	$ 4,420.5	$ 4,594.0	$ 5,014.9	$ (173.5)	$ (420.9)
Cash flows used in investing activities	$ (2,468.1)	$ (3,185.1)	$ (3,784.6)	$ 717.0	$ 599.5
Cash flows used in financing activities	$ (2,200.5)	$ (1,790.1)	$ (1,009.0)	$ (410.4)	$ (781.1)

Cash Flows from Investing Activities

Capital expenditures in 2024 included costs incurred in connection with the expansion of our research, preclinical manufacturing, and support facilities at our Tarrytown, New York corporate headquarters, as well as costs associated with the expansion of our manufacturing facilities in Rensselaer, New York (including the fill/finish facility). In addition, in September 2024, we acquired an approximate 1,000,000 square foot facility in Saratoga Springs, New York. We expect to incur capital expenditures of $850 million to $975 million in 2025, including in connection with the continued expansion of our facilities in Tarrytown, New York. We expect continued significant capital expenditures over the next several years related to this expansion.

Payments for the Libtayo intangible asset of $125.7 million, $207.8 million, and $1.027 billion in 2024, 2023, and 2022, respectively, related to our acquisition (including contingent consideration paid) of the exclusive right to develop, commercialize, and manufacture Libtayo worldwide.

Acquisitions, net of cash acquired, of $54.9 million and $230.3 million in 2023 and 2022 was related to our acquisitions of Decibel Therapeutics, Inc. and Checkmate Pharmaceuticals, Inc., respectively.

Cash Flows from Financing Activities

Proceeds from issuances of Common Stock, in connection with exercises of employee stock options, were $1.465 billion during 2024, compared to $1.146 billion during 2023 and $1.520 billion during 2022. In addition, payments in connection with Common Stock tendered for employee tax obligations were $1.029 billion during 2024, compared to $700.6 million during 2023 and $445.7 million during 2022. For information related to repurchases of Common Stock, see "*Share Repurchase Programs*" section below.

Credit Facility

The Company is party to an agreement with a syndicate of lenders (the "Credit Agreement") which provides for a $750.0 million senior unsecured five-year revolving credit facility (the "Credit Facility"). The Credit Agreement includes 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 $500.0 million, subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. The Credit Agreement also provides a $50.0 million sublimit for letters of credit.

As set forth in the Credit Agreement, we have the option to amend the Credit Agreement to establish environmental, social, and governance targets which will be used to adjust pricing under the Credit Facility, subject to parameters to be provided in the Credit Agreement.

Proceeds of the loans under the 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 Credit Facility. The Credit Agreement includes an option for us to elect to extend the maturity date of the Credit Facility beyond December 2027, subject to the consent of the extending lenders and certain other conditions. Amounts borrowed under the Credit Facility may be prepaid, and the commitments under the Credit Facility may be terminated, at any time without premium or penalty.

We had no borrowings outstanding under the Credit Facility as of December 31, 2024.

The Credit Agreement contains operating covenants and a maximum total leverage ratio financial covenant. We were in compliance with all covenants of the Credit Agreement as of December 31, 2024.

Share Repurchase Programs

In November 2021, our board of directors authorized a share repurchase program to repurchase up to $3.0 billion of our Common Stock. As of June 30, 2023, the Company had repurchased the entire $3.0 billion of its Common Stock it was authorized to repurchase under the program.

In January 2023, our board of directors authorized a share repurchase program to repurchase up to an additional $3.0 billion of our Common Stock. As of September 30, 2024, the Company had repurchased the entire $3.0 billion of its Common Stock it was authorized to repurchase under the program.

In April 2024, our board of directors authorized a share repurchase program to repurchase up to an additional $3.0 billion of our Common Stock. The share repurchase program permits 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. 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. The program has no time limit and can be discontinued at any time. There can be no assurance as to the timing or number of shares of any repurchases in the future.

The table below summarizes the shares of our Common Stock that we repurchased and the cost of such shares, which were recorded as Treasury Stock.

	Year Ended December 31,		
(In millions)	**2024**	**2023**	**2022**
Number of shares	2.8	2.9	3.3
Total cost of shares	$ 2,613.9	$ 2,214.6	$ 2,099.8

As of December 31, 2024, $1.917 billion remained available for share repurchases under the April 2024 program.

In February 2025, our board of directors authorized a 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 repurchase programs described above.

Dividend

In February 2025, our board of directors declared our first quarterly cash dividend, in the amount of $0.88 per share on our Common Stock and Class A Stock. The cash dividend will be payable on March 20, 2025 to shareholders of record as of February 20, 2025.

We currently intend to continue to pay a quarterly cash dividend on our outstanding Common Stock and Class A Stock. Amounts and timing of any future cash dividends are subject to authorization by our board of directors in its sole discretion, after taking into consideration our financial condition and other relevant factors described under "*There can be no assurance that we will continue to repurchase shares of our Common Stock or continue to declare cash dividends*" in Part I, Item 1A. "Risk Factors."

Tarrytown, New York Corporate Headquarters Lease

We lease laboratory and office facilities for our corporate headquarters in Tarrytown, New York (the "Facility") under the Third Amended and Restated Lease and Remedies Agreement (the "Lease") with BA Leasing BSC, LLC, an affiliate of Banc of America Leasing & Capital, LLC ("BAL"), as lessor, and the Third Amended and Restated Participation Agreement (the "Participation Agreement") with Bank of America, N.A., as administrative agent, and a syndicate of lenders (collectively with BAL, the "Participants"), as rent assignees. The Lease, Participation Agreement, and certain related agreements provide for $720.0 million of lease financing (previously advanced by the Participants in March 2017 in connection with the acquisition by BAL of the Facility and our lease of the Facility from BAL), which matures when the term of the Lease expires in March 2027, at which time all amounts outstanding thereunder will become payable in full. We have the option to further extend the maturity date of the Participation Agreement and the term of the Lease for an additional five-year period, subject to the consent of the Participants and certain other conditions. We also have the option to (a) purchase the Facility by paying an amount equal to the outstanding principal amount of the Participants' advances under the Participation Agreement, all accrued and unpaid yield thereon, and all other outstanding amounts under the Participation Agreement, Lease, and certain related documents or (b) sell the Facility to a third party on behalf of BAL.

Pursuant to the Lease, we 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 to satisfy the yield payable to the Participants on their outstanding advances under the Participation Agreement. Such advances accrue yield at a variable rate per annum based on the one-month forward-looking Secured Overnight Financing Rate ("SOFR") term rate, plus a spread adjustment, plus an applicable margin that varies with our debt rating and total leverage ratio.

The 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 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 Credit Agreement. We were in compliance with all such covenants as of December 31, 2024.

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 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 to continue to incur significant costs 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 $1.314 billion as of December 31, 2024. Due to their nature, there is a high degree of uncertainty regarding the period and amounts of potential future cash settlement with tax authorities. We expect the IRS to

conclude its examination of our 2017 and 2018 federal income tax returns within the next twelve months, and, as a result, we may be required to make a payment of approximately $120 million. 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 specific timing of these contingent payments cannot be predicted. See Note 3 to our Consolidated Financial Statements.

As described in Part I, Item 1. "Collaboration, License, and Other Agreements," under our collaborations with Sanofi and Bayer, we and our collaborator share profits in connection with commercialization of drug products. If the applicable collaboration is profitable, we have contingent contractual obligations to reimburse Sanofi and Bayer for a defined percentage (generally 50%) of agreed-upon development expenses funded by Sanofi and Bayer (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 Bayer, we elect to reimburse these expenses at a faster rate. As of December 31, 2024, our contingent reimbursement obligation to Sanofi in connection with the companies' Antibody Collaboration was approximately $1.635 billion and our contingent reimbursement obligation to Bayer was approximately $315 million. Therefore, we continue to expect that a portion of our share of profits from sales under our collaborations with Sanofi and Bayer will be used to reimburse our collaborators for these obligations.

Future Impact of Recently Issued Accounting Standards

See Note 1 to our Consolidated Financial Statements for a description of recently issued accounting standards.

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 $163.0 million and $98.7 million decrease in the fair value of our investment portfolio as of December 31, 2024 and 2023, 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 Corporate Headquarters Lease* "). Our interest rate exposure is 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 2024 and 2023, we did not recognize any charges for credit-related losses of our available-for-sale debt securities.

We are subject to credit risk associated with the receivables due from our collaborators, including Sanofi and Bayer. We are also subject to credit risk in connection with trade accounts receivable due from our customers from our product sales. As of December 31, 2024, two customers accounted on a combined basis for 79% of our net trade accounts receivables. We have contractual payment terms with each of our collaborators and customers, and 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 2024 and 2023, we did not recognize any charges for write-offs and allowances of accounts receivable related to credit risk for our collaborators or customers.

Foreign Exchange Risk

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 may impact our operating results and financial condition.

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 and/or commercialization-related expenses incurred by our collaborators.

We also incur worldwide development expenses for clinical products we are developing independently, incur expenses outside the United States in connection with our international operations, and record product sales of Libtayo outside the United States.

As sales outside the United States continue to grow, and as we expand our international operations, we will continue to assess and implement strategies, including foreign currency hedging, to mitigate our foreign exchange risk.

Market Price Risk

We are exposed to price risk on equity securities included in our investment portfolio. Our investments in equity securities primarily include companies with which we have entered into collaboration arrangements. As of December 31, 2024, our marketable securities included $1.095 billion of equity securities. Changes in the fair value of our equity securities are included in Other income (expense), net on the Statements of Operations. We recorded $117.7 million of net unrealized gains and $237.8 million of net unrealized losses on equity securities in Other income (expense), net in 2024 and 2023, 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, 2024 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, 2024. The effectiveness of the Company's internal control over financial reporting as of December 31, 2024 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, 2024 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

As disclosed in the table below, during the three months ended December 31, 2024, certain of our directors and/or executive officers adopted plans for trading arrangements intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act.

Name	Position	Date of Plan Adoption	Scheduled End Date of Trading Arrangement[(a)]	Total Number of Securities to Be Sold Under the Plan
Kathryn Guarini, Ph.D.	Director	11/1/2024	11/14/2025	1,000

[(a)] The trading arrangement may expire on an earlier date if and when all transactions under the arrangement are completed.

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 2025 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 2025 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 2025 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 2025 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 2025 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 SEC 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.)
3.2.1	Amendment to the Amended and Restated By-Laws effective June 9, 2023. (Incorporated by reference from the Form 8-K for the Registrant filed June 14, 2023.)
4.1	Description of Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
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. 2014 Long-Term Incentive Plan. (Incorporated by reference from the Registration Statement on Form S-8 for the Registrant, filed June 16, 2014.)
10.1.1 +	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.)
10.1.2 +	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.)
10.1.3 +	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.)
10.1.4 +	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.)
10.1.5 +	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.)
10.1.6 +	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 +	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 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.)

10.2.2 +	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 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.)
10.2.3 +	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 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.)
10.2.4 +	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.)
10.2.5 +	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.)
10.2.6 +	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.)
10.2.7 +	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.)
10.2.8 +	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 (revised 2019). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2019, filed February 7, 2020.)
10.2.9 +	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.)
10.2.10 +	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.)
10.2.11 +	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.)
10.3 +	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 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.)
10.3.3 +	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 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 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.)
10.3.5 +	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.)

10.3.6 +	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 (revised 2023). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2023, filed February 5, 2024.)
10.3.7 +	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 (revised 2023). (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2023, filed February 5, 2024.)
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.)
10.4.1 +	Waiver and Consent, dated as of April 14, 2023, pursuant to the 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-Q for the Registrant, for the quarter ended June 30, 2023, filed August 3, 2023.)
10.5 +	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.)
10.6 +	Regeneron Pharmaceuticals, Inc. Cash Incentive Bonus Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed June 17, 2015.)
10.6.1 +	First Amendment to Cash Incentive Bonus Plan. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2023, filed May 4, 2023.)
10.7*	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.)
10.8*	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.)
10.8.1**	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.
10.8.2**	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.)
10.9*	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.)
10.9.1**	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, 2023, filed August 3, 2023.)
10.9.2*	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.)
10.9.3**	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.)
10.9.4**	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.)
10.9.5**	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.)
10.10**	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.)
10.11	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.)
10.11.1	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.)

10.12***	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.)
10.13**	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.)
10.14*	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.)
10.15***	Third Amended and Restated Participation Agreement, dated as of March 27, 2023, 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 29, 2023.)
10.16***	Third Amended and Restated Lease and Remedies Agreement, dated as of March 27, 2023, 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 29, 2023.)
10.17***	Third Amended and Restated Guaranty, dated as of March 27, 2023, 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 29, 2023.)
10.18**	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.)
10.18.1**	Form of Co-Co Collaboration Agreement (Exhibit B to Master Agreement contained in Exhibit 10.1 8).
10.18.2**	Form of License Agreement (Exhibit C to Master Agreement contained in Exhibit 10.1 8).
10.18.3**	Amendment No. 1 to Master Agreement, dated as of April 10, 2023, 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, 2023, filed August 3, 2023.)
10.18.4**	Amendment No. 2 to Master Agreement, dated as of March 7, 2024, by and between the Registrant and Alnylam Pharmaceuticals, Inc. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended March 31, 2024, filed May 2, 2024.)
10.18.5**	Amendment No. 3 to Master Agreement, dated as of August 1, 2024, by and between the Registrant and Alnylam Pharmaceuticals, Inc. (Incorporated by reference from the Form 10-Q for the Registrant, for the quarter ended September 30, 2024, filed October 31, 2024.)
19.1	I nsider Trading Policy.
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.
97.1	Clawback Policy. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2023, filed February 5, 2024.)
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, 2024 and 2023; (ii) the Registrant's Consolidated Statements of Operations and Comprehensive Income for the years ended December 31, 2024, 2023, and 2022; (iii) the Registrant's Consolidated Statements of Stockholders' Equity for the years ended December 31, 2024, 2023, and 2022; (iv) the Registrant's Consolidated Statements of Cash Flows for the years ended December 31, 2024, 2023, and 2022; 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).

* Portions of this document have been omitted and filed separately with the SEC 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 SEC 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 SEC 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 5, 2025

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 and Christopher Fenimore, 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.	*Board co-Chair, President and Chief Executive Officer (Principal Executive Officer)*	February 5, 2025
/s/ CHRISTOPHER FENIMORE Christopher Fenimore	*Executive Vice President, Finance and Chief Financial Officer (Principal Financial Officer)*	February 5, 2025
/s/ JASON PITOFSKY Jason Pitofsky	*Vice President, Controller (Principal Accounting Officer)*	February 5, 2025
/s/ GEORGE D. YANCOPOULOS George D. Yancopoulos, M.D., Ph.D.	*Board co-Chair, President and Chief Scientific Officer*	February 5, 2025
/s/ BONNIE L. BASSLER Bonnie L. Bassler, Ph.D.	*Director*	February 5, 2025
/s/ MICHAEL S. BROWN Michael S. Brown, M.D.	*Director*	February 5, 2025
/s/ N. ANTHONY COLES N. Anthony Coles, M.D.	*Director*	February 5, 2025
/s/ JOSEPH L. GOLDSTEIN Joseph L. Goldstein, M.D.	*Director*	February 5, 2025
/s/ KATHRYN GUARINI Kathryn Guarini, Ph.D.	*Director*	February 5, 2025
/s/ CHRISTINE A. POON Christine A. Poon	*Director*	February 5, 2025
/s/ ARTHUR F. RYAN Arthur F. Ryan	*Director*	February 5, 2025
/s/ DAVID P. SCHENKEIN David P. Schenkein, M.D.	*Director*	February 5, 2025
/s/ GEORGE L. SING George L. Sing	*Director*	February 5, 2025
/s/ CRAIG B. THOMPSON Craig B. Thompson, M.D.	*Director*	February 5, 2025
/s/ HUDA Y. ZOGHBI Huda Y. Zoghbi, M.D.	*Director*	February 5, 2025

REGENERON PHARMACEUTICALS, INC.
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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, 2024 and 2023, 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, 2024, 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, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024 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, 2024, 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.

Certain Reserves for Uncertain Tax Positions

As described in Notes 1 and 15 to the consolidated financial statements, the Company's reserves for uncertain tax positions were $ 1,313.7 million as of December 31, 2024. Certain reserves for uncertain tax positions represent a significant portion of the consolidated balance. 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. Management 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 principal considerations for our determination that performing procedures relating to certain reserves for uncertain tax positions is a critical audit matter are (i) the significant judgment by management when determining certain reserves for uncertain tax positions; (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's determination of certain reserves for uncertain tax positions; (iii) the assessment and evaluation of audit evidence available to support certain reserves for uncertain tax positions is complex; and (iv) 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 relating to the recognition of reserves for uncertain tax positions. These procedures also included, among others (i) testing the information used in the calculation of certain reserves for uncertain tax positions, such as international and federal filing positions, and the related final tax returns; (ii) testing the calculation of certain reserves for uncertain tax positions; and (iii) evaluating management's assessment of the technical merits of the tax positions and estimates of the amount of tax benefits expected to be sustained, as well as the likelihood of the possible outcomes, for certain reserves for uncertain tax positions. Professionals with specialized skill and knowledge were used to assist in evaluating the technical merits and the tax benefits expected to be sustained and the application of relevant tax laws.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 5, 2025

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

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

	December 31,	
	2024	**2023**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,488.2	$ 2,730.0
Marketable securities	6,524.3	8,114.8
Accounts receivable, net	6,211.9	5,667.3
Inventories	3,087.3	2,580.5
Prepaid expenses and other current assets	349.2	386.6
Total current assets	18,660.9	19,479.2
Marketable securities	8,900.1	5,396.5
Property, plant, and equipment, net	4,599.7	4,146.4
Intangible assets, net	1,148.6	1,038.6
Deferred tax assets	3,314.1	2,575.4
Other noncurrent assets	1,136.0	444.1
Total assets	$ 37,759.4	$ 33,080.2
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 789.5	$ 606.6
Accrued expenses and other current liabilities	2,527.1	2,357.9
Deferred revenue	627.7	458.9
Total current liabilities	3,944.3	3,423.4
Long-term debt	1,984.4	1,982.9
Finance lease liabilities	720.0	720.0
Deferred revenue	185.7	126.7
Other noncurrent liabilities	1,571.4	854.1
Total liabilities	8,405.8	7,107.1
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, par value $ .01 per share; 30.0 shares authorized; shares issued and outstanding - none	—	—
Class A Stock, convertible, par value $ .001 per share; 40.0 shares authorized; shares issued and outstanding - 1.8 in 2024 and 2023	—	—
Common Stock, par value $ .001 per share; 320.0 shares authorized; shares issued - 136.0 in 2024 and 133.1 in 2023	0.1	0.1
Additional paid-in capital	12,855.9	11,354.0
Retained earnings	31,672.9	27,260.3
Accumulated other comprehensive loss	(7.9)	(80.9)
Treasury Stock, at cost; 28.2 shares in 2024 and 25.5 shares in 2023	(15,167.4)	(12,560.4)
Total stockholders' equity	29,353.6	25,973.1
Total liabilities and stockholders' equity	$ 37,759.4	$ 33,080.2

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,		
	2024	**2023**	**2022**
Statements of Operations			
Revenues:			
Net product sales	$ 7,629.2	$ 7,078.0	$ 6,893.7
Collaboration revenue	6,057.8	5,503.1	4,914.1
Other revenue	515.0	536.1	365.1
	14,202.0	13,117.2	12,172.9
Expenses:			
Research and development	5,132.0	4,439.0	3,592.5
Acquired in-process research and development	101.0	186.1	255.1
Selling, general, and administrative	2,954.4	2,631.3	2,115.9
Cost of goods sold	1,087.3	932.1	800.0
Cost of collaboration and contract manufacturing	883.2	883.7	760.4
Other operating expense (income), net	53.4	(2.1)	(89.9)
	10,211.3	9,070.1	7,434.0
Income from operations	3,990.7	4,047.1	4,738.9
Other income (expense):			
Other income (expense), net	844.4	225.2	179.3
Interest expense	(55.2)	(73.0)	(59.4)
	789.2	152.2	119.9
Income before income taxes	4,779.9	4,199.3	4,858.8
Income tax expense	367.3	245.7	520.4
Net income	$ 4,412.6	$ 3,953.6	$ 4,338.4
Net income per share - basic	$ 40.90	$ 37.05	$ 40.51
Net income per share - diluted	$ 38.34	$ 34.77	$ 38.22
Weighted average shares outstanding - basic	107.9	106.7	107.1
Weighted average shares outstanding - diluted	115.1	113.7	113.5
Statements of Comprehensive Income			
Net income	$ 4,412.6	$ 3,953.6	$ 4,338.4
Other comprehensive income (loss), net of tax:			
Unrealized gain (loss) on debt securities	73.6	158.2	(213.6)
Loss on foreign currency translation	(0.6)	(0.3)	—
Unrealized gain on cash flow hedges	—	—	1.0
Comprehensive income	$ 4,485.6	$ 4,111.5	$ 4,125.8

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

REGENERON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(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, 2021	1.8	$ —	126.2	$ 0.1	$ 8,087.5	$ 18,968.3	$ (26.2)	(19.4)	$ (8,260.9)	$ 18,768.8
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
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	3.5	—	1,152.2	—	—	—	—	1,152.2
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(0.8)	—	(708.4)	—	—	—	—	(708.4)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	66.6	—	—	0.1	7.5	74.1
Repurchases of Common Stock	—	—	—	—	—	—	—	(3.0)	(2,214.6)	(2,214.6)
Stock-based compensation charges	—	—	—	—	894.3	—	—	—	—	894.3
Net income	—	—	—	—	—	3,953.6	—	—	—	3,953.6
Other comprehensive income, net of tax	—	—	—	—	—	—	157.9	—	—	157.9
Balance, December 31, 2023	1.8	—	133.1	0.1	11,354.0	27,260.3	(80.9)	(25.5)	(12,560.4)	25,973.1

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	—	—	4.1	—	1,454.6	—	—	—	—	1,454.6
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(1.2)	—	(1,021.3)	—	—	—	—	(1,021.3)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	71.7	—	—	0.1	6.9	78.6
Repurchases of Common Stock	—	—	—	—	—	—	—	(2.8)	(2,613.9)	(2,613.9)
Stock-based compensation charges	—	—	—	—	996.9	—	—	—	—	996.9
Net income	—	—	—	—	—	4,412.6	—	—	—	4,412.6
Other comprehensive income, net of tax	—	—	—	—	—	—	73.0	—	—	73.0
Balance, December 31, 2024	1.8	$ —	136.0	$ 0.1	$ 12,855.9	$ 31,672.9	$ (7.9)	(28.2)	$ (15,167.4)	$ 29,353.6

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,		
	2024	**2023**	**2022**
Cash flows from operating activities:			
Net income	$ 4,412.6	$ 3,953.6	$ 4,338.4
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	482.9	421.0	341.4
Stock-based compensation expense	982.8	885.0	725.0
(Gains) losses on marketable and other securities, net	(118.3)	266.4	36.8
Other non-cash items, net	23.5	(0.1)	368.0
Deferred income taxes	(757.3)	(837.8)	(746.4)
Acquired in-process research and development in connection with asset acquisition	12.6	—	195.0
Changes in assets and liabilities:			
(Increase) decrease in accounts receivable	(554.0)	(338.8)	707.8
Increase in inventories	(619.7)	(271.7)	(696.5)
Increase in prepaid expenses and other assets	(407.5)	(120.1)	(148.6)
Increase in deferred revenue	227.8	37.9	32.4
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	735.1	598.6	(138.4)
Total adjustments	7.9	640.4	676.5
Net cash provided by operating activities	4,420.5	4,594.0	5,014.9
Cash flows from investing activities:			
Purchases of marketable and other securities	(16,617.4)	(11,646.0)	(7,487.9)
Sales or maturities of marketable and other securities	15,027.3	9,442.2	5,550.5
Capital expenditures	(755.9)	(718.6)	(590.1)
Proceeds from sale of property, plant, and equipment	20.1	—	—
Payments for Libtayo intangible asset	(125.7)	(207.8)	(1,026.8)
Acquisitions, net of cash acquired	(16.5)	(54.9)	(230.3)
Net cash used in investing activities	(2,468.1)	(3,185.1)	(3,784.6)
Cash flows from financing activities:			
Proceeds from issuance of Common Stock	1,465.3	1,145.5	1,519.5
Payments in connection with Common Stock tendered for employee tax obligations	(1,029.1)	(700.6)	(445.7)
Repurchases of Common Stock	(2,603.3)	(2,235.0)	(2,082.8)
Other	(33.4)	—	—
Net cash used in financing activities	(2,200.5)	(1,790.1)	(1,009.0)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(0.7)	(0.4)	—
Net (decrease) increase in cash, cash equivalents, and restricted cash	(248.8)	(381.6)	221.3
Cash, cash equivalents, and restricted cash at beginning of period	2,737.8	3,119.4	2,898.1
Cash, cash equivalents, and restricted cash at end of period	$ 2,489.0	$ 2,737.8	$ 3,119.4
Supplemental disclosure of cash flow information			
Cash paid for interest (net of amounts capitalized)	$ 52.6	$ 73.1	$ 53.7
Cash paid for income taxes	$ 743.0	$ 870.3	$ 1,502.4

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 invents, develops, manufactures, and commercializes medicines for people with serious diseases. The Company's products and product candidates in development are designed to help patients with eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, neurological diseases, hematologic conditions, infectious diseases, and rare diseases. The Company's research and development efforts have led to numerous products that have received marketing approval. The Company is a party to collaboration and license agreements to develop and commercialize, as applicable, certain products and product candidates (see Note 3).

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.

Segment Reporting

The Company operates in one business segment, which includes all activities related to the discovery, development, and commercialization of medicines for serious diseases. The determination of a single business segment is consistent with the consolidated financial information regularly provided to the Company's chief operating decision maker ("CODM"). The Company's CODM is its Chief Executive Officer, who reviews and evaluates consolidated net income for purposes of assessing performance, making operating decisions, allocating resources, and planning and forecasting for future periods.

In addition to the significant expense categories included within consolidated net income presented on the Company's Consolidated Statements of Operations, see below for disaggregated amounts that comprise research and development expenses:

	Year Ended December 31,		
(In millions)	**2024**	**2023**	**2022**
Direct research and development expenses [(a)]	$ 1,588.8	$ 1,295.6	$ 1,042.9
Indirect research and development expenses:			
Payroll and benefits	1,681.7	1,537.0	1,195.5
Lab supplies and other research and development costs	241.5	210.6	181.0
Occupancy and other operating costs	614.9	518.2	508.5
Total indirect research and development expenses	2,538.1	2,265.8	1,885.0
Clinical manufacturing costs	1,195.9	1,053.9	938.3
Reimbursement of research and development expenses by collaborators	(190.8)	(176.3)	(273.7)
Total research and development expenses	$ 5,132.0	$ 4,439.0	$ 3,592.5

[(a)] Direct research and development expenses are comprised primarily of costs paid to third parties for clinical and product development activities, and the portion of research and development expenses incurred by our collaborators that we are obligated to reimburse.

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.

Certain reclassifications have been made to prior period amounts to conform with the current period's presentation.

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 receivables from collaborators (see Note 3) are significant. In addition, concentrations of credit risk with respect to customer accounts receivable are also significant. As of December 31, 2024 and 2023, two individual customers accounted for 79 % and 83 % of the Company's net trade accounts receivable balances, respectively. 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 and for the years ended December 31, 2024 and 2023, 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 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. 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 may include options to extend or terminate a lease within the lease term 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).

Lease liabilities are recognized at the lease commencement date based on the present value of the remaining lease payments, discounted using the rate implicit in the lease. 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.

Acquisitions

The Company makes a determination whether a transaction should be accounted for as a business combination or as an asset acquisition.

In a business combination, the acquisition method of accounting generally requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values. Amounts allocated to acquired in-process research and development are capitalized as indefinite-lived intangible assets. Any excess of the purchase price (consideration transferred) over the fair values of net assets acquired is recorded as goodwill. Contingent consideration obligations are recorded at fair value as of the acquisition date and remeasured each subsequent reporting period until the contingencies have been resolved, with any changes in fair value recorded in Other operating (income) expense, net.

If it is determined that the assets acquired do not meet the definition of a business, or if substantially all of the fair value of the assets acquired are concentrated in a single identifiable asset, then the transaction is accounted for as an asset acquisition rather than a business combination. In an asset acquisition, assets acquired are recorded at cost, goodwill is not recognized, and acquired in-process research and development with no alternative future use is charged to expense.

Intangible Assets

Intangible assets acquired in a business combination are recorded at fair value, while intangible assets acquired in connection with an asset acquisition are recorded at cost.

Payments to acquire intangible assets in an asset acquisition may include up-front payments and contingent consideration. With regard to contingent consideration in an asset acquisition, 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. 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.

Indefinite-lived intangible assets are subject to impairment testing until completion or abandonment of the associated research and development efforts. Definite-lived 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.

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, an impairment loss is recognized within operating expenses and the intangible asset is written down to its fair value in the period in which the impairment occurs.

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 product 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. In general, the presentation of such amounts is summarized 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 expense
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; and premiums paid on equity securities	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 assesses, 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.

When the Company enters into an arrangement with another party to fund its research and development costs, the Company considers whether the costs that it may be obligated to repay represent a liability within the scope of Accounting Standards Codification ("ASC") 730-20, *Research and Development*. If the Company concludes that such funding does not represent a substantive and genuine transfer of risk, a liability is recorded.

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;
- 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 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. The forfeiture rate estimate is calculated by considering both historical forfeiture experience and an estimate of expected future forfeitures for currently outstanding unvested awards. This estimate is reviewed at least annually and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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 are recognized 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.

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, the effective settlement of matters subject to audit, information obtained during in-process audit activities, 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.

Recently Issued Accounting Standards

Standard/Description	Effective Date	Impact of Adoption on the Company's Financial Statements
ASU 2023-09: In December 2023, the FASB issued amended guidance related to improvements to **income tax disclosures**. The amendments require annually (i) enhanced disclosures in connection with an entity's effective tax rate reconciliation and (ii) income taxes paid disaggregated by jurisdiction.	January 1, 2025	No significant impact expected
ASU 2024-03: In November 2024, the FASB issued new guidance which requires disclosure of **disaggregated income statement expense** information about specific categories (including purchases of inventory, employee compensation, depreciation, and intangible asset amortization) in the notes to financial statements.	January 1, 2027 for annual reporting periods and January 1, 2028 for interim reporting periods	Currently evaluating impact

2. Product Sales

Net product sales consist of the following:

(In millions)		Year Ended December 31, 2024	2023	2022
EYLEA HD®	U.S.	$ 1,201.1	$ 165.8	$ —
EYLEA®	U.S.	4,767.1	5,719.6	6,264.6
Total EYLEA HD and EYLEA	U.S.	5,968.2	5,885.4	6,264.6
Libtayo®	U.S.	787.3	538.8	374.5
Libtayo[(a)]	Rest of world	429.5	324.3	73.0
Total Libtayo	Global	1,216.8	863.1	447.5
Praluent®	U.S.	241.7	182.4	130.0
Evkeeza®	U.S.	125.7	77.3	48.6
Inmazeb®	U.S.	76.8	69.8	3.0
		$ 7,629.2	$ 7,078.0	$ 6,893.7

[(a)] Effective July 1, 2022, the Company obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide and, as a result, began recording net product sales of Libtayo outside the United States. See Note 3 for further details.

As of December 31, 2024 and 2023, the Company had $ 4.278 billion and $ 3.888 billion, respectively, of trade accounts receivable that were recorded within Accounts receivable, net.

The Company had product sales to certain customers that each accounted for more than 10% of total gross product revenue for the years ended December 31, 2024, 2023, and 2022. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Year Ended December 31, 2024	2023	2022
Besse Medical, a subsidiary of Cencora, Inc.	50 %	51 %	55 %
McKesson Corporation	24 %	25 %	28 %

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, 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
Provisions	2,074.5	439.2	155.3	2,669.0
Credits/payments	(1,972.7)	(388.3)	(157.5)	(2,518.5)
Balance as of December 31, 2023	455.7	162.3	79.3	697.3
Provisions	2,447.3	462.7	143.0	3,053.0
Credits/payments	(2,363.9)	(497.2)	(128.8)	(2,989.9)
Balance as of December 31, 2024	$ 539.1	$ 127.8	$ 93.5	$ 760.4

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 as follows:

(In millions)	Statement of Operations Classification	Year Ended December 31, 2024	2023	2022
Antibody:				
Regeneron's share of profits	Collaboration revenue	$ 3,923.5	$ 3,136.5	$ 2,082.0 *
Sales-based milestones earned	Collaboration revenue	$ —	$ 50.0	$ 100.0
Reimbursement for manufacturing of commercial supplies	Collaboration revenue	$ 607.9	$ 613.0	$ 633.7
Other	Collaboration revenue	$ —	$ —	$ 28.7
Regeneron's obligation for its share of Sanofi R&D expenses, net of reimbursement of R&D expenses	(R&D expense)/Reduction of R&D expense	$ (46.8)	$ (83.7)	$ 43.0
Reimbursement of commercialization-related expenses	Reduction of SG&A expense	$ 655.4	$ 534.4	$ 437.4
Immuno-oncology[(a)]:				
Regeneron's share of profits in connection with commercialization of Libtayo outside the United States	Collaboration revenue	$ —	$ —	$ 6.7
Reimbursement for manufacturing of ex-U.S. commercial supplies	Collaboration revenue	$ —	$ —	$ 4.6
Reimbursement of R&D expenses	Reduction of R&D expense	$ —	$ —	$ 42.7
Reimbursement of commercialization-related expenses, net of Regeneron's obligation for its share of Sanofi commercialization-related expenses	Reduction of SG&A expense	$ —	$ —	$ 21.5
Regeneron's obligation for Sanofi's share of Libtayo U.S. gross profits	Cost of goods sold	$ —	$ —	$ (70.1)
Amounts recognized in connection with up-front payments received	Other operating income	$ —	$ —	$ 35.1

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

(a) 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, which had been entered into in connection with our acquisition of exclusive worldwide rights to Libtayo (cemiplimab). Pursuant to this amendment, the percentage of the Company's share of profits used to reimburse Sanofi for such development costs has increased from 10 % to 20 %. The estimated net present value differential between the 10 % repayment rate and the 20 % repayment rate 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 is 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 (i.e., "development balance") to Sanofi under the Antibody Collaboration was approximately $ 1.635 billion as of December 31, 2024.

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 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).

In addition to profit sharing, the Company was entitled to receive sales milestone payments from Sanofi. In 2023, the Company earned the final $ 50.0 million sales-based milestone from Sanofi upon aggregate annual sales of antibodies outside the United States exceeding $ 3.0 billion on a rolling twelve-month basis. In 2022, the Company earned two $ 50.0 million sales-based milestones from Sanofi, upon aggregate annual sales of antibodies outside the United States exceeding $ 2.0 billion and $ 2.5 billion, respectively, 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.

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

	As of December 31,	
(In millions)	**2024**	**2023**
Accounts receivable, net	$ 1,216.2	$ 1,029.1
Deferred revenue	$ 571.7	$ 427.7

Immuno-Oncology

The Company was previously a party to a collaboration with Sanofi for antibody-based cancer treatments in the field of immuno-oncology, including for the co-development and co-commercialization of 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 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. In connection with this agreement, 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 was eligible to earn an aggregate of $ 100.0 million in Libtayo sales-based milestones, of which it earned $ 65.0 million in 2022 and $ 35.0 million in 2023. 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.

b. Bayer

The Company is party to a license and collaboration agreement with Bayer for the global development and commercialization of EYLEA 8 mg (aflibercept 8 mg) and EYLEA (aflibercept) 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.

Bayer is responsible for commercialization activities outside the United States, and the companies share equally in profits from such sales. Within the United States, the Company is responsible for commercialization and retains profits from such sales. The Company is obligated to reimburse Bayer out of the Company's 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 $315 million as of December 31, 2024.

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, 2024	2023	2022
Regeneron's share of profits	Collaboration revenue	$ 1,403.3	$ 1,376.4	$ 1,317.4
Reimbursement for manufacturing of ex-U.S. commercial supplies	Collaboration revenue	$ 95.7	$ 111.1	$ 91.4
One-time payment in connection with change in Japan arrangement	Collaboration revenue	$ —	$ —	$ 21.9
Regeneron's obligation for its share of Bayer R&D expenses, net of reimbursement of R&D expenses	(R&D expense)/Reduction of R&D expense	$ (48.5)	$ (44.0)	$ 16.7

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

(In millions)	As of December 31, 2024	2023
Accounts receivable, net	$ 349.9	$ 381.7
Deferred revenue	$ 216.3	$ 138.2

c. Roche

The Company is a party to 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). Under the terms of the collaboration agreement, the Company has the right to distribute the product in the United States while Roche has the right to distribute the product outside the United States. The parties share gross profits from worldwide sales based on a pre-specified formula.

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

(In millions)	Statement of Operations Classification	Year Ended December 31, 2024	2023	2022
Regeneron's share of profits	Collaboration revenue	$ 1.4	$ 224.3	$ 627.3
Other	Collaboration revenue	$ —	$ (13.3)	$ —

Reimbursement of research and development expenses from Roche was not material for the years ended December 31, 2024, 2023, and 2022.

Contract balances in the Company's Balance Sheets in connection with the Roche collaboration were not material as of December 31, 2024 and 2023.

d. Other

In addition to the collaboration and license agreements discussed above, the Company has various other collaboration and license 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, research and development costs.

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

During the year ended December 31, 2024, the Company recorded as Acquired IPR&D expense a $ 45.0 million development milestone in connection with the Company's collaboration agreement with Sonoma Biotherapeutics, Inc.

During the year ended December 31, 2023, the Company recorded as Acquired IPR&D expense a $ 100.0 million development milestone in connection with its collaboration agreement with Alnylam Pharmaceuticals, Inc., a $ 45.0 million up-front payment in connection with its collaboration agreement with Sonoma, and a $ 30.0 million extension payment under its collaboration agreement with Intellia Therapeutics, Inc.

During the year ended December 31, 2022, the Company recorded as Acquired IPR&D expense a $ 195.0 million charge related to its acquisition of Checkmate Pharmaceuticals, Inc.

Royalties

The Company has also 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.

As described above, 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 paid royalties of 8.0 % on worldwide sales of Libtayo through December 31, 2023, and is obligated to pay royalties of 2.5 % from January 1, 2024 through December 31, 2026.

For the years ended December 31, 2024, 2023, and 2022, the Company recorded royalty expense (net of reimbursements from collaborators, as applicable) of $ 82.9 million, $ 117.6 million, and $ 84.5 million, respectively, based on product sales under various licensing agreements.

4. Marketable Securities

Marketable securities as of December 31, 2024 and 2023 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, 2024	**Cost Basis**	**Gains**	**Losses**	**Value**
Corporate bonds	$ 8,226.9	$ 25.1	$ (31.4)	$ 8,220.6
U.S. government and government agency obligations	4,820.5	3.4	(6.9)	4,817.0
Commercial paper	548.3	0.4	—	548.7
Certificates of deposit	380.6	0.5	—	381.1
Asset-backed securities	279.0	0.6	(0.3)	279.3
Sovereign bonds	82.7	0.1	(0.4)	82.4
	$ 14,338.0	$ 30.1	$ (39.0)	$ 14,329.1
As of December 31, 2023				
Corporate bonds	$ 6,492.5	$ 10.4	$ (104.9)	$ 6,398.0
U.S. government and government agency obligations	4,839.6	2.4	(8.6)	4,833.4
Commercial paper	636.8	0.2	(0.2)	636.8
Certificates of deposit	520.8	0.6	—	521.4
Asset-backed securities	88.2	0.1	(1.2)	87.1
Sovereign bonds	58.1	—	(0.9)	57.2
	$ 12,636.0	$ 13.7	$ (115.8)	$ 12,533.9

The Company classifies its investments in available-for-sale debt securities based on their contractual maturity dates. The available-for-sale debt securities as of December 31, 2024 mature at various dates through December 2029. The fair values of available-for-sale debt securities by contractual maturity consist of the following:

	As of December 31,	
(In millions)	**2024**	**2023**
Maturities within one year	$ 6,524.3	$ 8,114.8
Maturities after one year through five years	7,804.8	4,414.5
Maturities after five years	—	4.6
	$ 14,329.1	$ 12,533.9

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

	Less than 12 Months		12 Months or Greater		Total	
(In millions) **As of December 31, 2024**	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate bonds	$ 7,175.8	$ (14.2)	$ 1,044.8	$ (17.2)	$ 8,220.6	$ (31.4)
U.S. government and government agency obligations	4,675.3	(6.2)	141.7	(0.7)	4,817.0	(6.9)
Sovereign bonds	63.3	(0.3)	19.1	(0.1)	82.4	(0.4)
Asset-backed securities	265.4	(0.3)	13.9	—	279.3	(0.3)
	$ 12,179.8	$ (21.0)	$ 1,219.5	$ (18.0)	$ 13,399.3	$ (39.0)
As of December 31, 2023						
Corporate bonds	$ 2,363.3	$ (2.4)	$ 4,034.7	$ (102.5)	$ 6,398.0	$ (104.9)
U.S. government and government agency obligations	4,780.6	(6.0)	52.7	(2.6)	4,833.3	(8.6)
Sovereign bonds	12.4	(0.1)	44.8	(0.8)	57.2	(0.9)
Commercial paper	636.8	(0.2)	—	—	636.8	(0.2)
Asset-backed securities	61.8	(0.3)	25.3	(0.9)	87.1	(1.2)
	$ 7,854.9	$ (9.0)	$ 4,157.5	$ (106.8)	$ 12,012.4	$ (115.8)

The unrealized losses on corporate bonds were primarily driven by changes 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, 2024, 2023, and 2022, amounts reclassified from Accumulated other comprehensive loss into Other income (expense), net were related to realized gains/losses on sales of available-for-sale debt securities. For the years ended December 31, 2024, 2023, and 2022, realized gains/losses on sales of marketable securities were not material.

The Company recognized interest income of $ 711.4 million, $ 495.9 million, and $ 160.1 million for the years ended December 31, 2024, 2023, and 2022, respectively, in Other income (expense), net.

5. Fair Value Measurements

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

- Level 1 - Quoted prices in active markets for identical assets or liabilities
- 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, 2024	**Fair Value**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Cash equivalents	$ 1,452.2	$ 1,264.2	$ 188.0	$ —
Available-for-sale debt securities:				
Corporate bonds	8,220.6	—	8,220.6	—
U.S. government and government agency obligations	4,817.0	—	4,817.0	—
Commercial paper	548.7	—	548.7	—
Certificates of deposit	381.1	—	381.1	—
Asset-backed securities	279.3	—	279.3	—
Sovereign bonds	82.4	—	82.4	—
Equity securities (unrestricted)	1,052.1	1,052.1	—	—
Equity securities (restricted)[(a)]	43.2	43.2	—	—
Total assets	$ 16,876.6	$ 2,359.5	$ 14,517.1	$ —
Liabilities:				
Contingent consideration	$ 52.3	$ —	$ —	$ 52.3
As of December 31, 2023				
Assets:				
Cash equivalents	$ 928.1	$ 6.4	$ 921.7	$ —
Available-for-sale debt securities:				
Corporate bonds	6,398.0	—	6,398.0	—
U.S. government and government agency obligations	4,833.4	—	4,833.4	—
Commercial paper	636.8	—	636.8	—
Certificates of deposit	521.4	—	521.4	—
Asset-backed securities	87.1	—	87.1	—
Sovereign bonds	57.2	—	57.2	—
Equity securities (unrestricted)	864.5	864.5	—	—
Equity securities (restricted)	112.9	112.9	—	—
Total assets	$ 14,439.4	$ 983.8	$ 13,455.6	$ —
Liabilities:				
Contingent consideration	$ 43.7	$ —	$ —	$ 43.7

[(a)] Includes equity securities which are subject to transfer restrictions that expire in April 2026

In addition to the investments summarized in the table above, as of December 31, 2024 and 2023, the Company had $ 159.8 million and $ 74.3 million, respectively, in equity investments that do not have a readily determinable fair value. These

investments are recorded within Other noncurrent assets. Also recorded within Other noncurrent assets as of December 31, 2024 were equity investments of $ 52.0 million which are measured at fair value based on Level 3 inputs; no such investments were held by the Company as of December 31, 2023.

During the year ended December 31, 2024, the Company recorded $ 117.7 million of net unrealized gains on equity securities in Other income (expense), net. During the years ended December 31, 2023 and 2022, the Company recorded $ 237.8 million and $ 39.8 million, respectively, of net unrealized losses on equity securities in Other income (expense), net. In addition, during the year ended December 31, 2023, the Company recorded a write-down of $ 29.0 million in Other income (expense), net related to the Company's investments in private companies.

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 $ 1.484 billion and $ 1.528 billion as of December 31, 2024 and 2023, respectively.

6. Inventories

Inventories consist of the following:

	As of December 31,	
(In millions)	**2024**	**2023**
Raw materials	$ 879.5	$ 789.3
Work-in-process	1,342.3	1,121.8
Finished goods	139.8	147.3
Deferred costs	725.7	522.1
	$ 3,087.3	$ 2,580.5

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, 2024, 2023, and 2022, Cost of goods sold included inventory write-offs and reserves of $ 126.3 million, $ 102.3 million, and $ 258.7 million, respectively. Inventory write-offs and reserves for the year ended December 31, 2022 primarily related to REGEN-COV.

7. Property, Plant, and Equipment

Property, plant, and equipment, net consists of the following:

	As of December 31,	
(In millions)	**2024**	**2023**
Building and improvements	$ 2,573.2	$ 2,423.1
Leasehold improvements	154.5	133.9
Laboratory equipment	1,494.5	1,384.5
Computer equipment and software	450.8	389.7
Furniture, office equipment, and other	203.8	165.9
Land	288.2	283.1
Construction in progress	1,721.6	1,345.0
	6,886.6	6,125.2
Accumulated depreciation and amortization	(2,286.9)	(1,978.8)
	$ 4,599.7	$ 4,146.4

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

Depreciation and amortization expense on property, plant, and equipment was $ 354.1 million, $ 328.8 million, and $ 303.9 million for the years ended December 31, 2024, 2023, and 2022, respectively.

As of December 31, 2024 and 2023, $ 3.884 billion and $ 3.375 billion, respectively, of the Company's net property, plant, and equipment was located in the United States and $ 715.9 million and $ 771.4 million, respectively, was located outside the United States (primarily in Ireland).

8. Intangible Assets

Intangible assets, net consist of the following:

		As of December 31,					
		2024			2023		
(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	$ 1,347.7	$ (254.3)	$ 1,093.4	$ 1,119.1	$ (126.7)	$ 992.4
Other intangibles	8 years	10.0	(7.6)	2.4	10.0	(6.3)	3.7
Acquired in-process research and development	Indefinite	52.8	—	52.8	42.5	—	42.5
		$ 1,410.5	$ (261.9)	$ 1,148.6	$ 1,171.6	$ (133.0)	$ 1,038.6

During the years ended December 31, 2024 and 2023, the Company recorded additions to the Libtayo intangible asset related to contingent consideration due to Sanofi (see Note 3). In addition, during the years ended December 31, 2024 and 2023, the Company recorded indefinite-lived intangible assets in connection with the acquisition of in-process and research and development programs.

Amortization expense on intangible assets was $ 128.9 million, $ 92.2 million, and $ 37.6 million for the years ended December 31, 2024, 2023, and 2022, respectively.

As of December 31, 2024, assuming no changes in the gross carrying amount of intangible assets, amortization expense is estimated to be approximately $ 102 million for each of the years ending December 31, 2025 through December 31, 2029.

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	As of December 31,	
(In millions)	2024	2023
Accrued payroll and related costs	$ 640.9	$ 618.2
Accrued clinical expenses	315.7	292.2
Accrued sales-related costs	786.2	780.8
Income tax-related costs	213.2	11.7
Other accrued expenses and liabilities	571.1	655.0
	$ 2,527.1	$ 2,357.9

10. Debt

a. Senior Notes

Long-term debt, net of underwriting discounts and offering expenses (which are being amortized as additional interest expense over the period of issuance through maturity), consists of the following:

	As of December 31,	
(In millions)	2024	2023
1.750 % Senior Notes due September 2030	$ 1,243.3	$ 1,242.2
2.800 % Senior Notes due September 2050	741.1	740.7
	$ 1,984.4	$ 1,982.9

Interest on each series of senior notes is payable semi-annually until the applicable maturity dates. Interest expense related to the debt was $ 44.4 million in each of the years ended December 31, 2024, 2023, and 2022.

b. Credit Facility

The Company is party to an agreement with a syndicate of lenders (the "Credit Agreement") which provides for a $ 750.0 million senior unsecured five-year revolving credit facility (the "Credit Facility"). The Credit Agreement includes 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 $ 500.0 million, subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. The Credit Agreement also provides a $ 50.0 million sublimit for letters of credit.

Proceeds of the loans under the 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 Credit Facility. The Credit Agreement includes an option for the Company to elect to extend the maturity date of the Credit Facility beyond December 2027, subject to the consent of the extending lenders and certain other conditions.

The Company had no borrowings outstanding under the Credit Facility as of December 31, 2024.

The Credit Agreement contains operating covenants and a maximum total leverage ratio financial covenant. The Company was in compliance with all covenants of the Credit Agreement as of December 31, 2024.

11. Leases

The Company conducts certain of its research, development, and administrative activities at leased facilities. The Company also leases vehicles and other assets.

Tarrytown, New York Corporate Headquarters

The Company leases laboratory and office facilities for its corporate headquarters in Tarrytown, New York (the "Facility") under the Third Amended and Restated Lease and Remedies Agreement (the "Lease") with BA Leasing BSC, LLC, an affiliate of Banc of America Leasing & Capital, LLC ("BAL"), as lessor, and the Third Amended and Restated Participation Agreement (the "Participation Agreement") with Bank of America, N.A., as administrative agent, and a syndicate of lenders (collectively with BAL, the "Participants"), as rent assignees. The Lease, Participation Agreement, and certain related agreements provide for $ 720.0 million of lease financing (previously advanced by the Participants in March 2017 in connection with the acquisition by BAL of the Facility and the Company's lease of the Facility from BAL), which matures when the term of the Lease expires in March 2027, at which time all amounts outstanding thereunder will become payable in full. The Company has the option to further extend the maturity date of the Participation Agreement and the term of the Lease for an additional five-year period, subject to the consent of the Participants and certain other conditions. The Company also has the option to (a) purchase the Facility by paying an amount equal to the outstanding principal amount of the Participants' advances under the Participation Agreement, all accrued and unpaid yield thereon, and all other outstanding amounts under the Participation Agreement, Lease, and certain related documents or (b) sell the Facility to a third party on behalf of BAL.

Pursuant to the Lease, the Company pays 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 to satisfy the yield payable to the Participants on their outstanding advances under the Participation Agreement. Such advances accrue yield at a variable rate per annum based on the one-month forward-looking Secured Overnight Financing Rate ("SOFR") term rate, plus a spread adjustment, plus an applicable margin that varies with the Company's debt rating and total leverage ratio.

The Lease is 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 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 Credit Agreement. The Company was in compliance with all such covenants as of December 31, 2024.

Aggregate Lease Information

Amounts recognized in the Consolidated Balance Sheet related to the Company's leases are included in the table below.

		As of December 31,	
(In millions)	**Classification**	**2024**	**2023**
Assets:			
Finance lease right-of-use assets	Property, plant, and equipment, net [(a)]	$ 591.2	$ 605.7
Operating lease right-of-use assets	Other noncurrent assets [(b)]	217.4	78.0
		$ 808.6	$ 683.7
Liabilities:			
Finance lease liabilities - noncurrent	Finance lease liabilities	$ 720.0	$ 720.0
Operating lease liabilities - current	Accrued expenses and other current liabilities	30.3	19.0
Operating lease liabilities - noncurrent	Other noncurrent liabilities	204.1	68.7
		$ 954.4	$ 807.7

[(a)] Finance lease right-of-use assets were recorded net of accumulated amortization of $ 148.4 million and $ 133.9 million as of December 31, 2024 and 2023, respectively.

[(b)] Operating lease right-of-use assets were recorded net of accumulated amortization of $ 78.4 million and $ 44.6 million as of December 31, 2024 and 2023, respectively.

Lease costs consist of the following:

	Year Ended December 31,		
(In millions)	**2024**	**2023**	**2022**
Operating lease costs	$ 36.5	$ 19.2	$ 12.4
Finance lease costs:			
Amortization of finance lease right-of-use assets	14.5	14.5	14.5
Interest on finance lease liabilities	46.1	45.0	21.6
Total finance lease costs	60.6	59.5	36.1
Total lease costs	$ 97.1	$ 78.7	$ 48.5

Other information related to the Company's leases includes the following:

	As of December 31,	
	2024	**2023**
Weighted-average remaining lease term (in years):		
Finance leases	2.2	3.2
Operating leases	7.2	7.4
Weighted-average discount rate:		
Finance leases	5.03 %	5.08 %
Operating leases	5.52 %	5.38 %

Supplemental cash flow information related to the Company's leases includes the following:

	Year Ended December 31,		
(In millions)	**2024**	**2023**	**2022**
Cash paid for amounts included in the measurement of operating lease liabilities (included within cash flows from operating activities)	$ 41.4	$ 22.5	$ 7.7
Right-of-use assets obtained in exchange for operating lease liabilities	$ 188.1	$ 31.9	$ 35.1

The following is a maturity analysis of the Company's lease liabilities as of December 31, 2024:

(In millions)	**Finance Leases**	**Operating Leases**	**Total**
2025	$ 38.6	$ 43.1	$ 81.7
2026	36.8	44.8	81.6
2027	729.1	42.6	771.7
2028	—	33.2	33.2
2029	—	30.3	30.3
Thereafter	—	96.9	96.9
Total undiscounted lease payments	804.5	290.9	1,095.4
Imputed interest	(84.5)	(56.5)	(141.0)
Total lease liabilities	$ 720.0	$ 234.4	$ 954.4

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.

a. Share Repurchase Programs

In November 2021, the Company's board of directors authorized a share repurchase program to repurchase up to $ 3.0 billion of the Company's Common Stock. As of June 30, 2023, the Company had repurchased the entire $ 3.0 billion of its Common Stock it was authorized to repurchase under the program.

In January 2023, the Company's board of directors authorized a share repurchase program to repurchase up to an additional $ 3.0 billion of the Company's Common Stock. As of September 30, 2024, the Company had repurchased the entire $ 3.0 billion of its Common Stock that it was authorized to repurchase under the program.

In April 2024, the Company's board of directors authorized a share repurchase program to repurchase up to an additional $ 3.0 billion of the Company's Common Stock. The share repurchase program permits 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 Securities Exchange Act of 1934, as amended (the "Exchange Act")), privately negotiated transactions, accelerated share repurchases, block trades, and other transactions in compliance with Rule 10b-18 of the Exchange Act.

The table below summarizes the shares of the Company's Common Stock that the Company repurchased and the cost of such shares, which were recorded as Treasury Stock.

	Year Ended December 31,		
(In millions)	**2024**	**2023**	**2022**
Number of shares	2.8	2.9	3.3
Total cost of shares	$ 2,613.9	$ 2,214.6	$ 2,099.8

As of December 31, 2024, $ 1.917 billion remained available for share repurchases under the April 2024 program.

In February 2025, the Company's board of directors authorized a 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 repurchase programs described above.

b. Dividend

In February 2025, the Company's board of directors declared the Company's first quarterly cash dividend, in the amount of $ 0.88 per share on its Common Stock and Class A Stock. The cash dividend will be payable on March 20, 2025 to shareholders of record as of February 20, 2025.

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-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) non-qualified stock options and incentive 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. 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, 2024, there were 13.1 million shares available for future grants under the Second Amended and Restated 2014 Incentive Plan.

a. Stock Options

The table below summarizes the activity related to stock option awards under the Company's Incentive Plans during 2024.

		Number of Shares *(In millions)*	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Intrinsic Value *(In millions)*
Outstanding as of December 31, 2023		14.2	$ 534.13		
2024:	Granted	1.9	$ 786.79		
	Forfeited	(0.2)	$ 698.92		
	Exercised	(3.2)	$ 454.70		
Outstanding as of December 31, 2024		12.7	$ 588.47	6.1 years	$ 1,891.0
Vested and expected to vest as of December 31, 2024		12.3	$ 582.36	6.0 years	$ 1,888.5
Exercisable as of December 31, 2024		8.3	$ 495.19	4.7 years	$ 1,834.8

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 2024, 2023, and 2022 was $ 1.682 billion, $ 1.096 billion, and $ 1.214 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, 2024, 2023, and 2022.

	Number of Options Granted *(In millions)*	Weighted-Average Exercise Price	Weighted-Average Fair Value
2024:			
Exercise price equal to Market Price	1.9	$ 786.79	$ 235.32
2023:			
Exercise price equal to Market Price	1.6	$ 835.91	$ 264.37
2022:			
Exercise price equal to Market Price	2.0	$ 705.02	$ 220.88

For the years ended December 31, 2024, 2023, and 2022, the Company recognized $ 376.0 million, $ 357.1 million, and $ 341.9 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, 2024, there was $ 626.7 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 1.9 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 2024, 2023, and 2022.

	2024	2023	2022
Expected volatility	25 %	26 %	28 %
Expected lives from grant date	5.0 years	5.1 years	5.2 years
Expected dividend yield	0 %	0 %	0 %
Risk-free interest rate	4.11 %	4.29 %	3.50 %

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. During 2024, 2023, and 2022, the expected dividend yield was zero as the Company had not paid dividends nor did it expect to at the time of option grants. 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 2024 is summarized below.

		Number of Shares/Units *(In millions)*	Weighted-Average Grant Date Fair Value
Unvested as of December 31, 2023		2.3	$ 705.37
2024:	Granted	1.0	$ 787.15
	Vested	(0.7)	$ 617.50
	Forfeited	(0.1)	$ 704.57
Unvested as of December 31, 2024		2.5	$ 760.35

For the years ended December 31, 2024, 2023, and 2022, the Company recognized $ 554.7 million, $ 475.9 million, and $ 331.1 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, 2024, there was $ 1.219 billion 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 2.3 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. As of December 31, 2024 and 2023, 1.4 million PSUs were unvested with a weighted-average grant date fair value of $ 247.91 per unit. The number of unvested PSUs represents the maximum number of units that are eligible to be earned. During the year ended December 31, 2024, the Company did not grant new PSUs and no PSUs were vested, forfeited, or cancelled.

For each of the years ended December 31, 2024, 2023, and 2022 the Company recognized $ 52.1 million of stock-based compensation expense related to PSUs. As of December 31, 2024, there was $ 52.0 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 1.0 year.

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. The Company did not grant PSUs during 2024 and 2023.

	2022
Expected volatility	32 %
Expected dividend yield	0 %
Risk-free interest rate	3.3 %

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 the United States, which cover eligible employees.

Expenses recognized by the Company related to contributions to such plans were $ 90.2 million, $ 84.7 million, and $ 67.6 million for the years ended December 31, 2024, 2023, and 2022, 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)	**2024**	**2023**	**2022**
United States	$ (411.3)	$ (362.3)	$ 839.9
Foreign	5,191.2	4,561.6	4,018.9
	$ 4,779.9	$ 4,199.3	$ 4,858.8

Components of income tax expense consist of the following:

	Year Ended December 31,		
(In millions)	**2024**	**2023**	**2022**
Current:			
Federal	$ 1,092.6	$ 667.9	$ 968.5
State	(11.1)	7.7	7.4
Foreign	43.1	407.9	290.9
Total current tax expense	1,124.6	1,083.5	1,266.8
Deferred:			
Federal	(935.5)	(834.5)	(797.7)
State	(4.9)	(6.5)	(2.7)
Foreign	183.1	3.2	54.0
Total deferred tax benefit	(757.3)	(837.8)	(746.4)
	$ 367.3	$ 245.7	$ 520.4

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,		
	2024	**2023**	**2022**
U.S. federal statutory tax rate	21.0 %	21.0 %	21.0 %
Stock-based compensation	(4.9)	(4.6)	(2.9)
Taxation of non-U.S. operations	(4.0)	(6.6)	(5.5)
Income tax credits	(3.5)	(3.2)	(2.0)
Foreign-derived intangible income deduction	(0.8)	(0.3)	(1.0)
Other permanent differences	(0.1)	(0.4)	1.1
Effective income tax rate	7.7 %	5.9 %	10.7 %

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)	**2024**	**2023**
Deferred tax assets:		
Capitalized research and development expenses	$ 2,530.2	$ 1,728.2
Deferred compensation	419.7	413.6
Accrued expenses	185.0	214.1
Fixed assets and intangible assets	145.1	154.8
Tax attribute carryforwards	84.1	88.7
Other	43.0	26.4
Total deferred tax assets	3,407.1	2,625.8
Deferred tax liabilities:		
Unrealized gains on investments	(93.0)	(50.4)
Net deferred tax assets	$ 3,314.1	$ 2,575.4

The Company's federal income tax returns for 2017 through 2023 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 2020 to 2023 remain open to examination. The Company's income tax returns outside the United States remain open to examination from 2019 to 2023. 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 following table reconciles the beginning and ending amounts of unrecognized tax benefits:

(In millions)	**2024**	**2023**	**2022**
Balance as of January 1	$ 696.4	$ 542.8	$ 410.9
Gross increases related to current year tax positions	353.5	153.4	136.9
Gross increases (decreases) related to prior year tax positions	264.8	3.2	(5.0)
Gross decreases due to settlements and lapse of statutes of limitations	(1.0)	(3.0)	—
Balance as of December 31	$ 1,313.7	$ 696.4	$ 542.8

In 2024, 2023, and 2022, 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. Interest expense related to unrecognized tax benefits was $ 165.4 million, $ 77.2 million, and $ 38.0 million in 2024, 2023, and 2022, respectively. The Company expects the IRS to conclude its examination of the Company's 2017 and 2018 federal income tax returns within the next twelve months, and, as a result, the Company may be required to make a payment of approximately $ 120 million. The Company's unrecognized tax benefits for the years under examination exceed the expected payment amount, which would result in the Company recognizing a net tax benefit within the next twelve months.

The amount of net unrecognized tax benefits that, if settled, would impact the effective tax rate is $ 635.4 million, $ 442.5 million, and $ 373.7 million as of December 31, 2024, 2023, and 2022, respectively.

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 is unable to prevail in one or more of such proceedings, its consolidated financial position, results of operations, and future cash flows may be materially adversely 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, 2024 and 2023, 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 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"), the European Patent Office (the "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

U.S. Patent Litigation

On August 2, 2022, the Company filed a patent infringement lawsuit against Mylan, a wholly-owned subsidiary of Viatris Inc., in the United States District Court for the Northern District of West Virginia alleging that Mylan's filing for U.S. Food and Drug Administration ("FDA") approval of an aflibercept 2 mg biosimilar infringes certain Company patents. On June 5, 2023, Biocon, as successor-in-interest to the aflibercept 2 mg biosimilar, was joined as a defendant to the lawsuit. A trial was held from June 12, 2023 through June 23, 2023 concerning certain claims of the '601 Patent, the '572 Patent, and the Company's U.S. Patent No. 11,084,865 (the '"865 Patent"). On December 27, 2023, the court issued a decision finding that (i) the asserted claims of the '865 Patent were valid and infringed by Mylan and Biocon and (ii) the asserted claims of the '601 and '572 Patents were infringed by Mylan and Biocon but were invalid as obvious. On June 11, 2024, the court granted the Company's motion for a permanent injunction, enjoining Mylan and Biocon from selling in the United States their aflibercept 2 mg biosimilar until the expiration of the '865 Patent. On June 21, 2024, Mylan and Biocon filed a notice of appeal of the court's December 27, 2023 and June 11, 2024 decisions to the Federal Circuit. An oral hearing concerning Mylan and Biocon's appeal has been scheduled for February 7, 2025.

On November 8, November 22, and November 29, 2023, respectively, the Company filed patent infringement lawsuits against Celltrion, Samsung Bioepis, and Formycon AG in the United States District Court for the Northern District of West Virginia following service on Regeneron of each company's notice of commercial marketing. The lawsuits allege that each company has infringed certain Company patents, including based on each company's filing for FDA approval of an aflibercept 2 mg biosimilar. On December 27, 2023, the Company filed a second patent infringement lawsuit against Samsung Bioepis in the United States District Court for the Northern District of West Virginia alleging that Samsung's filing for FDA approval of an aflibercept 2 mg biosimilar infringes certain Company patents. On June 14, June 21, and June 28, 2024, respectively, the court granted the Company's motions for preliminary injunctions against Samsung Bioepis, Formycon, and Celltrion. On June 14, June 25, and July 8, 2024, respectively, Samsung Bioepis, Formycon, and Celltrion filed notices of appeal of the court's preliminary injunction decisions to the Federal Circuit. An oral hearing concerning the respective appeals of Samsung Bioepis and Formycon was held on December 5, 2024. On January 29, 2025, the Federal Circuit affirmed the lower court's preliminary injunction decisions against Samsung Bioepis and Formycon. An oral hearing concerning Celltrion's appeal has been scheduled for February 7, 2025.

On January 10, 2024, the Company filed a patent infringement lawsuit against Amgen in the United States District Court for the Central District of California alleging that Amgen's filing for FDA approval of an aflibercept 2 mg biosimilar infringes certain Company patents. On April 11, 2024, the United States Judicial Panel on Multidistrict Litigation granted the Company's motion to transfer this lawsuit to the United States District Court for the Northern District of West Virginia for coordinated and consolidated pretrial proceedings with the lawsuits described in the preceding paragraph. On June 7, 2024, the Company filed a motion for a preliminary injunction against Amgen. On September 23, 2024, the court denied the Company's motion for a preliminary injunction, and the Company filed (i) a notice of appeal of such decision to the Federal Circuit, (ii) a motion for an immediate administrative stay, and (iii) a motion for a temporary injunction preventing Amgen from launching its aflibercept 2 mg biosimilar during the pendency of such appeal. On September 25, 2024, the Federal Circuit issued an administrative stay pending its review of the Company's temporary injunction motion. On October 22, 2024, the Federal Circuit denied the Company's temporary injunction motion and lifted the administrative stay. An expedited oral hearing concerning the Company's appeal of the court's preliminary injunction decision was held on January 14, 2025.

On August 26, 2024, the Company filed a patent infringement lawsuit against Sandoz Inc. in the United States District Court for the District of New Jersey alleging that Sandoz's filing for FDA approval of an aflibercept 2 mg biosimilar infringes certain Company patents. On September 12, 2024, the United States Judicial Panel on Multidistrict Litigation granted the Company's motion to transfer this lawsuit to the United States District Court for the Northern District of West Virginia for coordinated and consolidated pretrial proceedings with the lawsuits described in the preceding paragraphs.

Post-Grant Proceedings Before the USPTO

On November 20, 2024, November 29, 2024, and January 15, 2025, Samsung Bioepis Co., Ltd., Formycon AG, and Celltrion Inc., respectively, filed *inter partes* review ("IPR") petitions in the USPTO against the Company's U.S. Patent No. 11,084,865 (the "'865 Patent"), each seeking a declaration that the '865 Patent is invalid.

Europe

EPO Post-Grant Proceedings

Various parties, including Amgen and other anonymous parties, are seeking revocation of the Company's European Patent Nos. 2,944,306 (the "'306 Patent"), 3,716,992 (the "'992 Patent"), and 3,384,049 (the "'049 Patent") before the Opposition Division of the EPO. On November 26, 2024, following an oral hearing, the Opposition Division ("OD") of the EPO announced its decision to revoke the '306 Patent. The Company plans to appeal the OD's decision. Oral proceedings concerning the '992 Patent are scheduled for October 2025.

Country-Specific Proceedings

Various parties, including Amgen, Samsung Bioepis, and Formycon and/or their affiliated entities, are seeking revocation of the '306 Patent, the '992 Patent, and the Company's European Patent No. 2,364,691 (the "'691 Patent") and/or a declaration that its aflibercept 2 mg biosimilar would not infringe these patents in several European national courts (including those in France, Germany, Italy, the Netherlands, and the United Kingdom). In the United Kingdom, the Company has filed a preemptive counterclaim against Formycon AG and Klinge Biopharma GmbH, Samsung Bioepis UK Limited, and Amgen Inc. for infringement of the '306 Patent and the '691 Patent. In Germany, a trial concerning the '691 Patent has been scheduled to begin in June 2025. In the United Kingdom, trials concerning the '691 and '306 Patents have been scheduled to begin in June 2025, and the '992 Patent proceedings are stayed pending resolution of the EPO proceedings concerning this patent. In the Netherlands, a trial concerning the '691 and '306 Patents has been scheduled to begin in July 2025.

The Company has commenced proceedings in Belgium against various parties, including Amgen Inc., Celltrion Inc., Sterigenics (Petit-Rechain) NV, and Sandoz GmbH, for infringement of the Company's European Patent No. 1,183,353 (as extended by Supplementary Protection Certificate 2013C/029).

Canada

Proceedings against Amgen Canada

On May 9, 2023, Amgen Canada Inc. ("Amgen Canada") filed invalidation proceedings against the Company in the Federal Court of Canada seeking revocation of the Company's Canadian Patent Nos. 2,654,510 (the "'510 Patent") and 3,007,276 (the "'276 Patent"). On September 14, 2023, the Company, Bayer Inc., and Bayer Healthcare LLC filed patent infringement lawsuits against Amgen Canada in the Federal Court of Canada seeking a declaration that the making, constructing, using, or selling of an aflibercept 2 mg biosimilar would directly or indirectly infringe one or more claims of Bayer Healthcare LLC's Canadian Patent No. 2,970,315 (the "'315 Patent"). On September 14, 2023, the Company and Bayer Inc. filed three separate patent infringement lawsuits against Amgen Canada in the Federal Court of Canada seeking a declaration that the making, constructing, using, or selling of an aflibercept 2 mg biosimilar would directly or indirectly infringe one or more claims of the Company's Canadian Patent Nos. 3,129,193 (the "'193 Patent"), 2,965,495 (the "'495 Patent"), and 2,906,768 (the "'768 Patent"), respectively. On October 11, 2023, the Company, Bayer Inc., and Bayer Healthcare LLC filed two separate patent infringement lawsuits against Amgen Canada in the Federal Court of Canada seeking a declaration that the making, constructing, using, or selling of an aflibercept 2 mg biosimilar would directly or indirectly infringe one or more claims of the Company's '510 Patent and '276 Patent, respectively. On May 7, 2024 and June 28, 2024, respectively, Amgen filed a summary trial motion with respect to the '510 Patent and a motion to delist the '276 Patent from the Canada Patent Register. On November 20, 2024, the court granted Amgen's motion to delist the '276 Patent from the Canada Patent Register, which decision has been appealed by the Company and Bayer. A trial for the lawsuits concerning the '510 Patent and the '276 Patent has been scheduled for May–June 2025; and a trial for the lawsuits concerning the '315 Patent and the '193 Patent has been scheduled for August–September 2025.

Proceedings against Sandoz

On January 24, 2025, the Company, Bayer Inc., and Bayer Healthcare LLC filed patent infringement lawsuits against Sandoz Canada Inc. in the Federal Court of Canada seeking a declaration that the making, constructing, using, or selling of an aflibercept 2 mg biosimilar would directly or indirectly infringe one or more claims of the '510 Patent, the '276 Patent, the '495 Patent, the '768 Patent, the '193 Patent, the '315 Patent, and Canadian Patent No. 3,137,326 (the "'326 Patent").

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 ("KIPO") against the Company's Korean Patent Nos. 1131429 (the "'429 Patent") and 1406811 (the "'811 Patent"), respectively, seeking revocation of each such patent in its entirety. On October 23, 2024, the KIPO maintained the '811 Patent as valid, and Samsung appealed this decision on November 6, 2024. On November 20, 2024, the KIPO maintained the '429 Patent as valid in an amended form that no longer contains claims to aflibercept.

The Company and, as applicable, Bayer Consumer Care AG, have also filed patent infringement lawsuits in the Seoul Central District Court against various parties including Samsung Bioepis Co., Ltd. and its parent company Samsung Biologics Co., Ltd., Sam Chun Dang Pharm. Co., Ltd. and OPTUS Pharmaceutical Co., Ltd, and Celltrion Inc. These lawsuits seek damages and/or injunctive relief and allege that the making, constructing, using, or selling of an aflibercept 2 mg biosimilar by the relevant defendant(s) would infringe one or more claims of the '811 Patent and/or the Company's Korean Patent Nos. 659477 (the "'477 Patent") and 2519234 (the "'234 Patent").

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 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 Novartis's U.S. Patent No. 9,220,631 (the "'631 Patent"). On November 13, 2024, this lawsuit was dismissed in light of the final resolution of the IPR proceeding discussed below.

On July 16, 2020, the Company initiated two IPR petitions in the USPTO seeking a declaration that the '631 Patent is invalid on two separate grounds. 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; and on September 23, 2024, the Federal Circuit affirmed the PTAB's decision invalidating all claims of the '631 Patent.

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 21, 2021, this lawsuit was transferred to the Northern District of New York. 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 (the "Second Circuit"). On March 18, 2024, the Second Circuit reversed the District Court's decision to dismiss the amended complaint and remanded the lawsuit to the District Court for further proceedings consistent with the Second Circuit's opinion. On November 19, 2024, the Company moved to transfer the lawsuit back to the Southern District of New York, which motion was granted on December 5, 2024.

Proceedings Relating to Praluent (alirocumab) Injection

United States

On May 27, 2022, the Company filed a lawsuit against Amgen Inc. 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 and 11, 2022, Amgen filed a motion to dismiss the complaint and a motion to stay these proceedings, respectively. On February 10, 2023, the court denied Amgen's motion to stay; and on March 21, 2023, the court denied Amgen's motion to dismiss. On August 28, 2023, the Company filed an amended complaint in this matter; and, as part of its response, on September 20, 2023, Amgen filed a counterclaim alleging that the Company engaged in unfair business practices in violation of state law. On May 22, 2024, Amgen filed a motion for summary judgment. An oral hearing on Amgen's motion for summary judgment was held on November 20, 2024. A trial has been scheduled to begin in May 2025.

Europe

On June 1, 2023, Sanofi filed an action in the Munich Central Division of the Unified Patent Court (the "UPC") seeking revocation of Amgen's European Patent No. 3,666,797 (the "'797 Patent"). The '797 Patent is a divisional patent of European Patent No. 2,215,124 (the "'124 Patent") (i.e., a patent that shares the same priority date, disclosure, and patent term of the parent '124 Patent), which was previously invalidated by the Technical Board of Appeal of the EPO. On July 16, 2024, following a trial, the Munich Central Division of the UPC issued a decision revoking the '797 Patent in its entirety. On September 16, 2024, Amgen appealed the decision of the Munich Central Division of the UPC to the Court of Appeal of the UPC. An oral hearing before the Court of Appeal of the UPC has been scheduled for May 2025.

Also on June 1, 2023, Amgen filed a lawsuit against the Company and certain of Sanofi's affiliated entities in the Munich Local Division of the UPC alleging infringement of the '797 Patent. The lawsuit seeks, among other things, a permanent injunction in several countries in Europe and monetary damages. On July 29, 2024, the Munich Local Division of the UPC ordered a stay of the infringement lawsuit in light of the decision of the Munich Central Division of the UPC to revoke the '797 Patent in its entirety (discussed above).

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. Effective December 5, 2024, the parties entered into a settlement agreement, pursuant to which this lawsuit has been dismissed.

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 (the "June 2020 Civil Complaint"). On August 24, 2020, the Company filed a motion to dismiss the June 2020 Civil 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. An oral hearing on the parties' respective motions for summary judgment was held on July 21, 2023. On September 27, 2023, the court (i) denied in part and granted in part the Company's motion for summary judgment and (ii) denied in its entirety the motion for partial summary judgment filed by the U.S. Attorney's Office for the District of Massachusetts. On October 25, 2023, the court certified for interlocutory appeal a portion of the court's September 27, 2023 order that addressed the causation standard applicable to the alleged violations of the federal Anti-Kickback Statute and federal False Claims Act; and on December 11, 2023, the U.S. Court of Appeals for the First Circuit certified for appeal (i.e., accepted for review) the court's September 27, 2023 order. An oral hearing concerning the appeal to the U.S. Court of Appeals for the First Circuit was held on July 22, 2024.

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. On July 25, 2023, the court granted in part and denied in part the Company's motion to dismiss. On September 1, 2023, the Company filed a second motion to dismiss the amended complaint or, in the alternative, a motion for judgment on the pleadings. On July 31, 2024 and August 15, 2024, respectively, the District Court granted the Company's second motion to dismiss the amended complaint with respect to the remaining causes of action under federal law and declined to exercise supplemental jurisdiction over the remaining causes of action under state law. On August 26, 2024, the qui tam plaintiffs filed a notice of appeal.

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 the Centers for Medicare & Medicaid Services. The CID covers the period from January 2011 through June 2021. On November 29, 2023, the U.S. Department of Justice informed the Company that it had filed a notice of partial intervention in this matter. On March 28, 2024, the Department of Justice and the U.S. Attorney's Office for the District of Massachusetts filed a civil complaint intervention (the "March 2024 Civil Complaint") in the U.S. District Court for the District of Massachusetts asserting causes of action under the federal False Claims Act and a claim for unjust enrichment. Also on March 28, 2024, the U.S. District Court of the District of Massachusetts unsealed a qui tam complaint against the Company, AmerisourceBergen, and Besse Medical by two qui tam plaintiffs (known as relators) purportedly on behalf of the United States and various states and municipalities, asserting causes of action under the federal False Claims Act and state and local laws, and alleging violations of the federal Anti-Kickback statute. On June 25, 2024, the States of Colorado, Georgia, Michigan, North Carolina, Texas, and Washington filed a civil complaint in partial intervention (the "June 2024 Civil Complaint") in the U.S. District Court for the District of Massachusetts asserting causes of action under various state laws. On July 18, 2024, the Company filed a motion to dismiss the March 2024 Civil Complaint and the June 2024 Civil Complaint. An oral hearing on the Company's motion to dismiss was held on December 16, 2024.

Proceedings Initiated by Other Payors

The Company is party to several lawsuits relating to the conduct alleged in the June 2020 Civil Complaint 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 ("RICO") 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 concerning the allegations in the June 2020 Civil Complaint. 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 concerning the allegations in the June 2020 Civil Complaint; and, in light of these stays, the parties to the Local 464A action have also agreed to stay that matter.

On June 24, 2024, a group of plaintiffs purporting to be assignees of claims by various Medicare Advantage plans and related entities filed a putative class action complaint in the U.S. District Court for the District of Columbia on behalf of Medicare Advantage plans and other payors. The lawsuit relates to the conduct alleged in the June 2020 Civil Complaint, March 2024 Civil Complaint, and June 2024 Civil Complaint discussed under "Department of Justice Matters" above. The lawsuit alleges causes of action under state law and RICO and seeks monetary damages and equitable relief. On October 22, 2024, the Company filed a motion to transfer the proceedings to the U.S. District Court for the District of Massachusetts or, in the alternative, to stay the proceedings or dismiss the proceedings. On January 28, 2025, pursuant to a stipulation among the parties, the proceedings were transferred to the U.S. District Court for the District of Massachusetts.

2021 Shareholder Derivative Complaint

On June 29, 2021, an alleged shareholder filed a shareholder derivative complaint in the New York Supreme Court, naming the then-current and certain former members of the Company's board of directors and certain then-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 June 2020 Civil Complaint 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 concerning the allegations in the June 2020 Civil Complaint. As a result of the stay, the court also terminated the Company's motion to dismiss the complaint without prejudice. The Company can therefore renew the motion to dismiss upon conclusion of the stay.

Class Action Civil Complaint

On January 7, 2025, a purported shareholder filed a putative class action civil complaint, on behalf of himself and all others similarly situated, in the U.S. District Court for the Southern District of New York against the Company and certain current and former executive officers of the Company. The complaint asserts violations of federal securities laws in connection with statements or disclosures purportedly related to the conduct alleged in the March 2024 Civil Complaint discussed under "Department of Justice Matters" above.

2025 Shareholder Derivative Complaints

On January 16 and January 22, 2025, purported shareholders filed two separate shareholder derivative complaints in the U.S. District Court for the Southern District of New York against 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 complaints each allege that the individual defendants, among other things, breached their fiduciary duties to the Company by failing to properly manage and oversee the Company in connection with the conduct alleged in the March 2024 Civil Complaint discussed under "Department of Justice Matters" above. The complaints also each allege that the individual defendants breached the federal securities laws, wasted corporate assets, and unjustly enriched themselves at the expense of the Company. The complaints each seek, among other things, an award of damages allegedly sustained by the Company as a result of the alleged misconduct of the individual defendants; an order requiring the individual defendants to take all necessary actions to reform and improve the Company's corporate governance and internal procedures; and costs and disbursements of the applicable action, including attorneys' fees.

Sanofi Litigation

On November 18, 2024, the Company filed a lawsuit (as amended on December 20, 2024) in the United States District Court for the Southern District of New York against Sanofi and certain of its affiliated entities. The lawsuit alleges that the defendants breached certain provisions of the parties' Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009 (as amended, the "Collaboration Agreement"), concerning Sanofi's obligation to provide Regeneron with full access to material information relating to the commercialization of Dupixent or other products commercialized pursuant to the Collaboration Agreement and Regeneron's audit rights under the Collaboration Agreement. The lawsuit seeks a declaratory judgment, injunctive relief, damages, and other relief.

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)	**2024**	**2023**	**2022**
Net income - basic and diluted	$ 4,412.6	$ 3,953.6	$ 4,338.4
Weighted average shares - basic	107.9	106.7	107.1
Effect of dilutive securities:			
Stock options	4.8	4.9	4.9
Restricted stock awards and restricted stock units	2.4	2.1	1.5
Weighted average shares - diluted	115.1	113.7	113.5
Net income per share - basic	$ 40.90	$ 37.05	$ 40.51
Net income per share - diluted	$ 38.34	$ 34.77	$ 38.22

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)	**2024**	**2023**	**2022**
Stock options	1.6	1.8	2.3

18. Statement of Cash Flows

The following provides a reconciliation of cash, cash equivalents, and restricted cash reported within the Consolidated Balance Sheets to the total of the same such amounts shown in the Consolidated Statements of Cash Flows:

	December 31,		
(In millions)	**2024**	**2023**	**2022**
Cash and cash equivalents	$ 2,488.2	$ 2,730.0	$ 3,105.9
Restricted cash included in Other current assets	0.8	—	—
Restricted cash included in Other noncurrent assets	—	7.8	13.5
Total cash, cash equivalents, and restricted cash shown in the Consolidated Statements of Cash Flows	$ 2,489.0	$ 2,737.8	$ 3,119.4

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)	**2024**	**2023**	**2022**
Accrued capital expenditures	$ 151.6	$ 75.4	$ 70.8
Accrued contingent consideration in connection with acquisitions	$ 62.7	$ 71.6	$ 135.5

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934

The following is a description of the common stock, par value $0.001 per share (the "Common Stock"), of Regeneron Pharmaceuticals, Inc. (the "Company") which is the only security of the Company registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The following also contains a description of the Class A Stock, par value $0.001 per share (the "Class A Stock"; Common Stock and Class A Stock are referred to herein, collectively, as the "Common Shares"), of the Company, which is not registered pursuant to Section 12 of the Exchange Act but is convertible into shares of Common Stock at any time at the option of the holder. The description of the Class A Stock is necessary to understand the material terms of the Common Stock.

General

The Company is authorized to issue 320,000,000 shares of Common Stock, par value $0.001 per share, and 40,000,000 shares of Class A Stock, par value $0.001 per share. The following description summarizes selected information regarding the Common Stock and the Class A Stock, as well as relevant provisions of: (i) the Company's Restated Certificate of Incorporation, as amended, as currently in effect (the "Articles"), (ii) the Company's Amended and Restated By-Laws, as amended, as currently in effect (the "By-Laws"), and (iii) the New York Business Corporation Law (the "NYBCL"). The following summary description of the Common Stock and the Class A Stock is qualified in its entirety by, and should be read in conjunction with, the Articles and the By-Laws, copies of which have been filed as exhibits to the Company's periodic reports under the Exchange Act, and the applicable provisions of the NYBCL.

Common Stock and Class A Stock

General. The rights of holders of Common Stock and holders of Class A Stock are identical except for voting rights, conversion rights, and restrictions on transferability.

Voting Rights. The holders of Common Stock are entitled to one vote per share and the holders of Class A Stock are entitled to ten votes per share. Except as otherwise expressly provided by law, holders of Common Shares have exclusive voting rights on all matters requiring a vote of shareholders. Except as provided by law, the holders of Common Stock and the holders of Class A Stock will vote together as a single class on all matters presented to the shareholders for their vote or approval, including the election of directors. Shareholders are not entitled to vote cumulatively for the election of directors and no class of outstanding Common Shares acting alone is entitled to elect any directors.

Dividends and Liquidation. Except as described in this paragraph, holders of Common Stock and holders of Class A Stock have an equal right to receive dividends when and if declared by the Company's board of directors out of funds legally available therefor. If a dividend or distribution payable in Class A Stock is made on the Class A Stock, the Company must also make a pro rata and simultaneous dividend or distribution on the Common Stock payable in shares of Common Stock. Conversely, if a dividend or distribution payable in Common Stock is made on the Common Stock, the Company must also make a pro rata and simultaneous dividend or distribution on the Class A Stock payable in shares of Class A Stock. In the event of the Company's liquidation, dissolution, or winding up, holders of Common Stock and Class A Stock are entitled to share equally, share-for-share, in the assets available for distribution after payment of all creditors and the liquidation preferences of any preferred stock.

Optional Conversion Rights. Each share of Class A Stock may, at any time and at the option of the holder, be converted into one fully paid and nonassessable share of Common Stock. Upon conversion, such shares of Common Stock would not be subject to restrictions on transfer that applied to the shares of Class A Stock prior to conversion except to the extent such restrictions are imposed under applicable securities laws. The shares of Common Stock are not convertible into or exchangeable for shares of Class A Stock or any other of the Company's shares or securities.

Other Provisions. Holders of Common Stock and holders of Class A Stock have no preemptive rights to subscribe for any additional securities of any class which the Company may issue and there are no redemption provisions or sinking fund provisions applicable to either such class, nor are the shares of Common Stock or Class A Stock subject to calls or assessments.

Transfer Restrictions. The Class A Stock is subject to certain limitations on transfer that do not apply to the Common Stock.

Listing. The Common Stock is listed on The Nasdaq Global Select Market under the symbol "REGN." The Class A Stock is not listed on a securities exchange.

Transfer Agent and Registrar. The transfer agent and registrar for the Common Stock is Equiniti Trust Company, LLC.

Anti-Takeover Effects of Provisions of the Articles, the By-Laws and the NYBCL

Under certain circumstances, certain provisions of the Company's Articles, the Company's By-Laws, and certain provisions of the NYBCL could have the effect of delaying or preventing a change in control of the Company or the Company's 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 the Common Stock.

Among other things, the Articles and the By-Laws provide:

- 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 the 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 the Company's 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 the Company's shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting; and
- 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.

Under the NYBCL, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder," a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon.

CERTAIN INFORMATION IN THIS DOCUMENT, MARKED BY [****], HAS BEEN EXCLUDED PURSUANT TO REGULATION S-K, ITEM 601(b)(10)(iv). SUCH EXCLUDED INFORMATION IS NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

RESTATED AMENDMENT AGREEMENT

This Amendment Agreement (this "Amendment Agreement") dated as of May 7, 2012, is by and between Regeneron Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of New York and having its principal office at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("Regeneron"), and Bayer Healthcare LLC, a limited liability company having a principal place of business at 511 Benedict Avenue, Tarrytown, NY 10591 ("Company").

INTRODUCTION

WHEREAS, Regeneron and BHC are Parties to a License and Collaboration Agreement, having an effective date of October 18, 2006, as amended on May 7, 2012 (the "LCA"); and

WHEREAS, Regeneron and BHC have mutually determined that, during the term of the Co-Promotion and Distribution Agreement, by and between Bayer Yakuhin, Ltd. ("BYL"), an Affiliate of BHC, and Santen Pharmaceutical Co., Ltd. ("Santen"), dated of even date herewith (the "Santen Co-Promotion Agreement") which is being executed and delivered concurrently with the execution and delivery of this Amendment, Licensed Products will be Commercialized in Japan pursuant to the Santen Co-Promotion Agreement.

WHEREAS, in connection with, and as a condition to Regeneron consenting to the Commercialization of Licensed Products in Japan pursuant to, the Santen Co-Promotion Agreement, this Amendment Agreement is being entered into to amend and supplement the LCA to (a) convert the financial arrangements with respect to the Commercialization of Licensed Products in Japan from a profit split as provided in the LCA to a purchase price adjustment payable by Bayer to Regeneron (subject to reversion to a profit split under certain circumstances), and (b) reflect the agreements among Company, BYL and Regeneron regarding the Commercialization of Licensed Products in Japan , including, in particular, the financial, governance and reporting provisions of the LCA with respect to Japan.

NOW, THEREFORE, in consideration of the foregoing, and the mutual promises and obligations set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

1. **Existing Definitions.** Capitalized terms used in this Amendment Agreement which are not defined herein and are defined in the LCA shall have the meanings ascribed to them in the LCA. Capitalized terms used in this Amendment Agreement which are not defined

herein and are not defined in the LCA shall have the meanings ascribed to them in the Santen Co-Promotion Agreement and such definitions are hereby deemed incorporated by reference into Article I of the LCA.

2. **New Definitions.** Article 1 of the LCA is hereby amended to add the following definitions:

(a) "[****]" shall mean [****].

(b) "Amendment Agreement" shall mean this Amendment Agreement, as it may be amended from time to time.

(c) "Bayer Market Net Sales" shall mean Net Sales in Japan calculated in accordance with the definition of Net Sales set forth in Article I of the LCA.

(d) "Bayer Sales" shall mean the number of units of Licensed Product sold by Bayer to Santen during the respective Quarter multiplied by [****] and multiplied by [****].

(e) "BYL" shall mean Bayer Yakuhin Ltd., an Affiliate of Company.

(f) "Japan Profit Share" shall have the meaning, and shall be calculated as, set forth in Schedule 2, Section I.B.

(g) "Japan Purchase Price Adjustment" shall have the meaning, and shall be calculated as, set forth in Schedule 2, Section I.A.

(h) "Japan Shared Promotion Expenses" shall have the meaning set forth in Schedule 2, Section I.B.(i).

(i) "Santen" shall mean Santen Pharmaceutical Co., Ltd., a Japanese corporation having its principal place of business at 3-9-19, Shimoshinjo, Higashiyodogawa-ku, Osaka 533-8651, Japan.

(j) "Santen Change of Control" shall mean any of the following events: (a) Company or any of its Affiliates, alone or together, acquire(s) shares of capital stock of Santen representing a majority of the total voting power represented by all classes of capital stock then outstanding of Santen normally entitled to vote in the election of members of the board of directors (or analogous governing body) of Santen; (b) Santen consolidates with or merges with or into Company or any of its Affiliates; or (c) Santen conveys, transfers or leases all or substantially all of its assets to Company or any of its Affiliates.

(k) "Santen Co-Promotion Agreement" shall mean the Co-Promotion and Distribution Agreement dated of even date herewith by and between BYL and Santen, as amended from time to time in accordance with the terms thereof and with the consent of Regeneron if required pursuant to the Amendment Agreement.

(l) "Santen Market Net Sales" shall mean the number of units of Licensed Product sold by Santen to wholesalers or other Third Parties during the respective Quarter multiplied by [****] and multiplied by [****].

3. **Amended Definitions.** The following definitions in Article I of or elsewhere in the LCA are hereby amended as follows:

   (a) References in the LCA to "Agreement" shall mean the LCA, as amended by this Amendment Agreement.

   (b) "Consolidated Payment Report". The definition of "Consolidated Payment Report" set forth in Article I of the LCA is amended by adding the following sentence at the end thereof: "In addition, the Consolidated Payment Report shall also include for such Quarter (i) if the Santen Co-Promotion Agreement is in effect and the Japan Purchase Price Adjustment is applicable for such Quarter and, in accordance with Schedule 2, is calculated based on Santen Market Net Sales, (A) Santen Market Net Sales, (B) the applicable NHI Price and (C) unit sales of the Licensed Product in Japan, (ii) if the Japan Purchase Price Adjustment is applicable for such Quarter and is calculated based on Bayer Market Net Sales in accordance with Schedule 2, Bayer Market Net Sales, and (iii) if the Santen Co-Promotion Agreement is in effect and the Japan Profit Share is applicable for such Quarter, (A) Bayer Sales, (B) COGS applicable to Bayer Sales and (C) Japan Shared Promotion Expenses incurred by BYL (following reconciliation with Santen) and by Regeneron, if any."

   (c) "Net Sales". The definition of "Net Sales" set forth in Article I of the LCA is amended by adding the following sentence at the end thereof: "So long as the Santen Co-Promotion Agreement remains in effect, Net Sales excludes sales of Licensed Products in the Field in Japan."

   (d) "Shared Promotion Expenses". The definition of "Shared Promotion Expenses" in Article I of the LCA is amended by adding the following sentence at the end thereof: "So long as the Santen Co-Promotion Agreement is in effect, Shared Promotion Expenses excludes any of the items listed in this definition to the extent related to the Commercialization of Licensed Products in Japan."

4. **Schedule 2.** Schedule 2 of the LCA is deleted in its entirety and replaced with the Amended and Restated Schedule 2 attached to this Amendment Agreement, and all references to Schedule 2 in this Amendment Agreement, or in the LCA from and after the date of this Amendment Agreement, refer to such Amended and Restated Schedule 2.

5. **Regeneron Consent to Sublicense Grant**. Regeneron hereby expressly agrees and consents for the Initial Term to a sublicense by BHC to BYL of BHC's rights under the Regeneron Intellectual Property granted by Regeneron to BHC pursuant to the LCA, provided such sublicense is in compliance with Section 4.3 of the LCA unless agreed in writing by Regeneron with BHC, and to BYL's further sublicense of such rights to Santen, to the extent that they comprise Licensed Intellectual Property, pursuant to the terms of the Santen Co-Promotion Agreement, provided that such agreement and consent shall not alter or affect in any manner BHC's obligations or Regeneron's rights under the LCA which shall remain in full force and effect, including without limitation under such Section 4.3.

6. **Commercialization Governance**. For so long as the Santen Co-Promotion Agreement remains in effect, all management and governance of the Commercialization efforts for the Licensed Product in Japan shall be determined under the LCA as if such efforts were conducted by Company alone (it being understood that for so long as the Santen Co-Promotion Agreement remains in effect, Company may fulfill its obligations under the first two sentences of Section 6.6 and Section 6.7 of the LCA through Santen), except that Regeneron shall not participate in the Joint Steering Committee (as defined in the Santen Co-Promotion Agreement) for Japan. For the avoidance of doubt, Company must still prepare and present to the JCC the Country Commercialization Plan for Japan in accordance with Section 6.3 of the LCA. If the Santen Co-Promotion Agreement is no longer in effect, this Section 6 of this Amendment shall have no further force or effect and the management and governance of the Commercialization efforts for the Licensed Product in Japan shall again be governed by and subject to the LCA in all respects. Company shall provide to Regeneron, within ten (10) Business Days of receipt, all reports and information provided to BYL or Company under Section 3.3 of the Santen Co-Promotion Agreement. Notwithstanding anything to the contrary in this Section 6, Company shall provide, or shall cause BYL to provide, to Regeneron such other reports and information required to be provided under the LCA in the form required by the LCA.

7. **Section 9.3(f)**. Section 9.3(f) of the LCA is amended by adding the following at the end thereof: “provided, that if the Santen Co-Promotion Agreement is in effect and the Japan Profit Share is applicable, within forty-five (45) days following the end of each Quarter commencing after the First Commercial Sale in Japan (or such earlier agreed upon calendar Quarter, if appropriate), each Party that has (or whose Affiliate has) incurred Japan Shared Promotion Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Japan Shared Promotion Expenses incurred by that Party or its Affiliates in such Quarter”.

8. **Section 9.3(g)**. Section 9.3(g) of the LCA is amended by adding immediately after the words “for such Quarter” the following: “and, if the Santen Co-Promotion Agreement is in effect and the Japan Profit Share is applicable, Company shall deliver electronically to Regeneron a written report setting forth (i) COGS applicable to Bayer Sales and (ii) COGS incurred by Company or its Affiliates applicable to Net Sales in the Territory excluding Japan”.

9. **Section 11.6.** Section 11.6 of the LCA is amended by adding the following at the end of the first sentence of such Section (after the word “materials” and before the period): “;and provided further that if including Regeneron’s name with equal prominence on materials exclusively related to each Licensed Product in the Field as provided above is prohibited under applicable Laws, Company will use Commercially Reasonable Efforts to include, to the extent permitted by applicable Laws, a reference to Regeneron and its contribution to such Licensed Product (e.g., ‘EYLEA was jointly developed by Regeneron and Bayer HealthCare’).

10. **Calculation of the Japan Profit Split**. Unless the Japan Profit Share is applicable as provided in Section 11 or Section 12 of this Amendment Agreement, the Japan Profit Split (as defined in Schedule 2, Section I.) shall be calculated as the Japan Purchase Price Adjustment, as defined in and in accordance with Schedule 2, Section I.A.

11. **Bayer Renegotiation Option**. If the actual [****] in a given calendar year is less than [****] of the Assumed [****] for such calendar year as set forth in the table in Schedule 2A attached to this Amendment Agreement, either Party may request in writing that the Japan Purchase Price Adjustment set forth in Schedule 2, Section I.A., be renegotiated to reflect the changed circumstances and to restore the economic basis of such financial arrangements. The Parties agree to renegotiate in good faith for thirty (30) days following the written request by a Party for renegotiation of such Japan Purchase Price Adjustment pursuant to this Section 11. If the Parties do not reach written agreement on adjustments to the Japan Purchase Price Adjustment within such thirty (30)- day period, the Japan Profit Split (as defined in Schedule 2, Section I.) shall thereafter be the Japan Profit Share, as defined in and calculated in accordance with Schedule 2, Section I.B., beginning in the next calendar Quarter commencing on or after the expiration of the thirty (30)-day period referenced above in this Section 11.

12. **Launch Delay Option**. In the event that the First Commercial Sale of a Licensed Product in Japan occurs after [****], either Party may request in writing that the schedule of annual Baseline A Santen Market Net Sales forth in Schedule 2, Section I.A., and, if the delay materially adversely affects the economic basis of the financial arrangements regarding the Commercialization of Licensed Products in Japan provided for in this Amendment Agreement (including Schedule 2), the Japan Purchase Price Adjustment, be renegotiated to reflect the delayed launch date and to restore the economic basis of such financial arrangements. The Parties agree to renegotiate in good faith for thirty (30) days following such a written request. If the Parties do not reach written agreement on a revised schedule of Baseline A Santen Market Net Sales and, if applicable, revised Japan Purchase Price Adjustment, within such thirty (30)-day period, the Japan Profit Split (as defined in Schedule 2, Section I.) shall thereafter be the Japan Profit Share, as defined in and calculated in accordance with Schedule 2, Section I.B., beginning in the next calendar Quarter commencing on or after the expiration of the thirty (30)-day period referenced above in this Section 12. If the schedule of Baseline A Santen Market Net Sales is adjusted, the schedule of Baseline B and Baseline C Santen Market Net Sales will also be adjusted proportionately.

13. [****].

    Beginning with the first commercial sale in Japan of [****], Company shall pay to Regeneron a royalty of [****] of Net Sales [****] in Japan (calculated consistent with Section 1.65 of the LCA) until the earlier of: (i) the expiration or termination of the Santen Co-Promotion Agreement, or (ii) a Santen Change of Control. [****].

14. **Calculation of Sales Milestones Payments**. For so long as the Santen Co-Promotion Agreement is in effect, Santen Market Net Sales shall be added to Net Sales in

calculating aggregate Net Sales for purposes of determining the achievement of the sales milestone events described on Schedule 3 to the LCA. If the Santen Co-Promotion Agreement is no longer in effect, Bayer Market Net Sales shall be utilized in calculating aggregate Net Sales for such purposes.

15. **Restrictions on BYL Actions under Santen Co-Promotion Agreement**

(a) Company will not, and will ensure that BYL does not, without Regeneron's prior written consent (such consent regarding subparagraphs (ii) and (iv) below not to be unreasonably withheld, delayed or conditioned):

(i) Agree to any amendment or modification of, waive or fail to enforce any material rights or grant any consent or approval under (including without limitation to permit Santen to conduct any Non-Approval Trial related to the Licensed Product in Japan), extend the Initial Term of, or terminate in part, the Santen Co-Promotion Agreement;

(ii) Agree to or permit any Public Relations Activity related to the Licensed Product in Japan;

(iii) Agree to or permit any reduction in the Minimum Audited Detail, or any downward revision in the Market Share Target percentage;

(iv) Enter into or thereafter amend any of the agreements referred to in Section 6.2 or 7.13 of the Santen Co-Promotion Agreement;

(v) Accept Santen's rejection of any delivery of Licensed Product if such rejection is based on actions or omissions of Regeneron in connection with the Manufacture of such Licensed Product, unless Regeneron has confirmed in writing the basis for such rejection in its reasonable judgment prior to such acceptance. For the avoidance of doubt, neither Santen nor BYL shall be required to introduce to the market or keep on the market any Licensed Product that they have tendered for rejection;

(vi) Resolve or agree to resolve any dispute under the Santen Co-Promotion Agreement if such resolution would diminish the economic benefit reasonably expected to accrue to Regeneron pursuant to the Japan Purchase Price Adjustment or Japan Profit Split, as applicable, or would adversely affect the Collaboration in the Territory outside Japan; or

(vii) Agree, pursuant to Section 7.11 of the Santen Co-Promotion Agreement, on an extension of the Minimum Remaining Shelf-Life of the Licensed Product to be delivered to Santen.

(b) If BYL is entitled to terminate the Santen Co-Promotion Agreement, Company and BYL will consult with Regeneron regarding the advisability of such termination, but BYL will have the ultimate decision on whether to terminate. Upon such termination, the Existing LCA, as amended by this Amendment Agreement, will govern Commercialization of the Licensed Product in Japan.

(c) For so long as the Santen Co-Promotion Agreement is in effect, Company will not and will ensure that BYL does not make any sales of Licensed Products in Japan. The foregoing does not apply to sales of Licensed Product by Company or BYL

to Santen as contemplated by the Santen Co-Promotion Agreement, or any other Commercialization activities expressly provided in the Santen Co-Promotion Agreement to be performed by Company or BYL.

16. **Supply Chain**. Notwithstanding the obligations set forth in the Santen Co-Promotion Agreement, Company and BYL will maintain a minimum inventory of [****] of work-in-process inventory of Licensed Product allocated for Japan for the first [****] following the First Commercial Sale in Japan, and thereafter, a minimum inventory of [****] of work-in-process inventory of Licensed Product allocated for Japan. The foregoing requirements shall be reviewed by the parties in good faith if [****]. For purposes of this paragraph 16, "work in progress inventory" shall mean Licensed Product in vials or syringes prior to labeling or blistering, filled vials or syringes of Licensed Product that are labeled or blistered prior to sterilization, or sterilized and filled vials or blisters of Licensed Product that are labeled or blistered prior to packaging.

17. **Public Announcement**. The Company and Regeneron will mutually agree upon the contents of any press release regarding the Santen Co-Promotion Agreement and this Amendment Agreement. Any other press release or public announcement concerning the Santen Co-Promotion Agreement or this Amendment Agreement shall be governed by Section 16.4 of the LCA. To the extent that a Party concludes in good faith that it is or may be required to file or register this Amendment Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Sections 16.4 and 20.8 of the LCA.

18. **Continuing Effect.** Except as specifically modified by this Amendment Agreement, all of the provisions of the LCA are hereby ratified and confirmed to be in full force and effect, and shall remain in full force and effect.

19. **Company Representation; Performance by BYL.** Company hereby represents and warrants to Regeneron that neither Company, BYL nor any of their Affiliates doing business principally in Japan has any current or planned agreement, arrangement or understanding with Santen or any of its Affiliates, other than the Santen Co-Promotion Agreement. Company shall cause BYL to perform all its obligations under the Santen Co-Promotion Agreement and will notify Regeneron if it or any of its Affiliates enters into any such agreement, arrangement or understanding with Santen or any of its Affiliates, other than the Santen Co-Promotion Agreement. For the avoidance of doubt, the foregoing representation and warranty, and the requirement to notify Regeneron, does not apply to agreements, such as routine Confidentiality Agreements, Material Transfer Agreements or the like, that do not relate to new business opportunities that have not been disclosed to Regeneron.

20. **No Offset.** For the avoidance of doubt, Bayer will have no right to offset the Japan Purchase Price Adjustment with any Bayer COGS, Shared Promotion Expenses or Japan Shared Promotion Expenses, as defined in Schedule 2, Section I.B.(i).

21. **Entire Agreement; Successors and Assigns.** The LCA, this Amendment Agreement, and any written agreements executed by both Parties pertaining to the subject matter therein or herein, contain the complete understanding and entire agreement of the Parties hereto with respect to subject matter hereof and thereof and said documents supersede all prior understandings and agreements, whether written or oral, relating to the subject matter hereof and thereof. This Amendment Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

22. **Headings.** Headings in this Amendment Agreement are for convenience of reference only and shall not be considered in construing this Amendment Agreement.

23. **Counterparts.** This Amendment Agreement may be executed in counterparts and by facsimile signatures, each of which shall be deemed an original, and shall become a binding agreement when one or more counterparts have been signed by each Party and delivered to the other Party.

24. **Miscellaneous.** The provisions of Section 20.1 of the LCA shall apply, mutatis mutandis, to this Amendment Agreement. If there is a direct conflict between the provisions of the LCA and this Amendment Agreement, this Amendment Agreement shall govern. This Amendment Agreement may be amended only by a writing executed by an authorized representative of each of the Parties.

[Signatures appear on following page]

IN WITNESS WHEREOF, each of the Parties has caused this Amendment to be executed as of the date hereof by a duly authorized corporate officer.

BAYER HEALTHCARE LLC

By: /s/ R. Scott Meece
Name: R. Scott Meece
Title: General Counsel, Senior Vice President and Secretary

Date: December 30, 2014

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray A. Goldberg
Name: Murray A. Goldberg
Title: Senior Vice President

Date: December 30, 2014

AMENDED AND RESTATED SCHEDULE 2

Quarterly True-Up

At the end of each Quarter, the Parties will calculate the net payment one Party shall be required to make to the other Party (the "Quarterly True-Up") equal to (a) the Territory Profit Split for such Quarter (as set forth in Part I), plus (b) the Regeneron Reimbursement Amount for such Quarter (as set forth in Part II), plus or minus (c) the Global True-Up (as set forth in Part III), minus (d) the Global Development Balance Payment (commencing in the Quarter of the First Commercial Sale in a Major Market Country) (as set forth in Part IV). In the event that the Quarterly True-Up is an amount greater than zero, such amount shall be payable by Company to Regeneron in accordance with the terms set forth in Article 9. In the event that the Quarterly True-Up is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Company in accordance with the terms set forth in Article 9. An example of the Quarterly True-Up is shown in Part V.

I. TERRITORY PROFIT SPLIT

The "Territory Profit Split" shall mean the sum of fifty percent (50%) of Territory Profits in the Quarter plus the Japan Profit Split in the Quarter. "Territory Profits" shall mean aggregate Net Sales in the Territory, excluding Japan, in the Quarter less the sum of aggregate COGS and aggregate Shared Promotion Expenses incurred by both Parties in the Territory, excluding Japan, in the Quarter.

The "Japan Profit Split" shall equal the US Dollar equivalent (calculated in accordance with Section 9.6) of (a) either (i) the Japan Purchase Price Adjustment, as defined below, or (ii) the Japan Profit Share, as defined below, as applicable for such Quarter, plus (b) the Regeneron Detail Default Payment, if any. The "Regeneron Detail Default Payment" shall equal [****] of the Detail Default Payment paid by Santen to the BYL in a Quarter, if any.

An example of a calculation of the Territory Profit Split in a Quarter would be:

	Aggregate	Company	Regeneron
Net Sales in the Territory*	1000	1000	
COGS*	(50)	(50)	0
Shared Promotion Expenses*	(350)	(300)	(50)
Territory Profits	600		
50% of Territory Profits	300		
Japan Profit Split	100		
Territory Profit Split	400		

* Excluding Japan

A. JAPAN PURCHASE PRICE ADJUSTMENT

The Japan Purchase Price Adjustment mechanism shall always apply unless the Parties cannot reach agreement for adjustments pursuant to paragraphs 9 and 10, in which case the Japan Profit Share will apply.

For each calendar year through December 31, 2021 that the Santen Co-Promotion Agreement is in effect, the "Japan Purchase Price Adjustment" shall equal the sum of (i) 33.5% of Santen Market Net Sales up to Baseline A Santen Market Net Sales for such year, (ii) [****] of Santen Market Net Sales in excess of Baseline A Santen Market Net Sales up to Baseline B Santen Market Net Sales for such year, (iii) [****] of Santen Market Net Sales in excess of Baseline B Santen Market Net Sales up to Baseline C Santen Market Net Sales for such year, and (iv) 40.0% of Santen Market Net Sales in excess of Baseline C Santen Market Net Sales.

For each calendar year through [****] that the Santen Co-Promotion Agreement is not in effect, the Japan Purchase Price Adjustment shall equal [****] of Bayer Market Net Sales.

From and after a Santen Change of Control, and in any event after [****], the Japan Purchase Price Adjustment shall equal [****] of Bayer Market Net Sales.

Baseline A Santen Market Net Sales, Baseline B Santen Market Net Sales, and Baseline C Santen Market Net Sales are set forth below:

	Santen Market Net Sales (in millions of Yen)		
Year	Baseline A	Baseline B (=[****] of Baseline A)	Baseline C (=[****] of Baseline A)
2012	[****]	[****]	[****]
2013	[****]	[****]	[****]
2014	[****]	[****]	[****]
2015	[****]	[****]	[****]
2016	[****]	[****]	[****]

2017	[****]	[****]	[****]
2018	[****]	[****]	[****]
2019	[****]	[****]	[****]
2020	[****]	[****]	[****]
2021	[****]	[****]	[****]

When the Santen Co-Promotion Agreement is in effect, the Japan Purchase Price Adjustment for a Quarter shall be calculated based on Santen Market Net Sales in such Quarter using a rate(s) based on aggregate year-to-date Santen Market Net Sales in accordance with the formula set forth above.

A series of examples of the calculation of the Japan Purchase Price Adjustment is set forth below:

[****]

B. JAPAN PROFIT SHARE

The Japan Profit Share applies only if the Parties cannot reach agreement for adjustments pursuant to paragraphs 11 and 12, otherwise the Japan Purchase Price Adjustment mechanism will apply.

Japan Profit Share – Santen Co-Promotion Agreement in Effect

If the Santen Co-Promotion Agreement is in effect, the "Japan Profit Share" shall equal fifty percent (50%) of Japan Profits in the Quarter. "Japan Profits" for this Paragraph (i) shall mean Bayer Sales in the Quarter less the sum of COGS applicable to Bayer Sales and Japan Shared Promotion Expenses incurred by BYL (following reconciliation with Santen) (and Regeneron, if any) in Japan in the Quarter. "Japan Shared Promotion Expenses" shall mean the sum of (a) Promotional Expenses (as defined in the Santen Co-Promotion Agreement) and (b) [****] of the Promotion Fee (as defined in the Santen Co-Promotion Agreement). The other [****] of the Promotion Fee will be borne by the Company and will not be included as a part of the calculation of Japan Profits.

Japan Profit Share – Santen Co-Promotion Agreement Not in Effect and no Japan Purchase Price Adjustment payable

If the Santen Co-Promotion Agreement is not in effect, the "Japan Profit Share" shall equal fifty percent (50%) of Japan Profits in the Quarter. "Japan Profits" for this Paragraph (ii) shall mean Bayer Market Net Sales in the Quarter less the sum of COGS applicable to Bayer Market Net Sales and Shared Promotion Expenses incurred by BYL (and Regeneron, if any) in Japan in the Quarter.

II. REGENERON REIMBURSEMENT AMOUNT

The "Regeneron Reimbursement Amount" for a Quarter shall mean (a) Shared Promotion Expenses incurred by Regeneron in the Quarter (if any), plus (b) Commercial Supply Costs incurred by Regeneron in the Quarter (if any), plus (c) Development Costs incurred by Regeneron under the Territory Development Plan in the Quarter (if any).

An example of a calculation of the Regeneron Reimbursement Amount in a Quarter would be:

Regeneron Shared Promotion Expenses	50
Regeneron Commercial Supply Costs	10
Regeneron Development Costs under Territory Development Plan	5
Regeneron Reimbursement Amount	65

III. GLOBAL TRUE-UP

The "Global True-Up" for a Quarter shall mean (a) fifty percent (50%) of the sum of (i) aggregate Development Costs incurred by both Parties under the Global Development Plan in the Quarter and (ii) aggregate Other Shared Expenses incurred by both Parties in the Quarter, minus (b) one hundred percent (100%) of the sum of (i) Development Costs incurred by Company under the Global Development Plan in the Quarter and (ii) Other Shared Expenses incurred by Company during the Quarter. If the Global True-Up is a positive number, it shall be added in the calculation of the Quarterly True-Up and, if it is a negative number, the absolute value of such amount shall be subtracted in the calculation of the Quarterly True-Up.

An example of a calculation of the Global True-Up in a Quarter would be:

	Aggregate	Company	Regeneron	Global True-Up
Development Costs under Global Development Plan	80	30	50	
Other Shared Expenses	40	35	5	
Total	120	65	55	(5)

IV. GLOBAL DEVELOPMENT BALANCE PAYMENT

The "Global Development Balance" for a Quarter shall mean (a) twenty-five percent (25%) of the aggregate amount of Development Costs incurred by both Parties under the Global Development Plan from January 1, 2007 through the close of such Quarter ([****]), plus (b) fifty percent (50%) of the aggregate amount of Development Costs incurred by both Parties under the Territory Development Plan from the Effective Date through the close of such Quarter ([****]), less (c) the aggregate amount of Global Development Balance Payments included in the calculation of the Quarterly True-Up in all prior Quarters. On the date of the First Commercial Sale in Japan, if the Japan Purchase Price Adjustment mechanism is applicable, the Global Development Balance shall never include Pre-Launch Marketing Expenses relating to Japan.

The "Global Development Balance Payment" shall mean, [****]

An example of a calculation of the Global Development Balance Payment in a Quarter would be:

Territory Profit Split	400
Global Development Balance	200
[****]	[****]
Global Development Balance Repayment	[****]

V. EXAMPLE OF QUARTERLY TRUE-UP

An example of a calculation of the Quarterly True-up in a Quarter would be:

Territory Profit Split	400
Regeneron Reimbursement Amount	65
Global True-Up	(5)
[****]	[****]
Quarterly True-Up	[****]

In this example, Company would pay Regeneron [****] in accordance with the terms set forth in Article 9.

SCHEDULE 2A

Assumed [****] by Year in Yen

Year	Assumed [****]
2012	[****]
2013	[****]
2014	[****]
2015	[****]
2016	[****]
2017	[****]
2018	[****]
2019	[****]
2020	[****]
2021	[****]
2022	[****]
2023	[****]
2024	[****]
2025	[****]
2026 and thereafter	[****]

REGENERON
SCIENCE TO MEDICINE

POLICY NAME:

230 Securities Investments

Effective Date: 01/14/01
Revised Date: 01/24/25
Contact: *@REGENERON.COM**

PURPOSE

Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") and its directors, officers, and employees and certain other related persons are subject to "insider trading" laws. These laws prohibit individuals with material non-public information about a company from buying or selling securities of that company or from giving such information ("tipping") to another person. These laws also require companies and supervisory personnel to affirmatively supervise the actions of employees to ensure compliance. It is also Regeneron's policy to comply with applicable securities laws concerning trading in Company Securities (as defined below) on Regeneron's behalf.

To assure Regeneron and its directors, officers, and employees and certain other related persons are attentive to these laws and to promote compliance with these laws, as well as to maintain the integrity and reputation of both the Company and such individuals, Regeneron has adopted the following policy.

SCOPE

This policy applies to all employees of Regeneron.

POLICY

1. General Policy and Prohibitions

No director, officer, or employee of the Company or any of its subsidiaries who is aware of material non-public information relating to the Company may, directly or indirectly through other persons or entities, (i) buy or sell Company Securities, except as expressly permitted under this policy, (ii) give, communicate, or in any way convey such information on a non-confidential basis to another person outside the Company (including, but not limited to, family, friends, business associates, investors, and expert consulting firms), (iii) recommend the purchase or sale of any Company Securities, or (iv) assist anyone engaged in the foregoing activities. Regeneron's policy also is to comply with applicable securities laws concerning trading in Company Securities on Regeneron's behalf.

The Company may also determine that other persons should be subject to this policy, such as contractors or consultants who have access to material non-public information. All of the persons referred to in the preceding two sentences of this paragraph are collectively referred to in this policy as "Company Personnel."

Except as specifically noted in this policy, there are no exceptions to this policy. Transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure), or small transactions, are not exempted from this policy. The securities laws do not recognize any mitigating circumstances, and, in any event, even the appearance of an

improper transaction must be avoided to preserve the Company's reputation for adhering to the highest standards of conduct.

a. Scope of Information

This policy also covers information about any company (i) with which the Company does business, such as the Company's strategic partners, collaborators, distributors, vendors, customers, or suppliers, or (ii) that is involved in a potential transaction or business relationship with the Company (collectively, "Company Partners"). Any material non-public information obtained by Company Personnel which relates to a Company Partner should be treated as Regeneron's information and, accordingly, any such Company Personnel may not trade in that Company Partner's securities until the information becomes public or is no longer material.

b. Persons Covered

This policy applies to all Company Personnel, family members who live in their household (including a spouse, a child, a child away at college, step-children, grandchildren, parents, step-parents, grandparents, siblings, and in-laws), others who live in their household, and any other people or entities that might reasonably be deemed to have a relationship (legal, personal, or otherwise) meriting coverage, such as those whose transactions in Company Securities are directed by a member of Company Personnel (for example, a family trust of which such member is trustee) or are subject to such member's influence or control (collectively, the "Covered Persons").

c. Securities Subject to the Policy

This policy applies to transactions in the Company's securities, including without limitation the Company's common stock, Class A stock, options to purchase common stock, or any other type of securities that the Company issued or may issue from time to time, whether equity or debt securities and whether derivative or non-derivative and convertible or non-convertible, including (but not limited to) preferred stock, bonds, notes, debentures, and warrants, as well as derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to any securities of the Company. The securities referred to in the immediately preceding sentence are collectively referred to in this policy as "Company Securities."

d. Individual Responsibility

Company Personnel and their respective Covered Persons have ethical and legal obligations to maintain the confidentiality of information about the Company and other information as provided in this policy and other Company policies and not to engage in transactions in Company Securities while aware of material non-public information relating to the Company. Each member of Company Personnel is responsible for making sure that he or she complies with this policy and any Covered Person of such member also complies with this policy, including by making any such Covered Person aware of the need to confer with such member before trading in Company Securities. Each member of Company Personnel should treat all transactions by his or her Covered Persons covered by this policy for the purposes of this policy and applicable securities laws as if the transactions were for such member's own account. In all cases, the responsibility for determining whether an individual is aware of material non-public information rests with that individual, and any action on the part of the Company, the General Counsel (as defined below), or any other employee or director pursuant to this policy (or otherwise)

does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by the Company for any conduct prohibited by this policy or applicable securities laws, as described below in more detail in paragraph 7 and under the heading "Legal Consequences."

e. Administration of this Policy

As used in this policy, "General Counsel" means the General Counsel of the Company or his or her designee, if any. The General Counsel shall be responsible for administration of this policy, and all determinations and interpretations by the General Counsel under this policy shall be final and not subject to further review.

f. What is Material Information?

The term "material information" should be construed broadly. Information is considered "material" if a reasonable investor would consider that information important in making a decision to buy, hold, or sell securities. Any information that could be expected to affect the price of Company Securities, whether it is positive or negative, should be considered material. There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by enforcement authorities with the benefit of hindsight. While it is not possible to define all categories of material information, some examples of information that ordinarily would be regarded as material are:

i. projections of future earnings or losses, or other guidance (including, without limitation, projections or other guidance relating to product sales; research and development expenses; selling, general, and administrative expenses; capital expenditures; and income tax obligations), or changes thereof;

ii. news of a pending or proposed merger, acquisition, or tender offer;

iii. news of a significant new business transaction or license agreement;

iv. significant regulatory developments or product approvals;

v. a declaration of a stock split or the offering of additional Company Securities;

vi. a change in management;

vii. bank borrowings or other financing transactions out of the ordinary course;

viii. a significant cybersecurity incident;

ix. significant new clinical results or discoveries;

x. significant litigation or litigation developments; and

xi. significant new contracts or loss of business.

Developments in the Company's laboratories, clinical studies, the work of the Company's partners and collaborators, and other scientific developments are examples of potential material inside information. Information as to the success, failure, or even the unchanging status of particular aspects of the Company's business can be considered material.

g. When is Information Deemed Public?

Company Personnel may trade only when they are certain that official announcements of material information have been sufficiently publicized so the public has had the opportunity to evaluate the information and to absorb it. Company Personnel may not attempt to "beat the market" by trading simultaneously with, or shortly after, the official release of material information. Insider trading is not made permissible merely because material information is reflected by rumors or other unofficial statements in the marketplace. Information would likely not be considered widely disseminated if it is available only to the Company's employees, or if it is only available to a select group of analysts, brokers, and institutional investors. Company Personnel should presume that information is non-public unless they can point to the official release of that information by the Company in at least one of the following ways: (i) publicly available filings with the Securities and Exchange Commission (the "SEC"); (ii) issuance of press releases via a major newswire; or (iii) the Company's media and investor relations website. As a general rule, Company Personnel should not engage in any transactions until 24 hours after an announcement is publicly released, but in any event no earlier than the next business day following the date of such public release. Depending on the particular circumstances, the Company may determine that a longer or shorter period should apply to the release of specific non-public information.

h. Prohibition of "Tipping"

Great care must be given to ensure that only approved non-public information is passed to persons outside the Company. Company Personnel have already signed confidentiality agreements. However, every practicable step to preserve the confidentiality of Company information must be affirmatively taken by all Company Personnel. For example:

i. Don't discuss new developments in elevators, hallways, restaurants, airplanes, taxicabs, or any other place where you can be overheard.

ii. Don't gossip.

iii. Don't read documents containing non-public information in public places or discard them where they can be retrieved by others.

iv. Don't carry documents with non-public information in elevators, hallways, etc., in an exposed manner.

v. Beware of conducting sensitive conversations on speaker telephones in offices or on cellular phones in public, etc.

vi. Cover confidential documents on your desk before you leave your room; don't leave confidential papers lying where visitors can see them.

vii. Under no circumstances are Company Personnel to copy Regeneron documents for their personal use without express consent of a supervising employee. This includes but is not limited to any documents relating to any of our partners or collaborators.

i. 10b5-1 Trading Plans

Notwithstanding the "General Prohibitions" in this paragraph 1 and the specific pre-clearance procedures set forth in paragraph 5, Company Personnel may, under the limited circumstances discussed below, establish written, predetermined trading programs ("Rule 10b5-1 Trading Plans") that meet the requirements of Rule 10b5-1(c) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Rule 10b5-1 provides for (i) scheduled trading of Company Securities based on predefined agreements, instructions or plans, or (ii) trading of Company Securities by an independent entity (such as a brokerage firm) when the individual making the investment decision is not aware of material nonpublic information regarding the Company and Company Securities, and the entity has implemented reasonable policies and procedures to prevent insider trading. Trading pursuant to a Rule 10b5-1 Trading Plan may occur even when the applicable Company Person is aware of material non-public information***. Each Rule 10b5-1 Trading Plan must be reviewed and pre-approved by the General Counsel on behalf of the Company prior to its effectiveness***. Refer to the Company's Rule 10b5-1 Trading Plan Guidelines attached as Exhibit A to this policy for specific requirements for Rule 10b5-1 Trading Plans.

Rule 10b5-1 Trading Plans generally must be established at a time when the applicable Company Personnel member is not aware of material non-public information. The Rule 10b5-1 Trading Plan documentation must specify, among other things, the amount of Company Securities to be purchased or sold, the price at which the transaction is to take place, and the date on which each transaction is to be performed. Alternatively, the Rule 10b5-1 Trading Plan may establish an objective formula for any or all of these criteria. A Rule 10b5-1 Trading Plan may also be structured to give complete discretion to a third party to control how, when, or whether to effect purchases or sales, provided that the person effecting the transactions is not aware of any material non-public information when effectuating any purchases or sales.

Once a Rule 10b5-1 Trading Plan is prepared and becomes effective, it cannot be changed or deviated from except in extremely limited circumstances and (i) with notice to and pre-approval from the General Counsel, and (ii) only at a time when the applicable Company Personnel member is not aware of material non-public information. In addition, Company Personnel may not engage in any separate transactions that directly or indirectly alter or offset the authorized transactions under a Rule 10b5-1 Trading Plan (such as a hedging transaction). At the discretion of the Company, the existence and/or the terms of a Rule 10b5-1 Trading Plan may be disclosed to the public through a press release, a filing with the SEC, or through other means to be determined by the Company. Directors and designated officers of the Company subject to Section 16 of the Exchange Act (collectively, "Section 16 Insiders") should be aware that the Company will be required to make quarterly disclosures regarding all Rule 10b5-1 Trading Plans entered into, amended, or terminated by Section 16 Insiders and the material terms of such plans, other than pricing information.

Note that the Company's acceptance of a Rule 10b5-1 Trading Plan does **NOT** mean the plan meets the requirements of Rule 10b5-1. The Company has no obligation to monitor your trading activities (whether to ensure you are complying with your Rule 10b5-1 Trading Plan or otherwise); however, the Company reserves the right to halt any

transaction that fails to meet the terms of the applicable Rule 10b5-1 Trading Plan or this policy.

2. Additional Prohibited and Certain Specific Transactions

The Company has determined there is a heightened legal risk and/or the appearance of improper or inappropriate conduct if the persons subject to this policy engage in certain types of transactions. Therefore, it is the Company's policy that any Company Personnel and their respective Covered Persons may not engage in any of the following transactions or must otherwise comply with the requirements described below:

a. Short Sales

Short sales of Company Securities (i.e., the sale of a security that the seller does not own) may evidence an expectation on the part of the seller that the securities will decline in value, and, therefore, have the potential to signal to the market the seller lacks confidence in the Company's prospects. In addition, short sales may reduce a seller's incentive to seek to improve the Company's performance.

For these reasons, short sales of Company Securities are prohibited. In addition, Section 16(c) of the Exchange Act prohibits officers and directors from engaging in short sales. (Short sales arising from certain types of hedging transactions are governed by the paragraph below captioned "Hedging Transactions.")

b. Publicly Traded Options

Transactions in options relating to Company Securities may create the appearance that a member of Company Personnel is trading based on material non-public information or focuses his or her attention on short-term performance at the expense of the Company's long-term objectives. Accordingly, transactions in put options, call options, or other similar derivative securities relating to Company Securities, on an exchange or in any other organized market, are prohibited by this policy. (Option positions arising from certain types of hedging transactions are governed by the next paragraph below.)

c. Hedging Transactions

Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars, and exchange funds. Such hedging transactions may permit Company Personnel to continue to own Company Securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, Company Personnel may no longer have the same objectives as the Company's other shareholders. Therefore, Company Personnel and their respective Covered Persons are prohibited from engaging in any such transactions.

d. Margin Accounts and Pledged Securities

Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material non-public information or otherwise is not permitted to trade in Company Securities, Company Personnel and their respective

Covered Persons are prohibited from holding Company Securities in a margin account or otherwise pledging Company Securities as collateral for a loan.

e. Standing and Limit Orders

Standing and limit orders (except standing and limit orders under approved Rule 10b5-1 Trading Plans, as described above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and, as a result, the broker could execute a transaction when a director, officer or other employee is aware of material non-public information. If a member of Company Personnel determines that he or she must use a standing order or limit order, the order should be limited to short duration and must otherwise comply with the general prohibitions set forth in paragraph 1 above, as well as the restrictions and procedures outlined in paragraph 5 below (if applicable).

3. Special Provisions for Lectures and Publications

Any scientist, researcher, or other Regeneron employee who intends or plans to (i) speak or otherwise actively participate in any seminar, lecture, or other public function, (ii) publish, circulate, or otherwise distribute any article, research memorandum, or other piece of research writing (except for internal distributions within Regeneron), (iii) in any way disseminate any other material information, pertaining to Regeneron or to scientific developments with which Regeneron is involved, must, prior to engaging in such activity, consult with the General Counsel in order to determine the repercussions of such engagement upon the Company's policy as set forth herein, and take such actions prior to such engagement as the General Counsel may deem appropriate. This requirement is consistent with the Regeneron employment agreement and Regeneron's protection of intellectual property rights.

4. Transactions Not Subject to Policy

This policy does not apply in the case of the following transactions, except as specifically noted:

a. *Bona Fide* Gifts of Company Securities Not Treated as Charitable Deductions

Bona fide gifts of Company Securities made in good faith for which the donor is not claiming a charitable deduction are not subject to this policy.

b. Stock Option Exercises

This policy does not apply to the exercise of an employee stock option acquired pursuant to the Company's plans to the extent the exercise is done in a manner where there is no market transaction and no transaction with a third party, nor does it apply to the exercise of a tax withholding right pursuant to which a person has elected to have the Company withhold shares subject to an option to satisfy tax withholding requirements. The payments in respect of the exercise price or tax withholding obligations can be made by cash, option shares, or tendered shares via "attestation" or actual share delivery. If you use attestation, you will not have to deliver physical Company Securities to the Company. Rather, you will provide the Company with evidence that you own and have held for at least six (6) months a number of Company Securities with a dollar value at least equal to the exercise price and/or the taxes. This policy does apply, however, to any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

c. Restricted Stock Awards

This policy does not apply to the exercise of a tax withholding right pursuant to which you elect to have the Company withhold Company Securities to satisfy tax withholding requirements upon the vesting of any restricted stock. The payments in respect of the tax withholding obligations can be made by cash or tendered shares via "attestation" or actual share delivery. If you use attestation, you will not have to deliver physical Company Securities to the Company. Rather, you will provide the Company with evidence that you own and have held for at least six (6) months a number of Company Securities with a dollar value at least equal to the taxes. This policy does apply, however, to any market sale of restricted stock. For the avoidance of doubt, this policy does not apply to the vesting of restricted stock.

d. 401(k) Plan

This policy does not apply to your acquisition of Company Securities in the Company's 401(k) savings plan resulting from any annual or quarterly matching contribution in Company Securities made by the Company in its discretion. The Company's 401(k) savings plan does not provide for an allocation of a portion of your period contributions to a Company stock fund, nor does it allow a liquidation of some or all of your Company stock fund balance in the case of a loan against your 401(k) savings plan balance or a pre-payment of your plan loan balance resulting in an allocation of loan proceeds to the Company stock fund. This policy does apply, however, to an election to make an intra-plan transfer of an existing account balance into or out of the Company stock fund or any market sale of Company Securities out of a 401(k) savings plan balance, other than an automatic minimum annual distribution made in accordance with relevant tax rules and regulations initiated by a third party not controlled by or influenced by Company Personnel or their respective Covered Persons.

e. Other Similar Transactions and Other Company Plans

Except as may be determined by the General Counsel, any other purchase of Company Securities from the Company or sales of Company Securities to the Company are not subject to this policy. In addition, this policy does not apply to any conversion of the Company's Class A stock (whether optional or mandatory) into common stock (however, this policy does apply to any sale of the common stock issued upon such conversion). In addition, this policy applies to the conversion of other Company Securities (such as convertible notes), other than employee stock options acquired pursuant to the Company's plans as described in paragraph 4.b above. To the extent the Company in the future adopts an employee stock purchase plan, a dividend reinvestment plan, or other similar plan, this policy will be amended to address such plan or plans and transactions and elections thereunder. In the absence of such an amendment, the General Counsel may, consistent with the principles set forth in this policy, address such issues in a written supplement to this policy, which shall be binding on Company Personnel and their respective Covered Persons.

5. Trading Window and Pre-Clearance Procedures

a. Additional Procedures Applicable to Designated Persons

Except for permitted transactions under Rule 10b5-1 Trading Plans, Section 16 Insiders, other designated officers of the Company, and other designated Company Personnel (together with their respective Covered Persons) (collectively, the "Designated Persons")

may (i) buy or sell Company Securities in the market or (ii) make a gift of Company Securities treated as a charitable deduction only (A) outside of a Blackout Period (as defined below) and (B) after obtaining prior approval ("Pre-Clearance") from the General Counsel. The restrictions set forth in this paragraph 5 are in addition to the "General Prohibitions" in paragraph 1.

b. Pre-Clearance Procedures

Pre-Clearance shall be documented in a completed Transaction Authorization Form countersigned by the General Counsel, which shall be submitted to the General Counsel at least two business days in advance of the proposed transaction. The General Counsel is under no obligation to approve a transaction submitted for Pre-Clearance, and may determine not to permit the transaction. If a Designated Person seeks Pre-Clearance and permission to engage in the transaction is denied, then he or she should refrain from initiating any transaction in Company Securities, and should not inform any other person of the restriction. When a request for Pre-Clearance is made, the requestor should carefully consider whether he or she may be aware of any material non-public information about the Company, and should describe fully those circumstances to the General Counsel. The requestor who is a Section 16 Insider should also indicate whether he or she has effected any non-exempt "opposite-way" transactions within the past six months, and should be prepared to report the proposed transaction on an appropriate Form 4 or Form 5. The requestor who is a Section 16 Insider should also be prepared to comply with Rule 144 under the Securities Act of 1933, as amended, and file Form 144, if necessary, at the time of any sale. Any transaction for which Pre-Clearance has been obtained must be effected within the number of days indicated in the Transaction Authorization Form (not to exceed five business days from the receipt of Pre-Clearance unless an extension or exception is granted by the General Counsel). Transactions not effected within this time frame are subject to new Pre-Clearance. If a request for Pre-Clearance is denied, the fact of such denial must be kept confidential by the person requesting such clearance.

c. Quarterly and Event-Specific Trading Restrictions

Designated Persons may not conduct any transactions involving Company Securities (other than as specified by this policy) during a "Blackout Period." As used in this policy, "Blackout Period" means (i) the period that generally begins on the first business day of the third month in the Company's fiscal quarter and ends at the start of market hours of the NASDAQ Stock Market regular trading session on the business day following the date on which the Company holds its quarterly conference call for investors and others (but, unless otherwise determined by the General Counsel, in any event no earlier than 24 hours after such call) (the "Quarterly Blackout Period") and (ii) an event-specific trading restriction period, as determined by the General Counsel (the "Event-Specific Blackout Period"). From time to time, an event may occur that is material to the Company and is known by only a few directors, officers, and/or employees. So long as the event remains material and non-public, the Designated Persons may not trade Company Securities. In addition, the Company's financial results may be sufficiently material in a particular fiscal quarter that, in the judgment of the General Counsel, the Designated Persons should refrain from trading in Company Securities even sooner than the typical Quarterly Blackout Period described above. In that situation, the General Counsel may notify the Designated Persons (or a subset thereof) that they should not trade in Company Securities, without disclosing the reason for the restriction. The existence of the Event-Specific Blackout Period or extension of a Quarterly Blackout Period will not be

announced to the Company as a whole, and should not be communicated to any other person. Even if you are not a Designated Person, you should not trade while aware of material non-public information. Exceptions will not be granted during any Blackout Period.

d. Permissible Stock-for-Stock (Net) Option Exercise and Class A Stock Conversion by Designated Persons During Blackout Period

Designated Persons engaging in a permissible stock-for-stock option exercise described in paragraph 4.b above may not sell, pledge, or otherwise engage in any transactions with respect to the Company Securities they obtain upon the exercise (or any other Company Securities they hold) until the Blackout Period has ended and Pre-Clearance for the transaction has been obtained. Similarly, Designated Persons converting any shares of Class A stock into shares of common stock as permitted under paragraph 4.e above may not sell, pledge, or otherwise engage in any transactions with respect to common stock issued upon such conversion (or any other Company Securities they hold) until the Blackout Period has ended and Pre-Clearance for the transaction has been obtained.

6. Post-Termination Transactions

If an individual is aware of material non-public information when his or her service terminates, that individual may not trade in Company Securities until that information has become public or is no longer material. In addition, although the Pre-Clearance procedures under paragraph 5.b above will cease to apply upon termination of service, individuals subject to a Blackout Period at the time of termination may not trade in Company Securities until such Blackout Period has ended.

7. Company Sanctions

In addition to the legal consequences associated with violations of "insider trading" laws (described below), Company Personnel who fail to comply with the policy as set forth in this statement of policy can be subjected to sanctions imposed directly by the Company, including dismissal for cause.

Legal Consequences

The consequences of violating insider trading laws are severe for both employees and companies. Individuals who trade on inside information or who "tip" information to others can face a civil penalty of up to three times the profit gained or loss avoided, a criminal fine (no matter how small the profit) of up to $5,000,000, and a jail term of up to 20 years. A company (as well as supervisory personnel) that fail to take appropriate steps to prevent illegal trading is subject to a civil penalty of the greater of $2,600,000 or three times the profit gained or loss avoided as a result of an employee's violation and a criminal penalty of up to $25,000,000. Even if an investigation by the SEC does not result in criminal or civil sanctions, the investigation itself can tarnish a person's or a company's reputation and irreparably damage a person's career.

FURTHER INFORMATION

Questions concerning this policy should be directed to the General Counsel.

Exhibit A

Regeneron Pharmaceuticals, Inc.

Rule 10b5-1 Trading Plan Guidelines

The following guidelines apply to all written trading plans ("Rule 10b5-1 Trading Plans") involving securities of Regeneron Pharmaceuticals, Inc. (the "Company") under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Capitalized terms not defined in these guidelines have the respective meanings given to such terms in the Insider Trading Policy (as defined below).

1. **Prior Approval.** All individuals subject to the Company's Policy 230, *Securities Investments* (the "Insider Trading Policy") (all such individuals, collectively, "Company Personnel") who wish to enter into a Rule 10b5-1 Trading Plan must comply in all respects with the Insider Trading Policy and applicable law and submit the Rule 10b5-1 Trading Plan to the General Counsel for advance approval (generally at least five business days prior to the planned entry into the Rule 10b5-1 Trading Plan). In addition, prior submission to the General Counsel is required for any amendment or early termination of an effective Rule 10b5-1 Trading Plan.

2. **Entry into a Plan.** A member of Company Personnel may enter into a Rule 10b5-1 Trading Plan only at a time when he or she is not aware of material non-public information regarding the Company or its securities and when a Blackout Period is not in effect with respect to such member under the Insider Trading Policy. Each Rule 10b5-1 Trading Plan must include a representation that, as of the date of adoption of such Rule 10b5-1 Trading Plan, the member of Company Personnel who wishes to enter into such Rule 10b5-1 Trading Plan is not aware of any material non-public information about the Company or its securities, and that the Rule 10b5-1 Trading Plan is being adopted in good faith and not as a part of a plan or scheme to evade the prohibitions of Rule 10b5-1.

3. **Waiting Period.** The waiting periods from the time a Rule 10b5-1 Trading Plan is adopted until the time of the first trade under the Rule 10b5-1 Trading Plan must comply with requirements of Rule 10b5-1. Specifically, Rule 10b5-1 Trading Plans established by directors and officers subject to Section 16 of the Exchange Act (collectively, "Section 16 Insiders") must include a waiting period consisting of the later of (i) 90 days after the adoption of the Rule 10b5-1 Trading Plan, or (ii) the period ending two business days following the disclosure of the Company's financial results in a Form 10-Q or Form 10-K for the completed fiscal quarter in which the Rule 10b5-1 Trading Plan was adopted (but in any event, this waiting period is subject to a maximum of 120 days after adoption of the Rule 10b5-1 Trading Plan). For all other individuals, the waiting period must be at least 30 days from adoption of the Rule 10b5-1 Trading Plan. For the avoidance of doubt, subject to further guidance from the SEC, Section 16 Insiders may not begin the first trade under a Rule 10b5-1 Trading Plan until the later of the 91st day from adoption of the Rule 10b5-1 Trading Plan or the third business day after the Company's filing of the applicable Form 10-Q or Form 10-K (but in any event no later than the 121st day from adoption of the Rule 10b5-1 Trading Plan), and individuals other than Section 16 Insiders may not begin the first trade until the 31st day from adoption of the Rule 10b5-1 Trading Plan.

4. **Multiple Plans.** Generally speaking, a member of Company Personnel entering into a Rule 10b5-1 Trading Plan may have only one Rule 10b5-1 Trading Plan in place at any time. An exception to this restriction applies for certain separate Rule 10b5-1 Trading Plans with different brokers that would be treated as a single "plan" such as

when a person holds Company securities in multiple brokerage accounts. Additionally, a member of Company Personnel may enter into one later-commencing Rule 10b5-1 Trading Plan so that the waiting period of the later plan can begin to run while an existing Rule 10b5-1 Trading Plan is in place, provided that the individual does not early terminate the first Rule 10b5-1 Trading Plan, in which case a full waiting period from the time of such termination must occur. Finally, Company Personnel may have an additional Rule 10b5-1 Trading Plan providing only for eligible sell-to-cover transactions, where the plan provides for sales of securities as are necessary to satisfy tax withholding obligations arising exclusively from the vesting of a compensatory stock award.

5. **Single Transaction.** Rule 10b5-1 prohibits more than one Rule 10b5-1 Trading Plan in any 12-month period that is designed to effect a single transaction. Single transaction Rule 10b5-1 Trading Plans are generally discouraged.

6. **Amendments.** Amendments to Rule 10b5-1 Trading Plans will be permitted only at a time when: (i) the member of Company Personnel is not aware of material non-public information regarding the Company or its securities and (ii) a Blackout Period is not in effect with respect to such member under the Insider Trading Policy. Furthermore, any amendment relating to the amount, price, or timing of the purchase or sale of securities will be subject to the same waiting periods as would be applicable to a new Rule 10b5-1 Trading Plan, as described above.

7. **Termination.** A Rule 10b5-1 Trading Plan may be terminated upon notification to the General Counsel at a time when the member of Company Personnel is not aware of material non-public information regarding the Company or its securities and a Blackout Period is not in effect with respect to such member under the Insider Trading Policy. However, terminating a Rule 10b5-1 Trading Plan is strongly discouraged because it may call into question whether the plan was entered into in good faith and not as part of a plan or scheme to evade the insider trading rules, which could affect the availability of the Rule 10b5-1 affirmative defense.

8. **Outside Trades.** Adoption of a Rule 10b5-1 Trading Plan does not preclude trading outside the Rule 10b5-1 Trading Plan that otherwise is in accordance with the Insider Trading Policy. However, Company Personnel should be cognizant of the fact that the Rule 10b5-1 affirmative defense will not apply to such trades outside a Rule 10b5-1 Trading Plan. In addition, under Rule 10b5-1, Company Personnel may not have further influence over whether, when, or how the trades under the Rule 10b5-1 Trading Plan are made once the Rule 10b5-1 Trading Plan is put in place, and, therefore, their trading outside the Rule 10b5-1 Trading Plan must not have direct or indirect influence on the trading instructions under the Rule 10b5-1 Trading Plan.

9. **Section 16.** Each Section 16 Insider understands that the approval or adoption of a Rule 10b5-1 Trading Plan in no way reduces or eliminates such Section 16 Insider's obligations under Section 16 of the Exchange Act, including such Section 16 Insider's disclosure and potential short-swing trading liabilities thereunder. If any questions arise, such Section 16 Insider should consult with his or her own counsel in implementing a Rule 10b5-1 Trading Plan. In addition, each Section 16 Insider must agree to cooperate with the Company in any reporting of the Rule 10b5-1 Trading Plan in the Company's SEC filings.

Exhibit 21.1

SUBSIDIARIES OF REGENERON PHARMACEUTICALS, INC.

Except as otherwise noted, each of the entities listed below is directly or indirectly wholly owned by Regeneron Pharmaceuticals, Inc.

Name of Subsidiary	**State or Other Jurisdiction of Incorporation or Organization**
Checkmate Pharmaceuticals, Inc.	Delaware
Decibel Therapeutics, Inc.	Delaware
Eastside Campus Holdings LLC	New York
Loop Road Holdings LLC	New York
Old Saw Mill Holdings LLC	New York
OSMR Holdings	Bermuda
Oxular Acquisitions Limited	United Kingdom
Oxular Inc.	Delaware
Oxular Limited	United Kingdom
Regeneron Assurance, Inc.	New York
Regeneron Atlantic Holdings	Bermuda
Regeneron Austria GmbH	Austria
Regeneron Belgium SRL	Belgium
Regeneron Canada Company	Canada
Regeneron France SAS	France
Regeneron Genetics Center LLC	Delaware
Regeneron GmbH	Germany
Regeneron Healthcare Solutions, Inc.	New York
Regeneron India Private Limited	India
Regeneron International Holdings LLC	Delaware
Regeneron Ireland Designated Activity Company	Ireland
Regeneron Italy S.r.l.	Italy
Regeneron Japan KK	Japan
Regeneron NL B.V.	The Netherlands
Regeneron Spain, S.L.U.	Spain
Regeneron Switzerland GmbH	Switzerland
Regeneron UK Limited	United Kingdom
Regeneron Ventures, L.P.*	Delaware
Rock County Holdings LLC	New York
Rockwood Road Holdings LLC	New York
RV Holding Corp.	Delaware

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* The sole limited partner of Regeneron Ventures, L.P. is RV Holding Corp., which is wholly owned by Regeneron Pharmaceuticals, Inc. The general partner of Regeneron Ventures, L.P. is a third-party investment manager.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-282927) and Form S-8 (Nos. 333-198794, 333-218669, and 333-239209) of Regeneron Pharmaceuticals, Inc. of our report dated February 5, 2025 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 5, 2025

Exhibit 31.1

Certification of Principal Executive Officer Pursuant to
Rule 13a-14(a) under the Securities Exchange Act
of 1934, as Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 5, 2025

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Christopher Fenimore, certify that:

1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 5, 2025

/s/ Christopher Fenimore

Christopher Fenimore

Executive Vice President, Finance and Chief Financial Officer

(Principal Financial Officer)

Exhibit 32

Certification of Principal Executive Officer and Principal Financial Officer Pursuant to
18 U.S.C. Section 1350,
As Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Principal Executive Officer of the Company, and Christopher Fenimore, as Principal Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.

President and Chief Executive Officer

(Principal Executive Officer)

February 5, 2025

/s/ Christopher Fenimore

Christopher Fenimore

Executive Vice President, Finance and Chief Financial Officer

(Principal Financial Officer)

February 5, 2025