

ANNUAL REPORT

2023



REGENERON[®]

REGENERON BY THE NUMBERS

12

medicines approved in the United States and/or other countries

~35

product candidates in clinical development

6

genetics medicines programs in the clinic

~50

countries with clinical trials

1M+

eligible patients received support from our patient support programs in 2023

~2.3M

exomes sequenced by Regeneron Genetics Center® since its founding

13.4K+

Regeneron colleagues worldwide at year end

23K+

hours of employee community service through our annual *Day for Doing Good* in 2023

~2.4M

students supported by Regeneron STEM initiatives since 2020

FORM 10-K

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, 2023

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:

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
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 \$76.7 billion, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2023, 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 25, 2024:

Class of Common Stock	Number of Shares
Class A Stock, \$.001 par value	1,818,146
Common Stock, \$.001 par value	107,943,750

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2024 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 92 to 96 of this filing.

REGENERON PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
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"Altibodies[™]," "ARCALYST[®]," "Evkeeza[®]," "EYLEA[®]," "EYLEA[®] HD," "Inmazole[®]," "Libtayo[®]," "Praluent[®]" (in the United States), "REGEN-COV[®]," "Regeneron[®]," "Regeneron Genetics Center[®]," "RGC[®]," "Veloci-Bi[®]," "VelociGene[®]," "VelociHum[®]," "VelociMab[®]," "VelociImmune[®]," "VelociMouse[®]," "VelociSuite[®]," "VelociT[®]," "Veopoz[™]," and "ZALTRAP[®]" are trademarks of Regeneron Pharmaceuticals, Inc. Trademarks and trade names of other companies appearing in this report are, to the knowledge of Regeneron Pharmaceuticals, Inc., the property of their respective owners. This report refers to products of Regeneron Pharmaceuticals, Inc., its collaborators, and other parties. Consult the product label in each territory for specific information about such products.

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 our late-stage 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;*
- uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) or recommendations and guidelines from governmental authorities and other third parties on the commercial success of Regeneron's Products and Regeneron's Product Candidates;*
- our ability to manufacture and manage supply chains for multiple products and product candidates;*
- the ability of our collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates;*
- the availability and extent of reimbursement of Regeneron's Products from third-party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid;*
- coverage and reimbursement determinations by such payors and new policies and procedures adopted by such payors;*
- unanticipated expenses;*
- the costs of developing, producing, and selling products; our ability to meet any of our financial projections or guidance, including without limitation capital expenditures, and changes to the assumptions underlying those projections or guidance;*
- the potential for any license or collaboration agreement, including our agreements with Sanofi and Bayer (or their respective affiliated companies, as applicable), to be cancelled or terminated;*
- the impact of public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) on our business; and*
- risks associated with intellectual property of other parties and pending or future litigation relating thereto (including without limitation the patent litigation and other related proceedings described further in Note 16 to our Consolidated Financial Statements included in this report), other litigation and other proceedings and government investigations relating to the Company and/or its operations (including without limitation those described in Note 16 to our Consolidated Financial Statements included in this report), the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on our business, prospects, operating results, and financial condition.*

These statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any such statements. In evaluating such statements, shareholders and potential investors should specifically consider the various

factors identified under Part I, Item 1A. "Risk Factors," which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update (publicly or otherwise) any forward-looking statement, whether as a result of new information, future events, or otherwise.

General

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

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, and to build on that foundation with our clinical development, manufacturing, and commercial capabilities. Our objective is to continue to 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:

<i>(In millions, except per share data)</i>	Year Ended December 31,		
	2023	2022	2021
Revenues	\$13,117.2	\$12,172.9	\$16,071.7
Net income	\$ 3,953.6	\$ 4,338.4	\$ 8,075.3
Net income per share - diluted	\$ 34.77	\$ 38.22	\$ 71.97

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

Products

Products that have received marketing approval are summarized in the table below. Certain products have also received marketing approval in countries outside the United States, European Union ("EU"), or Japan.

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

Product (continued)	Disease	Territory		
		U.S.	EU	Japan
Dupixent (dupilumab) Injection ^(b) (continued)	Asthma (in pediatrics 6–11 years of age)	✓	✓	
	Chronic rhinosinusitis with nasal polyposis ("CRSwNP")	✓	✓	✓
	Eosinophilic esophagitis ("EoE") (in adults and adolescents)	✓	✓	
	EoE (in pediatrics 1–11 years of age)	✓		
	Prurigo nodularis	✓	✓	✓
Libtayo [®] (cemiplimab) Injection ^(c)	Metastatic or locally advanced first-line non-small cell lung cancer ("NSCLC")	✓	✓	
	Metastatic or locally advanced first-line NSCLC (in combination with chemotherapy)	✓	✓	
	Metastatic or locally advanced basal cell carcinoma ("BCC")	✓	✓	
	Metastatic or locally advanced cutaneous squamous cell carcinoma ("CSCC")	✓	✓	
	Metastatic or recurrent second-line cervical cancer		✓	✓
Praluent [®] (alirocumab) Injection ^(d)	LDL-lowering in heterozygous familial hypercholesterolemia ("HeFH") or clinical atherosclerotic cardiovascular disease ("ASCVD")	✓	✓	
	HeFH in pediatrics and adolescents (8–17 years of age)		✓	
	Cardiovascular risk reduction in patients with established cardiovascular disease	✓	✓	
	Homozygous familial hypercholesterolemia ("HoFH")	✓		
REGEN-COV ^{®(e)}	COVID-19		✓	✓
Kevzara (sarilumab) Injection ^(b)	Rheumatoid arthritis ("RA")	✓	✓	✓
	Polymyalgia rheumatica ("PMR")	✓		
Evkeeza [®] (evinacumab) Injection ^(f)	HoFH (in adults, adolescents, and pediatrics aged 5 years and older)	✓	✓	✓
Inmazed [®] (atoltivimab, maftivimab, and odesivimab) Injection	Infection caused by <i>Zaire ebolavirus</i>	✓		
Veopoz [™] (pozelimab) Injection	CD55-deficient protein-losing enteropathy ("CHAPLE") (in adults, adolescents, and pediatrics aged 1 year and older)	✓		
ARCALYST [®] (rilonacept) Injection ^(g)	Cryopyrin-associated periodic syndromes ("CAPS"), including familial cold auto-inflammatory syndrome ("FCAS") and Muckle-Wells syndrome ("MWS") (in adults and adolescents)	✓		
	Deficiency of interleukin-1 receptor antagonist ("DIRA") (in adults, adolescents, and pediatrics)	✓		
	Recurrent pericarditis (in adults and adolescents)	✓		
ZALTRAP [®] (ziv-aflibercept) Injection for Intravenous Infusion ^(h)	Metastatic colorectal cancer ("mCRC")	✓	✓	✓

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

(a) In collaboration with Bayer outside the United States. 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) In collaboration with Sanofi prior to July 2022. Effective July 2022, the Company is solely responsible for the development, commercialization, and manufacturing of Libtayo. Refer to "Collaboration, License, and Other Agreements" section below for further details.

(d) The Company is solely responsible for the development and commercialization of Praluent in the United States and Sanofi is responsible for the development and commercialization of Praluent outside the United States.

(e) In collaboration with Roche. Product is known as REGEN-COV in the United States and Ronapreve™ in other countries.

(f) 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.

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

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

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

<i>(In millions)</i>	Year Ended December 31,								
	2023			2022			2021		
	U.S.	ROW ^(g)	Total	U.S.	ROW	Total	U.S.	ROW	Total
EYLEA HD ^(a)	\$ 165.8	\$ —	\$ 165.8	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
EYLEA ^(a)	\$ 5,719.6	\$ 3,495.2	\$ 9,214.8	\$ 6,264.6	\$ 3,382.8	\$ 9,647.4	\$ 5,792.3	\$ 3,450.9	\$ 9,243.2
Total EYLEA HD and EYLEA	\$ 5,885.4	\$ 3,495.2	\$ 9,380.6	\$ 6,264.6	\$ 3,382.8	\$ 9,647.4	\$ 5,792.3	\$ 3,450.9	\$ 9,243.2
Dupixent ^(b)	\$ 8,855.6	\$ 2,732.5	\$ 11,588.1	\$ 6,668.0	\$ 2,013.2	\$ 8,681.2	\$ 4,713.0	\$ 1,485.3	\$ 6,198.3
Libtayo ^(c)	\$ 538.8	\$ 330.0	\$ 868.8	\$ 374.5	\$ 203.5	\$ 578.0	\$ 306.3	\$ 151.9	\$ 458.2
Praluent ^(d)	\$ 182.4	\$ 456.5	\$ 638.9	\$ 130.0	\$ 337.4	\$ 467.4	\$ 170.0	\$ 251.1	\$ 421.1
REGEN-COV ^(e)	\$ —	\$ 618.8	\$ 618.8	\$ —	\$ 1,769.6	\$ 1,769.6	\$ 5,828.0	\$ 1,745.9	\$ 7,573.9
Kevzara ^(b)	\$ 214.7	\$ 171.2	\$ 385.9	\$ 199.7	\$ 158.3	\$ 358.0	\$ 161.9	\$ 176.1	\$ 338.0
Other products ^(f)	\$ 150.5	\$ 67.4	\$ 217.9	\$ 56.1	\$ 69.1	\$ 125.2	\$ 25.9	\$ 86.4	\$ 112.3

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

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

(c) Prior to July 1, 2022, Regeneron recorded net product sales of Libtayo in the United States and Sanofi recorded net product sales of Libtayo outside the United States. The parties equally shared profits/losses in connection with global sales of Libtayo. Effective July 1, 2022, the Company began recording net product sales of Libtayo outside the United States and pays Sanofi a royalty on global sales. Refer to "Collaboration, License, and Other Agreements" section below for further details. Included in this line item 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 until inventory on hand as of July 1, 2022 had been sold through to the end customers).

(d) Regeneron records net product sales of Praluent in the United States. Sanofi records net product sales of Praluent outside the United States and pays the Company a royalty on such sales.

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

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

(g) Rest of world ("ROW")

Programs in Clinical Development

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

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

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

Clinical Program	Phase 1	Phase 2	Phase 3	Regulatory Review ^(h)	2023 and 2024 Events to Date	Select Upcoming Milestones
Ophthalmology						
EYLEA HD (aflibercept) 8 mg^(a)			–RVO		<ul style="list-style-type: none"> –Approved by U.S. Food and Drug Administration ("FDA") for wAMD, DME, and DR –Approved by European Commission ("EC") and Japan's Ministry of Health, Labour and Welfare ("MHLW") for wAMD and DME –Reported positive two-year data from Phase 3 studies in wAMD and DME 	–Initiate Phase 3 study in RVO (mid-2024) to enable FDA submission
EYLEA (aflibercept)^(a)					–Approved by FDA for ROP	
Pozelimab^(f) (REGN3918) <i>Antibody to C5</i>						–Initiate Phase 3 study in combination with cemdisiran in geographic atrophy (second half 2024)
Immunology & Inflammation						
Dupixent (dupilumab)^(b) <i>Antibody to IL-4R alpha subunit</i>		<ul style="list-style-type: none"> –Ulcerative colitis –Eosinophilic gastroenteritis (Phase 2/3) 	<ul style="list-style-type: none"> –Chronic obstructive pulmonary disease ("COPD")^(d) –Bullous pemphigoid^(c) –Chronic spontaneous urticaria ("CSU") –Chronic pruritus of unknown origin 	<ul style="list-style-type: none"> –EoE in pediatrics (1–11 years of age) (EU) –COPD with type 2 inflammatory phenotype (U.S. and EU) –CSU in adults and adolescents (Japan) 	<ul style="list-style-type: none"> –Approved by EC for atopic dermatitis in pediatrics (6 months–5 years of age) –Approved by MHLW for atopic dermatitis in pediatrics and adolescents (6 months–14 years of age) –Approved by FDA for EoE in pediatrics (1–11 years of age) –Approved by EC for EoE in adults and adolescents –Approved by MHLW for prurigo nodularis 	<ul style="list-style-type: none"> –EC decision on regulatory submission for EoE in pediatrics (second half 2024) –FDA decision on supplemental Biologics License Application ("sBLA") (mid/second half 2024) and EC decision on regulatory submission (second half 2024) for COPD with type 2 inflammatory phenotype

Clinical Program (continued)	Phase 1	Phase 2	Phase 3	Regulatory Review ^(b)	2023 and 2024 Events to Date	Select Upcoming Milestones
Dupixent (dupilumab)^(b) (continued)					<p>–Reported that Phase 3 BOREAS trial in COPD with evidence of type 2 inflammation met its primary and all key secondary endpoints; presented at 2023 American Thoracic Society International Conference and published in <i>New England Journal of Medicine</i></p> <p>–Reported that results from interim analysis of replicate Phase 3 NOTUS trial in COPD with evidence of type 2 inflammation met its primary endpoint</p> <p>–FDA issued Complete Response Letter ("CRL") for sBLA for CSU due to requirement for additional efficacy data</p> <p>–Phase 3 trial in chronic cold induced urticaria did not meet its required efficacy endpoints</p> <p>–Discontinued further clinical development in allergic fungal rhinosinusitis and chronic rhinosinusitis without nasal polyposis</p>	<p>–MHLW decision on regulatory submission for CSU in adults and adolescents (first half 2024)</p> <p>–Report results from ongoing Phase 3 trial in CSU (in biologic-naïve patients) (fourth quarter 2024)</p> <p>–Report results from Phase 3 trial in bullous pemphigoid (second half 2024)</p> <p>–Initiate Phase 1 study in severe food allergy following transient livoseltamab treatment (2024)</p>
Kevzara (sarilumab)^(b) <i>Antibody to IL-6R</i>		<p>–Polyarticular-course juvenile idiopathic arthritis ("pcJIA") (pivotal study)</p> <p>–Systemic juvenile idiopathic arthritis ("sJIA") (pivotal study)</p>		<p>–PMR (EU)</p> <p>–pcJIA (U.S. and EU)</p>	<p>–Approved by FDA for PMR</p>	<p>–EC decision on regulatory submission for PMR (second half 2024)</p> <p>–FDA decision on sBLA (target action date of June 10, 2024) and EC decision (second half 2024) on regulatory submission for pcJIA</p>

Clinical Program (continued)	Phase 1	Phase 2	Phase 3	Regulatory Review ^(h)	2023 and 2024 Events to Date	Select Upcoming Milestones
Itepekimab^(b) (REGN3500) <i>Antibody to IL-33</i>			–COPD ^(e)		–Phase 3 COPD program passed interim futility analysis conducted by Independent Data Monitoring Committee ("IDMC")	–Report results from Phase 3 study in COPD (2025)
REGN5713-5714-5715 <i>Multi-antibody therapy to Bet v 1</i>			–Birch allergy			
Solid Organ Oncology						
Libtayo (cemiplimab)^(g) <i>Antibody to PD-1</i>		–Neoadjuvant CSCC –First-line NSCLC, BNT116 ^(t) combination	–Adjuvant CSCC		–Approved by EC for first-line NSCLC, chemotherapy combination	–Conduct interim analysis from Phase 3 study in adjuvant CSCC (second half 2024)
Fianlimab^(f) (REGN3767) <i>Antibody to LAG-3</i>	–Solid tumors and advanced hematologic malignancies	–First-line advanced NSCLC (Phase 2/3) (pivotal study)	–First-line metastatic melanoma ^(e) –First-line adjuvant melanoma		–Presented positive data from Phase 1 trial (in combination with Libtayo) in advanced melanoma at 2023 American Society of Clinical Oncology ("ASCO") Annual Meeting	–Initiate potentially pivotal Phase 2 study (in combination with Libtayo) in perioperative melanoma (first half 2024) –Initiate Phase 2 study (in combination with Libtayo) in perioperative NSCLC (first half 2024) –Initiate Phase 2 study (in combination with Libtayo) in perioperative head and neck squamous cell carcinoma (2024) –Report potentially pivotal initial results from Phase 2/3 study in first-line metastatic melanoma (second half 2024) –Report initial data from Phase 2/3 study in first-line advanced NSCLC (second half 2024)
Vidutolimod <i>Immune activator targeting TLR9</i>		–Solid tumors				

Clinical Program (continued)	Phase 1	Phase 2	Phase 3	Regulatory Review ^(h)	2023 and 2024 Events to Date	Select Upcoming Milestones
Ubamamab^(f) (REGN4018) <i>Bispecific antibody targeting MUC16 and CD3</i>		–Platinum-resistant ovarian cancer			–Presented results from Phase 1/2 study (in combination with Libtayo) in platinum-resistant ovarian cancer at European Society for Medical Oncology ("ESMO") Congress	
REGN5668^(m) <i>Bispecific antibody targeting MUC16 and CD28</i>	–Platinum- resistant ovarian cancer					
REGN5678 <i>Bispecific antibody targeting PSMA and CD28</i>	–Prostate cancer				–Discontinued enrollment in cohorts in combination with full-dose Libtayo (cemiplimab) –Expanded enrollment in monotherapy cohort	–Initiate cohorts in combination with REGN4336 in metastatic castration-resistant prostate cancer (first half 2024)
REGN4336 <i>Bispecific antibody targeting PSMA and CD3</i>	–Prostate cancer					
Davutamig (REGN5093) <i>Bispecific antibody targeting two distinct MET epitopes</i>	–MET-altered advanced NSCLC					
REGN5093-M114 <i>Bispecific antibody-drug conjugate targeting two distinct MET epitopes</i>	–MET overexpressing advanced cancer					
REGN6569 <i>Antibody to GITR</i>	–Solid tumors					
REGN7075 <i>Bispecific antibody targeting EGFR and CD28</i>	–Solid tumors					–Initiate dose-expansion cohorts (in combination with Libtayo) in EGFR- high tumors (first half 2024)

Clinical Program (continued)	Phase 1	Phase 2	Phase 3	Regulatory Review ^(h)	2023 and 2024 Events to Date	Select Upcoming Milestones
Hematology						
Pozelimab^(f) (REGN3918) <i>Antibody to C5</i>			–Myasthenia gravis, cemisiran combination ^{(c)(s)} –Paroxysmal nocturnal hemoglobinuria ("PNH"), cemdisiran combination ^{(c)(s)}		–Veopoz (pozelimab) approved by FDA for CHAPLE in adults and children aged 1 year and older, monotherapy	
Odronextamab^(m) (REGN1979) <i>Bispecific antibody targeting CD20 and CD3</i>	–Certain B-cell malignancies ^(c)	–B-cell non-Hodgkin lymphoma ("B-NHL") (pivotal study)	–Follicular lymphoma ("FL") –Diffuse large B-cell lymphoma ("DLBCL")	–Relapsed/refractory FL and DLBCL (U.S. and EU)	–Presented updated data from trials in patients with relapsed/refractory FL and DLBCL at American Society of Hematology ("ASH") Annual Meeting	–FDA decision on BLA (target action date of March 31, 2024) and EC decision on regulatory submission (second half 2024) for relapsed/refractory FL and DLBCL
REGN5837^(p) <i>Bispecific antibody targeting CD22 and CD28</i>	–B-NHL					
Linvoseltamab^(f) (REGN5458) <i>Bispecific antibody targeting BCMA and CD3</i>	–Multiple myeloma ^{(c)(e)}	–Multiple myeloma (pivotal study) ^{(c)(e)} –Earlier (pre-malignant) multiple myeloma	–Multiple myeloma ^{(c)(e)}	–Relapsed/refractory multiple myeloma (U.S. and EU)	–Presented updated positive data from pivotal trial in multiple myeloma at ASCO and ASH Annual Meetings	–FDA decision on BLA (second half 2024) and EC decision on regulatory submission (first half 2025) for relapsed/refractory multiple myeloma
REGN5459^(f) <i>Bispecific antibody targeting BCMA and CD3</i>	–Transplant desensitization in patients with chronic kidney disease					
REGN7257 <i>Antibody to IL2Rg</i>	–Aplastic anemia					
NTLA-2001^(f) <i>TTR gene knockout using CRISPR/Cas9</i>	–Transthyretin ("ATTR") amyloidosis ^(c)		–ATTR amyloidosis with cardiomyopathy ("ATTR-CM")			
REGN9933 <i>Antibody to Factor XI</i>		–Thrombosis				–Report results from Phase 2 study in thrombosis (second half 2024)
REGN7508 <i>Antibody to Factor XI</i>	–Thrombosis					

Clinical Program (continued)	Phase 1	Phase 2	Phase 3	Regulatory Review ^(h)	2023 and 2024 Events to Date	Select Upcoming Milestones
REGN7999 <i>Antibody to TMPRSS6</i>	–Transfusion dependent iron overload					
Internal Medicine/Genetic Medicines						
Praluent (alirocumab) <i>Antibody to PCSK9</i>			–HeFH in pediatrics and adolescents	–HeFH in pediatrics and adolescents (8–17 years of age) (U.S.)	–Approved by EC for HeFH in pediatrics and adolescents (8–17 years of age)	–FDA decision on sBLA for HeFH in pediatrics and adolescents (target action date of March 10, 2024)
Evkeeza^{(f)(l)} (evinacumab) <i>Antibody to ANGPTL3</i>					–Approved by FDA and EC for HoFH in pediatrics (5–11 years of age) and MHLW for HoFH in adults, adolescents, and pediatrics	
Garetosmab^(f) (REGN2477) <i>Antibody to Activin A</i>			–Fibrodysplasia ossificans progressiva ("FOP") ^{(c)(d)(e)}			
Trevogrumab^(f) (REGN1033) <i>Antibody to myostatin (GDF8)</i>						–Initiate Phase 2 study in combination with semaglutide with and without garetosmab (mid-2024)
Mibavademab^(f) (REGN4461) <i>Agonist antibody to leptin receptor ("LEPR")</i>		–Generalized lipodystrophy ^{(d)(e)}			–Presented results from Phase 2 study in generalized lipodystrophy at ENDO 2023	
REGN5381/REGN9035 <i>Agonist antibody to NPR1/reversal agent to REGN5381</i>	–Reversal agent in healthy volunteers	–Heart failure			–Resumed enrollment in previously paused Phase 1 and Phase 2 studies following protocol amendments	–Reported positive initial data from Phase 1 trial in healthy volunteers
REGN7544 <i>Antagonist antibody to NPR1</i>	–Healthy volunteers					
ALN-HSD^(o) <i>RNAi therapeutic targeting HSD17B13</i>		–Nonalcoholic steatohepatitis ("NASH")				

Clinical Program (continued)	Phase 1	Phase 2	Phase 3	Regulatory Review^(h)	2023 and 2024 Events to Date	Select Upcoming Milestones
ALN-PNP^(k) <i>RNAi therapeutic targeting PNPLA3</i>	-NASH					
ALN-APP^(k) <i>RNAi therapeutic targeting APP</i>	-Early-onset Alzheimer's disease ^(q)					-Reported positive interim data from single dose part of Phase 1 trial in early- onset Alzheimer's disease
DB-OTO <i>AAV-based gene therapy</i>	-Hearing loss in pediatrics ^(c) (Phase 1/2)					-Reported preliminary, positive safety and efficacy results from first patient dosed in Phase 1/2 trial in pediatrics with hearing loss
"Next Generation" Covid Antibody⁽ⁱ⁾ <i>Antibody to SARS-CoV-2 variants</i>	-Healthy volunteers					
REGN13335 <i>Antagonist antibody to PDGF-B</i>	-Healthy volunteers					

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

- (a) In collaboration with Bayer outside the United States
- (b) In collaboration with Sanofi
- (c) FDA granted orphan drug designation
- (d) FDA granted Breakthrough Therapy designation
- (e) FDA granted Fast Track designation
- (f) Sanofi did not opt-in to or elected not to continue to co-develop the product candidate. Under the terms of our agreement, Sanofi is entitled to receive royalties on sales of the product, if any.
- (g) Studied as monotherapy and in combination with other antibodies and treatments
- (h) Information in this column relates to U.S., EU, and Japan regulatory submissions only
- (i) We and the Biomedical Advanced Research and Development Authority ("BARDA") of the U.S. Department of Health and Human Services ("HHS") are parties to an agreement whereby HHS provides certain funding to support research and development activities.
- (j) In collaboration with Intellia
- (k) In collaboration with Alnylam
- (l) In collaboration with Ultragenyx outside the United States
- (m) FDA granted Fast Track designation for follicular lymphoma and diffuse large B-cell lymphoma
- (n) Studied in combination with ubamatamab
- (o) 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.
- (p) Studied in combination with odronextamab
- (q) Part B of the study (multi-dose regimen) placed on partial clinical hold in the U.S. by the FDA due to findings observed in prior non-clinical chronic toxicology studies
- (r) BioNTech's BNT116 is an mRNA cancer vaccine.
- (s) Under the terms of our license agreement for the combination consisting of cemdisiran and pozelimab, Alnylam is entitled to receive royalties on sales of the combination (if any), as well as sales milestones.

Additional Information - Clinical Development Programs

EYLEA HD (aflibercept) 8 mg

In August 2023, the FDA approved the BLA for EYLEA HD for the treatment of patients with wAMD, DME, and DR.

Previously, in June 2023, the FDA issued a CRL for the EYLEA HD BLA. The CRL was issued solely due to unresolved observations resulting from a May 2023 FDA inspection at a third-party contract manufacturing organization, Catalent, that the Company engaged to complete vial-filling for EYLEA HD. With the approval of EYLEA HD, the pre-approval inspection issues related to the BLA had been addressed.

In June 2023 and August 2023, the Company announced top-line, two-year (96 weeks) data for EYLEA HD from the pivotal PHOTON trial in patients with DME and the pivotal PULSAR trial in patients with wAMD, respectively. In addition, in July 2023, the results from the PHOTON trial were presented at the American Society of Retina Specialists annual meeting. During both trials, EYLEA HD patients were initially randomized to either 12- or 16-week dosing intervals (after three initial monthly doses) and were able to shorten or extend dosing intervals if pre-specified criteria were met. The longer-term data among EYLEA HD patients who completed the trials demonstrated that the vast majority of patients were able to maintain or further extend these dosing intervals through two years with:

PHOTON:

- 89% maintaining \geq 12-week dosing intervals through two years, compared to 93% through one year (48 weeks)
- 84% maintaining \geq 16-week dosing intervals through two years, compared to 89% maintaining a 16-week dosing interval through one year
- 44% meeting the criteria for \geq 20-week dosing intervals by week 96, including 17% and 27% who were eligible for 20- and 24-week dosing intervals, respectively

PULSAR:

- 88% on a \geq 12-week dosing interval at the end of two years
- 78% maintaining \geq 12-week dosing intervals through two years, compared to 83% throughout the first year of study (48 weeks)
- 71% meeting the extension criteria for even longer dosing intervals, including 47% for \geq 20-week intervals and 28% for 24-week intervals
- those assigned to \geq 16-week dosing regimen at baseline, 70% maintaining \geq 16-week dosing intervals throughout the two-year study period; at the end of two years, 78% were eligible for \geq 16-week dosing, with 53% eligible for \geq 20-dosing week intervals.

The visual gains for EYLEA HD remained consistent with the first year of the trials. In both PHOTON and PULSAR, the safety of EYLEA HD also continued to be similar to EYLEA through two years and remained consistent with the known safety profile of EYLEA from previous clinical trials for DME and wAMD.

In May 2023, Bayer announced that it initiated a Phase 3 study to evaluate the efficacy and safety of EYLEA HD at extended dosing intervals compared to the standard of care, EYLEA, in RVO to support potential future regulatory submissions outside the United States.

Dupixent

COPD

In March 2023, the Company and Sanofi announced that the primary and all key secondary endpoints were met in the BOREAS trial (the first of two Phase 3 trials) in adults currently on maximal standard-of-care inhaled therapy (triple therapy) with uncontrolled COPD and evidence of type 2 inflammation. In this trial, patients receiving Dupixent experienced a 30% reduction in moderate or severe acute COPD exacerbations (rapid and acute worsening of respiratory symptoms) compared to placebo over 52 weeks, while also demonstrating significant improvements in lung function, quality of life, and COPD respiratory symptoms.

In November 2023, the Company and Sanofi announced that the replicate Phase 3 NOTUS trial met its primary endpoint, showing Dupixent significantly reduced exacerbations by 34% compared to placebo over 52 weeks in patients with moderate-to-severe COPD with evidence of type 2 inflammation, confirming results from the BOREAS pivotal trial. Given the overwhelming positive efficacy of the primary endpoint in the interim analysis from the NOTUS trial, the results will be considered the primary analysis of the trial. In December 2023, the Company and Sanofi submitted the data from this interim analysis of the NOTUS trial, along with the results from the Phase 3 BOREAS trial, to the FDA.

The safety results for the BOREAS and NOTUS trials were generally consistent with the known safety profile of Dupixent in its approved indications.

CSU

In October 2023, the FDA issued a CRL for the sBLA for Dupixent in CSU. The CRL states that additional efficacy data are required to support an approval; it did not identify any issues with safety or manufacturing. An ongoing Phase 3 clinical trial (in biologic-naïve patients) continues to enroll patients, with results expected in late 2024.

REGN5678

In the ongoing Phase 1 study of REGN5678, the Company has observed antitumor activity in combination with Libtayo as well as with REGN5678 monotherapy. Due to the emerging safety profile, including two immune-mediated Grade 5 adverse events (death), the Company discontinued enrollment of patients receiving the combination of REGN5678 and full-dose Libtayo (cemiplimab). The Company has since expanded enrollment in a REGN5678 monotherapy cohort and plans to explore other REGN5678 combinations.

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 plays a major role in atopic dermatitis, asthma, CRSwNP, EoE, prurigo nodularis, and potentially other chronic allergic and inflammatory diseases, including COPD.

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.

REGN5713-5714-5715

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

Libtayo (cemiplimab)

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

Fianlimab

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

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 and myasthenia gravis.

Odronextamab

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

Linvoseltamab

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

NTLA-2001

NTLA-2001 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, NTLA-2001 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.

Praluent (alirocumab)

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

Evkeeza (evinacumab)

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

Garetosmab

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

Other Programs

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

Research and Development Technologies

Many proteins that play an important role in biology and disease are secreted by cells or located on the cell surface. Moreover, cells communicate through secreted factors and surface molecules. Our scientists have developed two different technologies to make protein therapeutics that potently and specifically block, activate, or inhibit the action of specific cell surface or secreted molecules. The first technology fuses receptor components to the constant region of an antibody molecule to make a class of drugs we call "Traps." EYLEA 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.

VelociSuite

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

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

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

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

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

The *VelociT* mouse extends our research and drug discovery capabilities into cell-mediated immunity and therapeutic TCRs for oncology and other indications. *VelociT* was developed by using our *VelociGene* technology to humanize genes encoding TCR α and TCR β variable sequences, CD4 and CD8 co-receptors, β 2m, 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 more than 2 million samples sequenced to date.

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

These efforts at the RGC have led to the identification of more than 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 and Intellia Therapeutics, Inc.

Collaboration, License, and Other Agreements

Sanofi

Antibody

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

Under our collaboration agreement, Sanofi records product sales for commercialized products, and Regeneron has the right to co-commercialize such products on a country-by-country basis. We co-commercialize Dupixent in the United States and in certain countries outside the United States. We supply certain commercial bulk product to Sanofi. We and Sanofi equally share profits from sales within the United States. We and Sanofi share profits outside the United States on a sliding scale based on sales starting at 65% (Sanofi)/35% (us) and ending at 55% (Sanofi)/45% (us). In each of 2020 and 2021, we earned a \$50.0 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent, which was previously included in the LCA) exceeding \$1.0 billion and \$1.5 billion, respectively, on a rolling twelve-month basis. In 2022, we earned two additional \$50.0 million sales-based milestones, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding \$2.0 billion and \$2.5 billion, respectively, on a rolling twelve-month basis, and in 2023, we earned the final \$50.0 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding \$3.0 billion on a rolling twelve-month basis.

Immuno-Oncology

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

commercialization activities outside the United States. The parties shared equally in profits and losses in connection with the commercialization of Libtayo.

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 (the "A&R IO LCA"). In connection with the A&R IO LCA, in 2022, the Company made a \$900.0 million up-front payment to Sanofi, as well as a \$100.0 million regulatory milestone payment. In addition, Sanofi was eligible to earn an aggregate of \$100.0 million in Libtayo sales-based milestones under the terms of the A&R IO LCA, of which they earned \$65.0 million in 2022 and \$35.0 million in 2023. We also pay Sanofi an 11% royalty on net product sales of Libtayo through March 31, 2034. The parties have also entered into a transition services agreement, a transitional distribution agreement, and a manufacturing services agreement, pursuant to which, during certain transitional periods, Sanofi will perform for the Company certain transition, distribution, and manufacturing services, respectively.

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

Bayer

We and Bayer are parties to a license and collaboration agreement for the global development and commercialization of EYLEA 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 Pharmaceuticals, Inc. entered into a global, strategic collaboration to discover, develop, and commercialize RNAi therapeutics for a broad range of diseases by addressing therapeutic disease targets expressed in the eye and central nervous system ("CNS"), in addition to a select number of targets expressed in the liver. In connection with the collaboration, the Company made an up-front payment of \$400.0 million to Alnylam, and also purchased shares of Alnylam common stock for \$400.0 million. For each program, we provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation. During 2023, we paid a \$100.0 million development milestone to Alnylam upon the achievement of specified proof-of-principle criteria for the ALN-APP 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") (under which the parties are advancing ALN-APP and ALN-PNP, which are currently in clinical development) or a license agreement structure. The initial target nomination and discovery period is five years (which may under certain situations automatically be extended for up to seven years in the aggregate) (the "Research Term"). In addition, we have an option to extend the Research Term for an additional five-year period for a research extension fee 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. Alnylam is the lead party for ALN-APP, and we are the lead party for ALN-PNP.

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.

The parties have entered into various license agreements, including for a combination consisting of cemdisiran (an siRNA therapeutic targeting the C5 component of the human complement pathway being developed by Alnylam) and pozelimab, with us as the licensee.

Intellia

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

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

In September 2023, we further expanded our existing collaboration 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 October 2023, we elected to extend the period for selecting targets under the 2016 license and collaboration agreement for an additional two years until April 2026; as a result, we became obligated to make a \$30.0 million extension payment to Intellia.

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 August 2023, we entered into an Agreement and Plan of Merger to acquire Decibel, and in September 2023, we completed the acquisition of Decibel. We paid \$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, which entitles the holder to receive up to \$3.50 per share in cash upon achievement of certain clinical development and regulatory milestones for DB-OTO within specified time periods. The maximum aggregate amount that holders of the CVRs may be entitled to receive if all the milestones contemplated by the CVRs are achieved is approximately \$97 million.

BARDA

In August 2023, we expanded our existing Other Transaction Agreement ("OTA") with BARDA, pursuant to which the HHS is obligated to fund up to 70% of our costs incurred for certain development activities related to a next-generation COVID-19 monoclonal antibody therapy for the prevention of SARS-CoV-2 infection. Pursuant to the terms of the expanded agreement, we could receive payments of up to approximately \$326 million in the aggregate to support clinical development, clinical manufacturing, and the regulatory licensure process.

Manufacturing

We currently manufacture bulk drug materials and products at our manufacturing facilities in Rensselaer, New York and Limerick, Ireland. These facilities consist of owned and leased research, manufacturing, office, laboratory, and warehouse space. In addition, 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, and to

supply various raw materials and other products. See Part I, Item 1A. "Risk Factors - Risks Related to Manufacturing and Supply" for further information.

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

Commercial

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

In the United States, we sell our marketed products primarily to wholesalers and specialty distributors that serve pharmacies, hospitals, government agencies, physicians, and other healthcare providers. We had sales to two customers (Besse Medical, a subsidiary of Cencora, Inc., and McKesson Corporation) that each accounted for more than 10% of total gross product revenue for the year ended December 31, 2023. On a combined basis, our product sales to these customers accounted for 76% of our total gross product revenue for the year ended December 31, 2023. 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 agreement. In addition, we are in process of building additional commercial capabilities outside the United States as a result of us obtaining the rights, in 2022, to commercialize Libtayo outside the United States.

Competition

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

Marketed Products

The table below provides an overview of the current competitive landscape for 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	Yesafili [®] (aflibercept) (biosimilar referencing EYLEA)	Biocon Biologics Ltd	wAMD, DME, macular edema following RVO (including CRVO and BRVO), and mCNV	EU
	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

Marketed Product (continued)	Competitor Product	Competitor	Indication	Territory^(a)
EYLEA HD and EYLEA (continued)	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 Bausch + Lomb	wAMD, DME, macular edema following RVO (including CRVO and BRVO), DR, and CNV	EU
	Cimerli™ (ranibizumab-eqrn) (biosimilar referencing Lucentis)	Formycon AG, Bioeq AG, Coherus BioSciences, Inc., 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	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
	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	Eucrisa®/Staquis® (crisaborole)	Pfizer Inc.	Mild-to-moderate atopic dermatitis	United States, EU
	Opzelura® (ruxolitinib)	Incyte Corporation	Mild-to-moderate atopic dermatitis	United States
	Olumiant® (baricitinib)	Eli Lilly and Company/ Incyte Corporation	Moderate-to-severe atopic dermatitis	EU, Japan
	Cibinqo® (abrocitinib)	Pfizer	Moderate-to-severe atopic dermatitis	United States, EU, Japan
	Rinvoq® (upadacitinib)	AbbVie	Moderate-to-severe atopic dermatitis	United States, EU, Japan
	Adbry™/Adtralza® (tralokinumab)	LEO Pharma Inc.	Moderate-to-severe atopic dermatitis	United States, EU, Japan
	Ebglyss® (lebrikizumab)	Almirall S.A.	Moderate-to-severe atopic dermatitis	EU
	Corectim® (delgocitinib)	Japan Tobacco Inc./Torii Pharmaceutical Co., Ltd.	Atopic dermatitis	Japan
	Mitchga® (nemolizumab)	Maruho Co., Ltd./Chugai Pharmaceutical Co., Ltd.	Pruritus associated with atopic dermatitis	Japan
	Xolair® (omalizumab)	Roche/Novartis	Asthma, nasal polyps	United States, EU, Japan (asthma); United States, EU (nasal polyps)

Marketed Product (continued)	Competitor Product	Competitor	Indication	Territory^(a)
Dupixent (continued)	Nucala [®] (mepolizumab)	GlaxoSmithKline ("GSK")	Asthma, nasal polyps	United States, EU, Japan (asthma); United States, EU (nasal polyps)
	Cinqair [®] (reslizumab)	Teva	Asthma	United States, EU
	Fasenra [®] (benralizumab)	AstraZeneca	Asthma	United States, EU, Japan
	Tezspire [™] (tezepelumab-ekko)	AstraZeneca/Amgen	Asthma	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

^(a) This table focuses on the United States, EU, and Japan. Certain products have also received marketing approval in countries outside the United States, EU, and Japan.

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 are becoming more active in seeking patent and other intellectual property protection and licensing arrangements to

collect royalties or other consideration for use of the technology they have developed. Products developed in this manner may compete directly with products we develop. We also compete with others in acquiring technology from these institutions, agencies, and organizations.

Patents, Trademarks, and Trade Secrets

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

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing on the proprietary rights of third parties (see Part I, Item 1A. "Risk Factors - Risks Related to Intellectual Property and Market Exclusivity - *We may be restricted in our development, manufacturing, and/or commercialization activities by patents or other proprietary rights of others, and could be subject to awards of damages if we are found to have infringed such patents or rights*"; and Note 16 to our Consolidated Financial Statements). Our policy is to file patent applications to protect technology, inventions, and improvements that we consider important to our business and operations. We hold an ownership interest in a number of issued patents in the United States and 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 issued patents covering these technologies generally expire between 2022 and 2032. However, we continue to file patent applications directed to improvements to these technology platforms.

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

The following table describes our U.S. patents, European patents ("EP"), and Japanese patents ("JP") that are of particular relevance to key products marketed or otherwise commercialized by us and/or our collaborators, including the territory, patent number, general subject matter class, and expected expiration dates. The noted expiration dates include any patent term adjustments. Certain of these patents may also be entitled to term extensions. We continue to pursue additional patents and patent term extensions in the United States and other jurisdictions covering various aspects of our products that may, if issued, extend exclusivity beyond the expiration of the patents listed in the table below. One or more patents with the same or earlier expiry date may fall under the same "general subject matter class" for certain products and may not be separately listed. 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	afibercept (8 mg)	US	10,066,458	Formulation	June 14, 2027
		US	11,084,865	Formulation	June 14, 2027
		US	11,103,552	Formulation	May 15, 2039
		US	11,732,024	Formulation	June 14, 2027
		US	9,254,338	Methods of Treatment	May 22, 2032
		US	10,130,681	Methods of Treatment	January 11, 2032
		US	10,828,345	Methods of Treatment	January 11, 2032
		JP	7,235,770	Formulation	May 10, 2039
EYLEA ^(a)	afibercept (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	9,254,338	Methods of Treatment	May 22, 2032
		US	9,669,069	Methods of Treatment	January 11, 2032
		US	10,130,681	Methods of Treatment	January 11, 2032
		US	10,828,345	Methods of Treatment	January 11, 2032
		US	10,888,601	Methods of Treatment	January 11, 2032

Product (continued)	Molecule	Territory	Patent No.	General Subject Matter Class	Expiration
EYLEA ^(a) (continued)		US	11,253,572	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	8,945,559	Formulation	October 17, 2032
		US	9,238,692	Formulation	October 5, 2031
		US	10,435,473	Formulation	October 5, 2031
		US	11,059,896	Formulation	October 5, 2031
		US	8,075,887	Methods of Treatment	April 17, 2028
		US	8,337,839	Methods of Treatment	October 2, 2027
		US	9,290,574	Methods of Treatment	July 10, 2034
		US	9,574,004	Methods of Treatment	December 22, 2033
		US	11,421,036	Methods of Treatment	July 10, 2034
		US	10,137,193	Methods of Treatment	March 18, 2036
		US	10,485,844	Methods of Treatment	September 21, 2037
		US	10,059,771	Methods of Treatment	June 20, 2034
		US	11,214,621	Methods of Treatment	March 11, 2036
		US	11,167,004	Methods of Treatment	September 21, 2037
		US	11,034,768	Methods of Treatment	March 23, 2039
		US	11,292,847	Methods of Treatment	May 10, 2039
		EP	2356151	Composition of Matter	October 27, 2029 ^(b)
		EP	2356151	Composition of Matter (Supplementary Protection Certificate)	(September 28, 2032) ^(b) /(March 28, 2033) ^(c)
		EP	3010539	Methods of Treatment	June 20, 2034
		EP	2888281	Methods of Treatment	August 20, 2033
		EP	3064511	Methods of Treatment	October 27, 2029
		EP	3107575	Methods of Treatment	February 20, 2035
		EP	3470432	Methods of Treatment	August 20, 2033
		EP	3019191	Methods of Treatment	July 10, 2034
		EP	3703818	Methods of Treatment	October 29, 2038
		EP	4011915	Methods of Treatment	August 20, 2033
		EP	2624865	Formulation	October 5, 2031
		EP	3354280	Formulation	October 5, 2031
		JP	5,291,802	Composition of Matter	October 27, 2029 – October 27, 2034 ^(d)
JP	5,918,246	Formulation	October 5, 2031 – September 14, 2035 ^(d)		

Product (continued)	Molecule	Territory	Patent No.	General Subject Matter Class	Expiration
Dupixent (continued)		JP	6,306,588	Methods of Treatment	August 20, 2033 – August 29, 2034 ^(d)
		JP	6,353,838	Methods of Treatment	September 4, 2033
		JP	6,673,840	Methods of Treatment	February 20, 2035
		JP	6,463,351	Methods of Treatment	June 20, 2034 – September 2, 2035 ^(d)
		JP	6,861,630	Methods of Treatment	November 13, 2035
		JP	7,164,530	Methods of Treatment	September 21, 2037
		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
		US	10,457,725	Methods of Treatment	May 12, 2037
		US	11,292,842	Methods of Treatment	July 18, 2038
		US	11,505,600	Methods of Treatment	July 2, 2038
		EP	3097119	Composition of Matter	January 23, 2035
		EP	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	6,999,577	Methods of Treatment	May 12, 2037
JP	7,054,680	Methods of Treatment	May 12, 2037		
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, could reduce the duration of market exclusivity for our products*"). For example, in the United States, the regulatory exclusivity period for EYLEA (i.e., the period during which no biosimilar product can be approved by the FDA) extends through May 17, 2024 following the pediatric exclusivity granted by the FDA. The effect of expiration of a patent relating to a particular product also depends upon other factors, such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product, and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

We also are the nonexclusive licensee of a number of additional patents and patent applications. These include a license agreement with Bristol-Myers Squibb, E. R. Squibb & Sons, L.L.C., and Ono Pharmaceutical Co., Ltd. to obtain a license under certain patents owned and/or exclusively licensed by one or more of these parties that includes the right to develop and sell Libtayo. Under the agreement, we 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 conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of, an Institutional Review Board ("IRB") for each clinical site within the United States or, where applicable, an Ethics Committee and/or the competent authority for clinical sites outside the United States. Companies sponsoring the clinical trials, investigators, and IRBs/Ethics Committees also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study patients, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of a BLA if the study was conducted in accordance with GCPs and the FDA is able to validate the data. The sponsor of a clinical trial or the sponsor's designated responsible party may be required to register certain information about the trial and disclose certain results on government or independent registry websites, such as clinicaltrials.gov.

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

The results of the preclinical and clinical testing of a biologic product candidate are then submitted to the FDA in the form of a BLA for evaluation to determine whether the product candidate may be approved for commercial sale under the Public Health Service Act. 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 average manufacturer price increases more than inflation (measured by reference to the Consumer Price Index - Urban). Until December 31, 2023, the rebate was capped at 100 percent of the average manufacturer price, but effective January 1, 2024, this cap on the rebate has been removed, and the rebate liability of manufacturers could increase accordingly.

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. The federal Patient Protection and Affordable Care Act (the "PPACA") made significant changes to the Medicaid Drug Rebate program, and thereafter CMS issued a final regulation to implement the changes to the Medicaid Drug Rebate program under the PPACA. CMS has since modified Medicaid Drug Rebate program regulations to, among other things, permit reporting multiple best price figures with regard to value-based purchasing arrangements and provide definitions for "line extension," "new formulation," and related terms with the practical effect of expanding the scope of drugs considered to be line extensions.

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over or that are disabled as well as those with certain health conditions. Medicare Part B generally covers drugs that must be administered by physicians or other health care practitioners; are provided in connection with certain durable medical equipment; or are certain oral anti-cancer drugs and certain oral immunosuppressive drugs. Medicare Part B pays for such drugs under a payment methodology based on the average sales price of the drugs. Manufacturers, including us, are required to report average sales price information to CMS on a quarterly basis. The manufacturer-submitted information may be used by CMS to calculate Medicare payment rates. Manufacturers must pay refunds to Medicare for single-source drugs or biological products, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties. Further, 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 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. It is currently unclear how HRSA will apply its enforcement authority under this regulation. 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. On November 30, 2022, HRSA issued a notice of proposed rulemaking that proposes several changes to the ADR process; and, following the solicitation of public comments, in October 2023 HRSA submitted a final version of the rule to the White House Office of Management and Budget for review. HRSA also implemented a price reporting system under which we are required to report our 340B ceiling prices to HRSA on a quarterly basis, which then publishes those prices to 340B covered entities.

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

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

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

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

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

To the extent we collect California resident personal data, we are also subject to the CCPA. The CCPA includes certain transparency requirements and grants California residents several rights with regard to their personal data. In addition, in November 2020, California voters approved the California Privacy Rights Act ("CPRA") ballot initiative which introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency ("CPPA"). The amendments introduced by the CPRA went into effect on January 1, 2023. Failure to comply with such laws may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with data privacy incidents involving certain elements of personal data. These claims may result in significant liability and damages. Similarly, there are a number of legislative proposals in the United States, at both the federal and state level, that could impose new obligations or limitations in the area of consumer protection. Several additional state consumer privacy laws went into effect in 2023 and many other consumer privacy laws are expected to come into effect in the near future that have or will impose new obligations or limitations in areas affecting our business. We may be subject to fines, penalties, or private actions in the event of non-compliance with such laws.

Outside the United States, our clinical trial programs, research collaborations, and other processing activities implicate international data protection laws, including the EU General Data Protection Regulation 2016/679 ("GDPR"). The GDPR has increased our responsibility and liability in relation to the processing of personal data of individuals located in the EU. The GDPR, together with the national legislation of the EU member states governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data and samples from clinical trials and adverse event reporting. In particular, these obligations and restrictions may concern the consent of the individuals to whom the personal data relate, the information provided to the individuals, the sharing of personal data with third parties, the transfer of personal data out of the EU, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for violations of the data protection obligations. In 2021, the European Commission published new standard contractual clauses required to be incorporated into new and existing agreements in order to continue to lawfully transfer personal data outside the EU. Different EU member states, as well as the United Kingdom and Switzerland, have promulgated national privacy laws that impose additional requirements, which add to the complexity of processing and transferring EU personal data. In October 2022, the United States issued an executive order to implement the EU-U.S. Data Privacy Framework, for which the European Commission adopted an adequacy decision in July 2023 concluding that personal data can flow freely from the EU to companies in the United States that participate in the EU-U.S. Data Privacy Framework.

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

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

Business Segments

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

Human Capital Resources

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

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

Employee Profile

As of December 31, 2023, we had 13,450 full-time employees, consisting of 10,875 employed in the United States, 1,939 employed in Ireland, and 636 employed in other countries (primarily in the United Kingdom, Japan, and Germany). Of these employees, 2,393 were within our research and preclinical development organization, 2,002 were within our global clinical development and regulatory affairs organization, and 6,124 were within our industrial operations and product supply organization. Company-wide, over 1,500 of our full-time employees hold a Ph.D. and/or M.D. We also supplement our workforce with independent contractors, contingent workers, and temporary workers, as needed. None of our employees are represented by a labor union, and our management considers its relations with our employees to be good.

Diversity, Equity, and Inclusion

Our employees represent a broad range of backgrounds, just like the people who take our medicines, and bring a wide array of perspectives and experiences that have helped us achieve our leadership position in the biotechnology and pharmaceuticals industries and the global marketplace. A key component of our culture is our commitment to diversity, equity, and inclusion ("DEI"). We believe this commitment allows us to better drive innovation and achieve our mission to repeatedly bring important new medicines to patients with serious diseases. Our strategy is rooted in the understanding that DEI 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. We empower employee-led cross-functional resource groups, functional/site-level DEI councils, and other interest groups, who connect around a common passion to build a culture of inclusion and collaboration. In 2023, we 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 April 2020, we announced our 2025 global responsibility goals, including a commitment to increase diversity in leadership and foster inclusion. Making progress toward this goal, since then we hired our Chief DEI Officer; launched a DEI strategy focused on creating a better workplace, better science, and better world; and implemented a new governance model that includes both an executive DEI council and a DEI leadership council. These councils are comprised of senior leaders who provide oversight and guidance on our DEI efforts and support the execution of our DEI strategy. In order to better understand our employees' perspectives, we also measure inclusion and belonging as part of our annual employee engagement survey. Our board of directors receives a detailed update on our DEI efforts at least once a year and continues to monitor our progress.

2023 Workforce Diversity Representation *

Female Representation (Global)	49.9%
People of Color Representation (U.S. Only)**	30.5%

* Based on full-time employees as of December 31, 2023

** 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 34.9%.

Externally, we support DEI efforts in our community, including by supporting young scientific talent in underrepresented communities. For example, as part of our \$100 million, 10-year commitment to support the Regeneron Science Talent Search ("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 recently announced an additional \$34 million, 5-year commitment. 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 representation in STEM careers. In addition, we have developed a STEM pilot program with post-primary-school and high-school students in the New York State Capital Region and Limerick, Ireland that aspires to build long-term relationships with students from disadvantaged socio-economic groups, to encourage and support them in their studies, to inspire them to attend college, and, ultimately, to build a deeper more diverse talent pipeline. We also continue to take steps to further integrate diversity considerations into the design and selection of sites for our clinical studies to make sure they reflect the diversity of patients with the diseases under investigation.

Employee Wellness, Health, and Safety

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

Occupational health and safety is critical to our success. We are committed to meeting or exceeding all environmental, health, safety ("EHS") and security regulations and have a range of programs, plans, and procedures to ensure the safety of all people who come to work at Regeneron. In addition, our 2025 global responsibility goals include a commitment to focus on workplace injury prevention in our drive toward zero incidents.

Employee Growth and Development

We invest significant resources to develop talent with the right capabilities to deliver the growth and innovation needed to support our continued success. Our Talent department is dedicated to promoting individual, leader, team, and organizational development through a number of tools and services. We offer a variety of professional development courses for our employees and support employee continuing education, including through educational reimbursement and tuition forgiveness programs. In addition, we continue to invest in our current and future leaders through a number of leadership development courses and programs and feedback and coaching opportunities. In 2023, over 25% of job openings were filled by existing employees who were seeking career development opportunities.

Employee Engagement

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

We are also committed to fostering employee volunteerism to reach our 2025 global responsibility goal of driving employee volunteer levels above national standards. Employees are encouraged and empowered to support organizations and causes that are important to them including through, among other things, our matching gift program, volunteer-time-off policy, and our annual company-wide service event, *Day for Doing Good*. In 2023, over 7,300 employees volunteered approximately 39,600 hours, including approximately 51% of our employees who volunteered nearly 23,600 hours to approximately 230 nonprofits during our

Day for Doing Good. Additionally, through our Matching Gift Program, we matched approximately \$2.4 million in employee contributions in 2023, supporting nearly 2,000 charities. In 2023, we were named to the Civic 50 of most community-minded companies in the United States for the seventh consecutive year.

The success of our employee engagement efforts is demonstrated by our employee retention rate of 93.6% in 2023, 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 13 years in *Science* magazine's annual "Top Employers Survey" of the global biotechnology and pharmaceutical industry.

Compensation and Benefits

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

Corporate Information

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

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

Investors and other interested parties should note that we use our media and investor relations website (<http://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, could reduce the duration of market exclusivity for our products, including EYLEA and EYLEA HD.

Manufacturing and Supply Risks

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

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

Other Regulatory and Litigation Risks

- If the testing or use of our products harms people, or is perceived to harm them even when such harm is unrelated to our products, we could be subject to costly and damaging product liability claims.
- Our business activities have been, and may in the future be, challenged under U.S. federal or state and foreign healthcare laws, which may subject us to civil or criminal proceedings, investigations, or penalties.
- If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions, and fines.
- We face risks from the improper conduct of our employees, agents, contractors, or collaborators, including those relating to potential non-compliance with relevant laws and regulations such as the Foreign Corrupt Practices Act and the U.K. Bribery Act.
- Our operations are subject to environmental, health, and safety laws and regulations, including those governing the use of hazardous materials.
- Changes in laws and regulations affecting the healthcare industry could adversely affect our business.
- Tax liabilities and risks associated with our operations outside 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 our ophthalmology portfolio, which consists 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, 2023 and 2022, our aggregate EYLEA HD and EYLEA net product sales in the United States represented 45% and 51% of our total revenues, respectively. For the year ended December 31, 2023, aggregate EYLEA HD U.S. and EYLEA U.S. net product sales decreased by 6%, compared to the same period in 2022. 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 were to experience difficulty with the commercialization of EYLEA HD or EYLEA in the United States or if

Bayer were to experience 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. In the United States, the regulatory exclusivity period for EYLEA (i.e., the period during which no biosimilar product can be approved by the FDA) will expire after May 17, 2024. See "Risks Related to Intellectual Property and Market Exclusivity - *Loss or limitation of patent rights, and regulatory pathways for biosimilar competition, could reduce the duration of market exclusivity for our products*" below. As a result, we face the risk of lower EYLEA net product sales due to biosimilar competition following such expiration, which may have a material adverse impact on our results of operations. The degree to which EYLEA HD net product sales may offset any potential decrease in EYLEA net product sales, resulting from the factors discussed above or otherwise, is uncertain.

In addition, we are substantially dependent on our share of profits from the commercialization of Dupixent under our Antibody Collaboration with Sanofi. If we or Sanofi were to experience any difficulty with the commercialization of Dupixent or if we or Sanofi are unable to maintain current marketing approvals of Dupixent, we may experience a reduction in revenue and our business, prospects, operating results, and financial condition 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 health care 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 and REGEN-COV (described further in Note 16 to our Consolidated Financial Statements included in this report), as well as other risks relating to our marketed products and product candidates associated with intellectual property of other parties and pending or future litigation relating thereto (as discussed under "Risks Related to Intellectual Property and Market Exclusivity" below);
- the outcome of the pending government proceedings and investigations and other matters described in Note 16 to our Consolidated Financial Statements included in this report (including the civil complaint filed against us on June 24, 2020 in the U.S. District Court for the District of Massachusetts by the U.S. Attorney's Office for the District of Massachusetts); and
- the results of post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and studies of other products that could implicate an entire class of products or are perceived to do so.

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

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

We and our collaborators are subject to significant ongoing regulatory obligations and oversight with respect to the products we or they commercialize for the products' currently approved indications in the United States, EU, Japan, and other countries where such products are approved. If we or our collaborators fail to maintain regulatory compliance or satisfy other obligations for such products' currently approved indications (including because the product does not meet the relevant endpoints of any required post-approval studies (such as those required under an accelerated approval by the FDA or other similar type of approval), or for any of the reasons discussed below under "Risks Related to Maintaining Approval of Our Marketed Products and the Development and Obtaining Approval of Our Product Candidates and New Indications for Our Marketed Products - *Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain. 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 health care 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. 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 commercial capabilities outside the United States for Libtayo, Dupixent, and any other 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 develop 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. Some states have also enacted or are considering legislation to control the prices and reimbursement of prescription drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any prescription drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform measures in the future that will impose additional constraints on prices and reimbursements for our marketed products.

Further, there have been several recent U.S. Congressional inquiries and recently approved or proposed federal and state legislation, 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 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 the average sales price or average manufacturer price of drugs covered under Medicare Parts B and D, respectively, exceeds 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.

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

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

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

EYLEA and 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); biosimilar versions of Lucentis commercialized in the United States by Biogen Inc. and Coherus BioSciences, Inc.; and Biocon Biologics Ltd's biosimilar version of EYLEA recently approved in the EU. 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. 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 and other approved anti-VEGF treatments. Other potentially competitive products in development include products for use in combination with EYLEA and/or other anti-VEGF treatments, small-molecule tyrosine kinase inhibitors, gene therapies, and other eye-drop formulations, devices, and oral therapies. There also is a risk that third parties repackage ZALTRAP for off-label use and sale for the treatment of diseases of the eye, even though ZALTRAP has not been manufactured and formulated for use in intravitreal injections. We are aware of claims by third parties, including those based on published clinical data, alleging that ZALTRAP may be safely administered to the eye.

EYLEA HD was approved by the FDA in August 2023 for the treatment of wAMD, DME, and DR. As a newly approved product, EYLEA HD has 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, 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 topical and systemic JAK inhibitors and antibodies against IL-13 approved for atopic dermatitis. In addition, a number of companies are developing antibodies against IL-4Ra, IL-13Ra1, OX40(L), and/or IL-31R that may compete with Dupixent in atopic dermatitis and other indications (including asthma and/or prurigo nodularis), as applicable. In asthma, competitors to Dupixent include antibodies against the IL-5 ligand or the IL-5 receptor, immunoglobulin E, or thymic stromal lymphopoietin

("TSLP"); and some of these antibodies are either approved or in development for indications that also compete or may compete in the future with Dupixent in CRSwNP and EoE. There are several other potentially competitive products in development that may compete with Dupixent in asthma, as well as potential future indications, including antibodies against the IL-33 ligand. Dupixent also faces competition from inhaled products in asthma and potential future indications.

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

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

Product Candidates

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

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

While we have established our own sales and marketing organization for EYLEA 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 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.

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

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

We sell our marketed products for which we record net product sales in the United States to several distributors and specialty pharmacies, as applicable (collectively, "distributor customers"), which generally sell the product directly to healthcare providers or other pharmacies (as applicable). For the years ended December 31, 2023 and 2022, our product sales to two distributor customers accounted on a combined basis for 76% and 83% 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 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 commercial capabilities outside the United States for Libtayo, Dupixent, and any other products we intend to commercialize or co-commercialize outside the United States, our business, prospects, operating results, and financial condition may be adversely affected.

We have limited commercial capabilities outside the United States and have not yet fully established an organization for the sales, marketing, and distribution of marketed products outside the United States. We are in the process of establishing these capabilities outside the United States for Libtayo in connection with the 2022 amendment to the IO Collaboration whereby all rights to develop, commercialize, and manufacture Libtayo will be transferred exclusively to our Company, on a worldwide basis, over the course of a defined transition period. In addition to fully establishing these commercial capabilities by the end of the transition period, we will also need to obtain and/or maintain regulatory approvals and secure pricing and reimbursement for Libtayo in many jurisdictions outside the United States (including Europe and Japan). Further, following the exercise of our option under the Antibody Collaboration to co-commercialize Dupixent in certain jurisdictions outside the United States, we have established certain co-commercialization capabilities for Dupixent in some of these jurisdictions and are in the process of establishing these capabilities in others. 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 our sales, marketing, distribution, regulatory, managerial, and other capabilities in the relevant markets or make arrangements with third parties to perform these services, any of which will likely be expensive and time consuming and could delay product launch or the co-commercialization of a product in one or more markets outside the United States. We cannot be certain that we will be able to successfully develop commercial capabilities outside the United States (particularly as it relates to Libtayo, for which we plan to expand our global commercialization footprint as noted above) 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 and submit the data before it will reconsider our application. Depending on the extent of these or any other studies that might be required, approval of any applications that we submit may be delayed significantly, or we may be required to expend more resources. It is also possible that any such additional studies, if performed and completed, may not be considered sufficient by the FDA to make our applications approvable. If any of these outcomes occur, we may be forced to delay or abandon our applications for approval. 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 an ongoing Phase 3 clinical trial (in biologic-naïve patients) continues to enroll patients and results are expected in late 2024, there can be no assurance that such data will ultimately result in FDA approval.

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

The FDA may also require us to conduct additional clinical trials after granting approval of a product. The FDA has the explicit authority to require post-marketing studies (also referred to as post-approval or Phase 4 studies), labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. Post-approval studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other data about our marketed products (or data about products similar to our marketed products that implicate an entire class of products or are perceived to do so) may result in changes in product labeling, restrictions on use, product withdrawal or recall, loss of approval, or lower sales of our products. Obligations equivalent in scope, but which can vary widely in application, apply in 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 may be delayed because the FDA requests additional information or for other reasons, including those beyond our control. For example, in 2022, an FDA travel complication related to scheduling a routine clinical trial site inspection in eastern Europe delayed by nearly two months the FDA's approval of our sBLA for the combination treatment of Libtayo with chemotherapy in NSCLC.

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

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 present a challenging environment 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 June 2023, the FDA issued a CRL concerning the Company's BLA for EYLEA HD for the treatment of wAMD, DME, and DR due to unresolved observations resulting from an inspection at the contract manufacturing organization Catalent, which resulted in a delay of the FDA approval of EYLEA HD by nearly two months. For additional information, see *"Risks Related to Manufacturing and Supply - Our or our collaborators' failure to meet the stringent requirements of governmental regulation in the manufacture of drug products or product candidates could result in incurring substantial remedial costs, delays in the development or approval of our product candidates or new indications for our marketed products and/or in their commercial launch if regulatory approval is obtained, and a reduction in sales."* Our business, prospects, operating results, and financial condition may be materially harmed as a result of noncompliance with the requirements and regulations described in this paragraph.

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

In addition to the 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; this will be the case for Libtayo in many jurisdictions outside the United States (including Europe and Japan) once we complete the transition from Sanofi pursuant to the amendment to the IO Collaboration 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 Marketing Authorization Application ("MAA") in the EU. In addition, such authorities often have the authority to require post-approval studies, such as a PASS and/or PAES, which involve various risks similar to those described above. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval of the product by the comparable regulatory authorities in 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 the FDA's GLPs or GCPs. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

Additionally, conducting clinical trials in 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 IDMCs. These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, we previously discontinued actively treating patients with fasinumab following a recommendation from the responsible IDMC that the program be terminated based on available evidence at that time; and we later discontinued further clinical development of fasinumab. The recommended termination or material modification of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business, prospects, operating results, and financial condition may be materially harmed.

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

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

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

With respect to EYLEA and 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

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

market. Further, failure to successfully develop or supply and manufacture these devices, or to gain or maintain their approval, could adversely affect sales of the related products.

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

Risks Related to Intellectual Property and Market Exclusivity

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

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

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements and other means. If our trade secrets are improperly disclosed, by our current or former employees, our collaborators, or otherwise, it could help our competitors and adversely affect our business. 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 described in Note 16 to our Consolidated Financial Statements included in this report. Post-grant proceedings are increasingly common in the United States and are costly to defend. In addition, patent applications filed outside the United States may be challenged by other parties, for example, by filing pre-grant third-party observations that argue against patentability or a post-grant opposition. Such opposition proceedings are increasingly common in Europe and are costly to defend. For example, in 2021, anonymous parties initiated opposition proceedings in the European Patent Office ("EPO") against our European Patent No. 2,944,306 (which concerns pre-filled syringes comprising ophthalmic formulations containing VEGF antagonists such as aflibercept for intravitreal administration), as described in Note 16 to our Consolidated Financial Statements included in this report. We have pending patent applications in the United States Patent and Trademark Office (the "USPTO"), the EPO, and the patent offices of other foreign jurisdictions, and it is likely that we will need to defend patents from challenges by others from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions or our ability to obtain, maintain, and enforce our intellectual property rights. Any such changes could also affect the value of our intellectual property or narrow the scope of our patents. 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 would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia.

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

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

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

We have been in the past, are currently, and may in the future be involved in patent litigation and other proceedings involving patents and other intellectual property. For example, we 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, in the EU, a designated orphan drug is provided up to 10 years of market exclusivity in the orphan indication, during which time the EMA is generally precluded from accepting a MAA for a similar medicinal product unless it can be demonstrated that it is safer, more effective, or otherwise clinically superior to the original orphan medicinal product.

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

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

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

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

A number of jurisdictions outside 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. A biosimilar version of EYLEA was recently approved in the EU and we are aware of several other companies developing biosimilar versions of EYLEA, as discussed further under "Risks Related to Commercialization of Our Marketed Products, Product Candidates, and New Indications for Our Marketed Products - *The commercial success of our products and product candidates is subject to significant competition - Marketed Products*" above. In the United States, the regulatory exclusivity period for EYLEA (i.e., the period during which no biosimilar product can be approved by the FDA) extends through May 17, 2024 following the pediatric exclusivity granted by the FDA. 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.*"). The loss of market exclusivity for a product (such as EYLEA or EYLEA HD) 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 may in the future further exacerbate certain of these risks. For example, the impact of prioritizing certain manufacturing-related resources for our COVID-19 monoclonal antibodies has included and may in the future include, among other things, drawing down inventory safety stock levels for certain of our other products (including Dupixent and EYLEA). Depending on the demand for our products and other relevant factors, we may not be able to replenish our inventory safety stock to the levels we deem prudent or supply our products and product candidates in sufficient quantities to satisfy our commercial and development needs. We also rely entirely

on other parties and our collaborators for filling and finishing services. Generally, in order for other parties to perform any step in the manufacturing and supply chain, we must transfer technology to the other party, which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these other parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to directly or through other parties manufacture and supply sufficient commercial and clinical quantities of our products on acceptable terms, or if we should encounter delays or other difficulties with our collaborators, contract manufacturers, warehouses, shipping, testing laboratories, or other parties involved in our supply chain which adversely affect the timely manufacture and supply of our products or product candidates, our business, prospects, operating results, and financial condition may be materially harmed.

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

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

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

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

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

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

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

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

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

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

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

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

We and our collaborators and other third-party providers are required to maintain compliance with cGMPs, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or

modifications of methods of manufacturing may require amending our application(s) to the FDA or such comparable foreign agencies and acceptance of the change by the FDA or such comparable foreign agencies prior to release of product(s). Because we produce multiple products and product candidates at our facilities in Rensselaer, New York and Limerick, Ireland, there are increased risks associated with cGMP compliance. Our inability, or the inability of our collaborators and third-party fill/finish or other service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of any marketed products, and could also delay or prevent our obtaining regulatory approval for our product candidates or new indications for our marketed products. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product or product candidate as a result of a failure of our facilities or the facilities or operations of our collaborators or other third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop, obtain approval for, and successfully commercialize our products, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs, cause us to delay the development of our product candidates, result in delay in our obtaining, or our not obtaining, regulatory approval of product candidates or new indications for our marketed products, and cause us to lose revenue from any marketed products, which could be seriously detrimental to our business, prospects, operating results, and financial condition. For example, in June 2023, the FDA issued a CRL concerning the Company's BLA for EYLEA HD for the treatment of wAMD, DME, and DR due to unresolved observations resulting from an inspection at a third-party fill/finish provider, the contract manufacturing organization Catalent, which resulted in a delay of the FDA approval of EYLEA HD by nearly two months. 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 may also be subject to claims by patients who use our approved products, or our product candidates if those product candidates receive regulatory approval and become commercially available, that they have been injured by a side effect associated with the drug. Even in a circumstance in which we do not believe that an adverse event is related to our products or product candidates, the related investigation may be time consuming or inconclusive and may have a negative impact on our reputation or business. We may face product liability claims and be found responsible even if injury arises from the acts or omissions of third parties who provide fill/finish or other services. To the extent we maintain product liability insurance in relevant periods, such insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

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

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

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

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

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

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

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

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

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

In addition, the final regulation issued by HRSA regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities has affected our obligations and potential liability under the 340B program. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that we have violated the requirements of the program or the regulation could negatively impact our financial results. Moreover, HRSA established an ADR process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could subject us to onerous procedural requirements and could result in additional liability. On November 30, 2022, HRSA issued a notice of proposed rulemaking that proposes several changes to the ADR process; and, following the solicitation of public comments, in October 2023 HRSA submitted a final version of the rule to the White House Office of Management and Budget for review. Further, any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the PPACA or otherwise could affect our 340B ceiling price calculations and negatively impact our results of operations.

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

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

Pursuant to applicable law, knowing provision of false information in connection with price reporting or contract-based requirements under the VA/FSS and/or Tricare programs can subject a manufacturer to civil monetary penalties. These program and contract-based obligations also contain extensive disclosure and certification requirements. If we overcharge the government in connection with our arrangements with FSS or Tricare, we are required to refund the difference to the government. Failure to make necessary disclosures or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and/or response to a government investigation or enforcement

action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations, and future prospects.

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

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

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

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

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

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

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, intellectual property rights, and the framework for dispute resolution and asserting our rights against others, are subject to extensive legislation and regulation. Changes in applicable U.S. federal, state, and foreign laws and agency regulations 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 several 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 are in the process of establishing commercial capabilities related to Libtayo in many jurisdictions outside the United States following the 2022 amendment to the IO Collaboration; 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, trade protection measures, import or export licensing requirements, trade embargoes, and sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), and other trade barriers;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

We have large-scale manufacturing operations in Limerick, Ireland and have also established offices in the United Kingdom, Germany, 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 Organization for Economic Co-operation and Development ("OECD") Global Anti-Base Erosion Model Rules ("Pillar Two") have 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 data privacy laws in the United States and abroad.

We have operations and conduct business in several countries outside the United States and plan to significantly expand 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.*" These activities subject us to additional data protection authority oversight and require us to comply with stringent local and regional data privacy laws, including the EU's General Data Protection Regulations ("GDPR"). The GDPR has a wide range of compliance obligations, including increased consent and transparency requirements and data subject rights. Violations of the GDPR carry significant financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher)). In addition to the GDPR, certain EU Member States have issued or will be issuing their own implementation legislation. In June 2021, the EC introduced new standard contractual clauses required to be incorporated into certain new and existing agreements within prescribed timeframes in order to continue to lawfully transfer personal data outside the EU. Many of the countries that have comprehensive data privacy laws have modeled their requirements after the GDPR. Compliance with these requirements has been and is expected to continue to be costly and time consuming.

We conduct clinical trials in many countries around the world, which have new or evolving data privacy laws that are often not interpreted consistently by regulatory authorities, institutional review boards/ethics committees, or clinical trial sites. This complexity has resulted in increased liability in the management of clinical trial data, as well as additional compliance, contractual, and due-diligence obligations that could lead to a delay in clinical trial site start-up. There also has been an increase of enforcement activities in various EU countries that require evidence of compliance with local data privacy requirements. While we continue to monitor these developments, there remains some uncertainty surrounding the legal and regulatory environment for these evolving privacy and data protection laws. Complying with varying jurisdictional requirements could increase the costs and complexity of compliance, including the risk of substantial financial penalties for insufficient notice and consent, failure to respond to data subject rights requests, lack of a legal basis for the transfer of personal information out of the EU or other countries with localization laws (i.e., laws mandating that personal data collected in a foreign country be processed and stored within that country), or improper processing of personal data. Failure by our collaborators to comply with the strict rules on the transfer of personal data into the U.S. could result in the imposition of criminal and administrative sanctions on such collaborators or impact the flow of personal data, which could adversely affect our business.

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

Consumer protection laws impact the manner in which we develop and maintain processes to support our patient assistance programs, product marketing activities, and the sharing of employee and clinical data for internal and third-party commercial activities. Several U.S. states have proposed and passed consumer privacy laws, which were modeled after the CCPA and influenced by the GDPR. The CCPA is a consumer protection law that establishes requirements for data use and sharing transparency and provides California residents with personal data privacy rights regarding the use, disclosure, and retention of their personal data. Amendments to the CCPA have, among other things, imposed new obligations to provide notice where personal data will be de-identified. Failure to comply with the CCPA may result in, among other things, significant civil penalties and injunctive relief, or statutory or actual damages. In addition, California residents have the right to bring a private right of action in connection with data privacy incidents involving certain elements of personal data. These claims may result in significant liability and damages. These laws and regulations are constantly evolving and may impose limitations on our business activities. Several additional state consumer privacy laws went into effect in 2023 and many other consumer privacy laws are

expected to go into effect in the near future. Notably, these state laws provide more restrictions on the use of sensitive personal data, including health information. These states require robust consent and authorizations prior to any collection or use of this data, which may have a large impact on our ability to market to individuals in these jurisdictions based on their health conditions. At the federal level, Section 5 of the FTC Act is a consumer protection law that bars unfair and deceptive acts and practices and requires, among other things, companies to notify individuals that they will safeguard their personal data and that they will fulfil the commitments made in their privacy notices. The FTC has brought legal actions against organizations that have violated consumers' privacy rights or have misled them by failing to maintain appropriate security. For example, in 2023 the FTC issued several enforcement actions related to privacy in the healthcare space, under both Section 5 of the FTC Act and the Health Breach Notification Rule, involving companies allegedly using consumer health data for marketing purposes in violation of their own policies and assurances.

Furthermore, health privacy laws, data breach notification laws, consumer protection laws, data localization laws, biometric privacy laws, and genetic privacy laws may apply directly 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. Individuals about whom we or our collaborators obtain health or other personal data, as well as the providers and third parties who share this data with us, may have statutory or contractual limits that impact our ability to further use and disclose the data. Many of these laws differ from each other in significant ways and have different effects. Many of the state laws enable a state attorney general to bring actions and provide private rights of action to consumers as enforcement mechanisms. Compliance with these laws requires a flexible privacy framework as they are constantly evolving. Federal regulators, state attorneys general, and plaintiffs' attorneys have been active in this space.

If we or any collaborators fail to comply with applicable federal, state, local, or foreign regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to commercialize our products. 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 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. 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. 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 commercial capabilities outside the United States for Libtayo, Dupixent, and any other 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 commercial capabilities outside the United States for Libtayo, Dupixent, and any other 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. The process of proposing, negotiating, completing, and integrating any such acquisition is lengthy and complex. Other companies may compete with us for such acquisitions. In addition, we may not be able to integrate any acquired business successfully or operate any acquired business profitably. Integrating any newly acquired business could be expensive and time consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational, and financial resources, result in a loss of key personnel of the acquired business, and could prove to be more difficult or expensive than we predict. The diversion of our management's attention and any delay or difficulties encountered in connection with any acquisitions we may consummate could result in the disruption of our ongoing business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, products, or product candidates, which may result in dilution for shareholders or the incurrence of indebtedness.

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

In addition, we may experience significant charges to earnings in connection with our efforts, if any, to consummate acquisitions. For transactions that are ultimately not consummated, these charges may include fees and expenses for investment bankers, attorneys, accountants, and other advisors in connection with our efforts. Even if our efforts 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 President and Chief Executive Officer, and George D. Yancopoulos, M.D., Ph.D., our President and Chief Scientific Officer. We are also highly dependent on the expertise and services of other senior management members leading our research, development, manufacturing, and commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the research, development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

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

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

In addition, our systems are potentially vulnerable to data security breaches - whether by employees or others - which may expose sensitive data to unauthorized persons. Data security breaches could lead to the loss of trade secrets or other intellectual property,

result in demands for ransom or other forms of blackmail, or lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, customers, and others. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage or extortion) and expertise, including by organized criminal groups, "hacktivists," nation states, and others. As a company with an increasingly global presence, our systems are subject to frequent attacks. There is the potential that our systems may be directly or indirectly affected as nation-states conduct global cyberwarfare, including in connection with the current Russia-Ukraine 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 the COVID-19 pandemic or other 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, 2023, we had an aggregate of \$2.703 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, our revenues will increase, having a positive impact on net income, but our overall expenses will increase, having a negative impact. Conversely, if the U.S. dollar strengthens against a specific foreign currency, our revenues will decrease, having a negative impact on net income, but our overall expenses will decrease, having a positive impact. Therefore, significant changes in foreign exchange rates can impact our operating results and the financial condition of our Company. 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, 2023, we had \$2.730 billion in cash and cash equivalents and \$13.511 billion in marketable securities (including \$977.4 million 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, as well as 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;
- 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;
- public concern as to the safety or effectiveness of any of our marketed products or product candidates or new indications for our marketed products;
- pricing or reimbursement actions, decisions, or recommendations by government authorities, insurers, or other organizations (such as health maintenance organizations and PBMs) affecting the coverage, reimbursement, or use of any of our marketed products or competitors' products;
- our ability to raise additional capital as needed on favorable terms;
- developments in our relationships with collaborators or key customers;
- developments in the biotechnology industry or in government regulation of healthcare, including those relating to compounding (i.e., a practice in which a pharmacist, a physician, or, in the case of an outsourcing facility, a person under the supervision of a pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient);
- large sales of our Common Stock by our executive officers or other employees, directors, or significant shareholders (or the expectation of any such sales);
- changes in tax rates, laws, or interpretation of tax laws;
- arrivals and departures of key personnel;
- general market conditions;
- 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;
- trading activity that results from the rebalancing of stock indices in which our Common Stock is included, or the inclusion or exclusion of our Common Stock from such indices;
- other factors identified in these "Risk Factors"; and
- the perception by the investment community or our shareholders of any of the foregoing factors.

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

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

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of December 31, 2023, our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39.3% 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, 2023. If our significant shareholders or we sell substantial amounts of our Common Stock in the public market, or there is a perception that such sales may occur, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

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

In January 2023, our board of directors authorized a share repurchase program to repurchase up to \$3.0 billion of our Common Stock (of which \$1.531 billion remained available as of December 31, 2023). There can be no assurance of any future share repurchases or share repurchase program authorizations. Any share repurchases will depend upon, among other factors, our cash balances and potential future capital requirements, our results of operations and financial condition, the price of our Common Stock on the NASDAQ Global Select Market, and other factors that we may deem relevant. We can provide no assurance that we will repurchase shares of our Common Stock at favorable prices, if at all.

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

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of December 31, 2023, holders of Class A Stock held 14.5% 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, 2023:

- our current executive officers and directors beneficially owned 6.1% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2023, and 17.7% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2023; and
- our five largest shareholders plus Dr. Schleifer, our Chief Executive Officer, beneficially owned approximately 39.3% 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, 2023. In addition, these five shareholders plus our Chief Executive Officer held approximately 46.5% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of December 31, 2023.

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 risks based on probability and potential impact to key business systems and processes. 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 reported to the Technology Risk Management Committee and tracked as part of our overall risk management program 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 third-party cybersecurity risk management process to conduct due diligence on external entities, including those that perform cybersecurity services.

Cybersecurity threats, including those resulting from any previous cybersecurity incidents, have not materially affected our Company, including our business strategy, results of operations, or financial condition. We do not believe that cybersecurity threats resulting from any previous cybersecurity incidents of which we are aware are reasonably likely to materially affect our Company. 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 description of 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 information security 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, the Audit Committee of our board of directors, and the Audit Committee chair.

Item 2. Properties

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

Tarrytown, New York

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

Rensselaer, New York

We own facilities in Rensselaer, New York totaling approximately 1,260,000 square feet of manufacturing, research, office, and warehouse space. In addition, we have constructed an approximately 341,000 square foot fill/finish facility in Rensselaer, New York that is undergoing process validation as required by regulatory authorities.

Limerick, Ireland

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

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market for Registrant's Common Equity

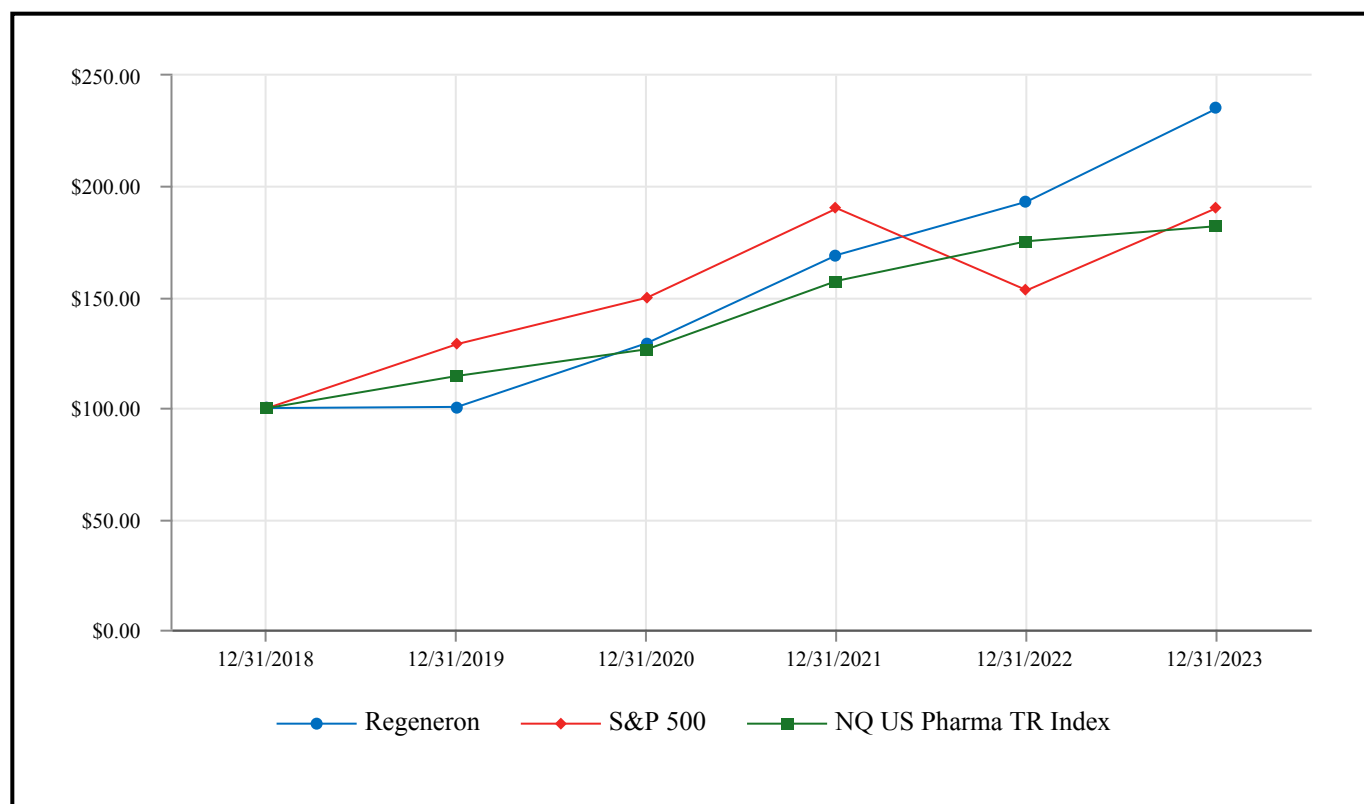
Our Common Stock, par value \$.001 per share, is quoted on The NASDAQ Global Select Market under the symbol "REGN." Our Class A Stock, par value \$.001 per share, is not publicly quoted or traded.

As of January 25, 2024, there were 153 shareholders of record of our Common Stock and 14 shareholders of record of our Class A Stock.

We have never paid cash dividends on our Common Stock or Class A Stock and do not currently have plans to do so.

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, 2018 through December 31, 2023. The comparison assumes that \$100 was invested on December 31, 2018 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.



	<u>12/31/2018</u>	<u>12/31/2019</u>	<u>12/31/2020</u>	<u>12/31/2021</u>	<u>12/31/2022</u>	<u>12/31/2023</u>
Regeneron	\$ 100.00	\$ 100.53	\$ 129.35	\$ 169.08	\$ 193.17	\$ 235.15
S&P 500	\$ 100.00	\$ 128.88	\$ 149.83	\$ 190.13	\$ 153.16	\$ 190.27
NQ US Pharma TR Index	\$ 100.00	\$ 114.51	\$ 126.56	\$ 157.42	\$ 175.29	\$ 182.08

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

Issuer Purchases of Equity Securities

The table below reflects shares of Common Stock we repurchased under our share repurchase programs, as well as Common Stock withheld by us for employees to satisfy their tax withholding obligations arising upon the vesting of restricted stock granted under one of our long-term incentive plans, during the three months ended December 31, 2023. 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 (In millions)
11/1/2023–11/30/2023	272,952	\$ 802.55	269,976	\$ 1,609.1
12/1/2023–12/31/2023	558,642	\$ 849.22	93,108	\$ 1,530.6
Total	831,594 ^(a)		363,084 ^(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.

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, 2022 (filed with the SEC on February 6, 2023) for additional discussion of our financial condition and results of operations for the year ended December 31, 2021, as well as our financial condition and results of operations for the year ended December 31, 2022 compared to the year ended December 31, 2021.

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 eleven FDA-approved products that have received marketing approval and approximately 35 product candidates in clinical development, almost all of which were homegrown in our laboratories.

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

Critical Accounting Estimates

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

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

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. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In addition, we reassess our forfeiture rate assumptions at least annually, considering both historical forfeiture experience and an estimate of future forfeitures for currently outstanding unvested awards. The assumptions used in computing the fair value of equity awards reflect our best estimates but involve uncertainties related to market and other conditions, many of which are outside our control. Changes in any of these assumptions may materially affect the fair value of awards granted and the amount of stock-based compensation recognized in future periods.

We use the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility is estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our historical exercise experience with previously issued employee and board of director option grants. The expected dividend yield is zero as we have never paid dividends and do not currently have plans to do so.

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 the future economic benefit is expected to be realized; otherwise, such costs are expensed. The determination to capitalize inventory costs is based on various factors, including status and expectations of the regulatory approval process, any known safety or efficacy concerns, potential labeling restrictions, and any other impediments to obtaining regulatory approval.

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

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

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. In a business combination, 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

<i>(In millions, except per share data)</i>	Year Ended December 31,		
	2023	2022	2021
Revenues	\$ 13,117.2	\$ 12,172.9	\$ 16,071.7
Operating expenses	9,070.1	7,434.0	7,124.9
Income from operations	4,047.1	4,738.9	8,946.8
Other income (expense)	152.2	119.9	379.0
Income before income taxes	4,199.3	4,858.8	9,325.8
Income tax expense	245.7	520.4	1,250.5
Net income	<u>\$ 3,953.6</u>	<u>\$ 4,338.4</u>	<u>\$ 8,075.3</u>
Net income per share - diluted	\$ 34.77	\$ 38.22	\$ 71.97

Revenues

(In millions)	Year Ended December 31,			\$ Change	
	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Net product sales:					
EYLEA HD - U.S.	\$ 165.8	\$ —	\$ —	\$ 165.8	\$ —
EYLEA - U.S.	5,719.6	6,264.6	5,792.3	(545.0)	472.3
Total EYLEA HD and EYLEA - U.S.	5,885.4	6,264.6	5,792.3	(379.2)	472.3
Libtayo - U.S.	538.8	374.5	306.3	164.3	68.2
Libtayo - ROW*	324.3	73.0	—	251.3	73.0
Total Libtayo - Global	863.1	447.5	306.3	415.6	141.2
Praluent - U.S.	182.4	130.0	170.0	52.4	(40.0)
REGEN-COV - U.S.	—	—	5,828.0	—	(5,828.0)
Evkeeza - U.S.	77.3	48.6	18.4	28.7	30.2
Inmazoleb - U.S.	69.8	3.0	—	66.8	3.0
ARCALYST - U.S.**	—	—	2.2	—	(2.2)
Total net product sales	\$ 7,078.0	\$ 6,893.7	\$ 12,117.2	\$ 184.3	\$ (5,223.5)
Collaboration revenue:					
Sanofi	\$ 3,799.5	\$ 2,855.7	\$ 1,902.2	\$ 943.8	\$ 953.5
Bayer	1,487.5	1,430.7	1,409.3	56.8	21.4
Roche	211.0	627.3	361.8	(416.3)	265.5
Other	5.1	0.4	—	4.7	0.4
Other revenue	536.1	365.1	281.2	171.0	83.9
Total revenues	\$ 13,117.2	\$ 12,172.9	\$ 16,071.7	\$ 944.3	\$ (3,898.8)

* Effective July 1, 2022, the Company became solely responsible for the research, development, and commercialization of Libtayo worldwide and began recording net product sales of Libtayo outside the United States.

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

Net Product Sales

Net product sales of EYLEA in the United States decreased in 2023, compared to 2022, primarily due to changing market dynamics, resulting in a lower net selling price and lower volumes. EYLEA volumes in 2023 were impacted by the August 2023 launch of EYLEA HD and subsequent transition of EYLEA patients to EYLEA HD.

During the year ended December 31, 2021, we recorded net product sales of REGEN-COV in connection with our agreements with the U.S. government. As of December 31, 2021, the Company had completed its final deliveries of drug product under its agreements with the U.S. government; as a result, there were no net product sales of REGEN-COV in the United States recorded during the years ended December 31, 2023 and 2022.

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.

<i>(In millions)</i>	Rebates, Chargebacks, and Discounts	Distribution- Related Fees	Other Sales- Related Deductions	Total
Balance as of December 31, 2020	\$ 202.2	\$ 77.2	\$ 44.8	\$ 324.2
Provisions	1,047.1	363.6	150.4	1,561.1
Credits/payments	<u>(1,034.7)</u>	<u>(360.8)</u>	<u>(127.6)</u>	<u>(1,523.1)</u>
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	<u>(1,398.0)</u>	<u>(399.7)</u>	<u>(127.2)</u>	<u>(1,924.9)</u>
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	<u>(1,972.7)</u>	<u>(388.3)</u>	<u>(157.5)</u>	<u>(2,518.5)</u>
Balance as of December 31, 2023	<u>\$ 455.7</u>	<u>\$ 162.3</u>	<u>\$ 79.3</u>	<u>\$ 697.3</u>

Sanofi Collaboration Revenue

<i>(In millions)</i>	Year Ended December 31,		
	2023	2022	2021
Antibody:			
Regeneron's share of profits in connection with commercialization of antibodies	\$ 3,136.5	\$ 2,082.0	\$ 1,363.0
Sales-based milestones earned	50.0	100.0	50.0
Reimbursement for manufacturing of commercial supplies ^(a)	613.0	633.7	488.8
Other	—	28.7	—
Total Antibody	<u>3,799.5</u>	<u>2,844.4</u>	<u>1,901.8</u>
Total Immuno-oncology ^(b)	—	11.3	0.4
Total Sanofi collaboration revenue	<u>\$ 3,799.5</u>	<u>\$ 2,855.7</u>	<u>\$ 1,902.2</u>

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

^(b) As the A&R IO LCA became effective July 1, 2022, the three months ended June 30, 2022 was the last quarter in which Sanofi collaboration revenue was recognized in connection with the IO Collaboration.

Antibody

Global net product sales of Dupixent and Kevzara are recorded by Sanofi in connection with the Antibody Collaboration, and we and Sanofi share profits on such sales. As described in Part I, Item 1. "Business - Collaboration, License, and Other Agreements - Sanofi - Antibody", on July 1, 2022, an amendment to the LCA became effective, pursuant to which the percentage of Regeneron's share of profits in any calendar quarter used to reimburse Sanofi for development costs which were funded by Sanofi increased from 10% to 20%.

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

<i>(In millions)</i>	Year Ended December 31,		
	2023	2022	2021
Dupixent and Kevzara net product sales	\$ 11,974.0	\$ 9,039.2	\$ 6,536.3
Regeneron's share of collaboration profits	3,596.3	2,405.5	1,511.5
Reimbursement of development expenses incurred by Sanofi in accordance with Regeneron's payment obligation ^(a)	(459.8)	(266.6)	(148.5)
One-time payment in connection with amendment to the Antibody License and Collaboration Agreement	—	(56.9)	—
Regeneron's share of profits in connection with commercialization of antibodies	\$ 3,136.5	\$ 2,082.0	\$ 1,363.0
Regeneron's share of profits as a percentage of Dupixent and Kevzara net product sales	26%	23%	21%

^(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 in connection with commercialization of antibodies during the year ended December 31, 2023, compared to 2022, was driven by higher profits associated with Dupixent sales, partly offset by the impact of the amendment to the LCA.

During the year ended December 31, 2023, the Company earned the final \$50.0 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding \$3.0 billion on a rolling twelve-month basis. During the year ended December 31, 2022, the Company earned two \$50.0 million sales-based milestones from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding \$2.0 billion and \$2.5 billion, respectively, on a rolling twelve-month basis.

Reimbursements for manufacturing of commercial supplies primarily relate to Dupixent and are recognized when the product is sold by Sanofi to third-party customers; such reimbursements decreased during the year ended December 31, 2023, compared to 2022, primarily due to lower manufacturing costs resulting from the transition to a higher-yielding manufacturing process.

Bayer Collaboration Revenue

<i>(In millions)</i>	Year Ended December 31,		
	2023	2022	2021
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	\$ 1,376.4	\$ 1,317.4	\$ 1,349.2
Reimbursement for manufacturing of ex-U.S. commercial supplies ^(a)	111.1	91.4	60.1
One-time payment in connection with change in Japan arrangement ^(b)	—	21.9	—
Total Bayer collaboration revenue	\$ 1,487.5	\$ 1,430.7	\$ 1,409.3

^(a) Corresponding costs incurred by the Company in connection with such production 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 outside the United States. Regeneron's share of profits in connection with commercialization of EYLEA outside the United States is summarized below:

<i>(In millions)</i>	Year Ended December 31,		
	2023	2022	2021
EYLEA net product sales outside the United States	\$ 3,495.2	\$ 3,382.8	\$ 3,450.9
Regeneron's share of collaboration profit from sales outside the United States	\$ 1,436.1	\$ 1,375.1	\$ 1,408.3
Reimbursement of development expenses incurred by Bayer in accordance with Regeneron's payment obligation ^(a)	(59.7)	(57.7)	(59.1)
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	\$ 1,376.4	\$ 1,317.4	\$ 1,349.2
Regeneron's share of profits as a percentage of 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

<i>(In millions)</i>	Year Ended December 31,		
	2023	2022	2021
Global gross profit payment from Roche in connection with sales of REGEN-COV and Ronapreve	\$ 224.3	\$ 627.3	\$ 361.8
Other	(13.3)	—	—
Total Roche collaboration revenue	\$ 211.0	\$ 627.3	\$ 361.8

Roche distributes and records net product sales of Ronapreve outside the United States, and the parties share gross profits from worldwide sales.

Other Revenue

Other revenue in 2023 included the recognition of \$50.4 million of revenue in connection with our August 2023 agreement with BARDA to fund certain costs for a next-generation COVID-19 monoclonal antibody therapy for the prevention of SARS-CoV-2 infection. In addition, Other revenue increased in 2023, compared to 2022, primarily due to the following:

- higher reimbursements for the manufacture of commercial supplies for Sanofi related to Praluent outside the United States;
- higher share of profits earned in connection with sales of ARCALYST pursuant to our license agreement with Kiniksa Pharmaceuticals, Ltd.; and
- royalties earned in connection with our license agreement with Novartis, under which we receive royalties on worldwide sales of Novartis' Ilaris[®] (canakinumab).

Expenses

<i>(In millions, except headcount data)</i>	Year Ended December 31,			Change	
	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Research and development ^(a)	\$ 4,439.0	\$ 3,592.5	\$ 2,860.1	\$ 846.5	\$ 732.4
Acquired in-process research and development	186.1	255.1	48.0	(69.0)	207.1
Selling, general, and administrative ^(a)	2,631.3	2,115.9	1,824.9	515.4	291.0
Cost of goods sold	932.1	800.0	1,773.1	132.1	(973.1)
Cost of collaboration and contract manufacturing ^(b)	883.7	760.4	664.4	123.3	96.0
Other operating (income) expense, net	(2.1)	(89.9)	(45.6)	87.8	(44.3)
Total operating expenses	<u>\$ 9,070.1</u>	<u>\$ 7,434.0</u>	<u>\$ 7,124.9</u>	<u>\$ 1,636.1</u>	<u>\$ 309.1</u>
Average headcount	12,698	11,115	9,884	1,583	1,231

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

^(b) Includes costs incurred in connection with producing commercial drug supplies for collaborators and others

Operating expenses in 2023 and 2022 included a total of \$885.0 million and \$725.0 million, respectively, of stock-based compensation expense related to equity awards granted under our long-term incentive plans. As of December 31, 2023, unrecognized stock-based compensation expense related to unvested stock options and unvested restricted stock (including performance-based restricted stock units) was \$589.6 million and \$1.127 billion, respectively. We expect to recognize this stock-based compensation expense related to stock options and restricted stock over weighted-average periods of 1.8 years and 2.3 years, respectively.

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 includes pre-launch commercial supplies which did not meet the criteria to be capitalized as inventory (see "Critical Accounting Policies and Use of Estimates - Inventories" above). The table below also includes reimbursements of research and development expenses by collaborators, as when we are entitled to reimbursement of all or a portion of such expenses that we incur under a collaboration, we record those reimbursable amounts in the period in which such costs are incurred.

<i>(In millions)</i>	Year Ended December 31,			\$ Change	
	2023	2022*	2021*	2023 vs. 2022	2022 vs. 2021
Direct research and development expenses:					
Dupixent (dupilumab)	\$ 168.0	\$ 156.5	\$ 146.4	\$ 11.5	\$ 10.1
Fianlimab	112.2	43.4	8.7	68.8	34.7
Libtayo (cemiplimab)	105.3	138.0	146.2	(32.7)	(8.2)
Odronextamab	96.3	66.0	34.9	30.3	31.1
EYLEA HD (aflibercept) 8 mg	96.2	67.9	73.5	28.3	(5.6)
Linvoseltamab	78.7	45.5	18.7	33.2	26.8
Itepekimab	70.3	26.5	—	43.8	26.5
Pozelimab	60.2	72.4	28.3	(12.2)	44.1
REGEN-COV	(5.6)	32.8	309.8	(38.4)	(277.0)
Other product candidates in clinical development and other research programs	514.0	393.9	429.7	120.1	(35.8)
Total direct research and development expenses	1,295.6	1,042.9	1,196.2	252.7	(153.3)
Indirect research and development expenses:					
Payroll and benefits	1,537.0	1,195.5	981.4	341.5	214.1
Lab supplies and other research and development costs	210.6	181.0	142.0	29.6	39.0
Occupancy and other operating costs	518.2	508.5	414.9	9.7	93.6
Total indirect research and development expenses	2,265.8	1,885.0	1,538.3	380.8	346.7
Clinical manufacturing costs	1,053.9	938.3	621.7	115.6	316.6
Reimbursement of research and development expenses by collaborators	(176.3)	(273.7)	(496.1)	97.4	222.4
Total research and development expenses	\$ 4,439.0	\$ 3,592.5	\$ 2,860.1	\$ 846.5	\$ 732.4

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

Total research and development expenses increased in 2023, compared to 2022, partially due to the impact of the amendments to the Sanofi collaboration agreements (which were effective July 1, 2022) described above in Part I, Item 1. "Business - Collaboration, License, and Other Agreements - Sanofi", as (i) Sanofi is no longer reimbursing us for 50% of Libtayo development costs (such reimbursements were previously included in Reimbursement of research and development expenses by collaborators in the table above) and (ii) we recognize our 50% share of research and development expenses in connection with the Sanofi Antibody Collaboration.

Research and development expenses included stock-based compensation expense of \$488.7 million and \$406.8 million in 2023 and 2022, 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 pharmaceutical product, potential opportunities and/or uncertainties related to future indications to be studied, and the estimated cost and scope of the projects. The lengthy process of seeking FDA and other applicable approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business. We are unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows.

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

Acquired IPR&D in 2023 included:

- \$100.0 million charge in connection with a development milestone for the Phase 1 ALN-APP program, which is in collaboration with Alnylam;
- \$45.0 million up-front payment in connection with our collaboration agreement with Sonoma Biotherapeutics, Inc.; and
- \$30.0 million charge to extend the period for selecting targets under our collaboration agreement with Intellia.

Acquired IPR&D in 2022 included:

- \$195.0 million charge related to our acquisition of Checkmate Pharmaceuticals, Inc.;
- \$30.0 million up-front payment in connection with our collaboration agreement with CytomX Therapeutics, Inc.; and
- \$20.0 million opt-in payment in connection with a product candidate under our collaboration agreement with Adicet Bio, Inc.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased in 2023, compared to 2022, primarily due to higher headcount and headcount-related costs, an increase in commercialization-related expenses for Libtayo (including acquisition and integration-related costs for Libtayo outside the United States as effective July 1, 2022, the Company became solely responsible for the commercialization of Libtayo worldwide), and, to a lesser extent, commercialization-related expenses for various other products, and higher contributions to an independent not-for-profit patient assistance organization. Selling, general, and administrative expenses also included \$307.1 million and \$256.4 million of stock-based compensation expense in 2023 and 2022, respectively.

Cost of Goods Sold

Cost of goods sold increased in 2023, compared to 2022, primarily due to higher start-up costs for our Rensselaer, New York fill/finish facility and an increase in period costs at our manufacturing facilities resulting from lower production volumes, partly offset by lower inventory write-offs and reserves. Inventory write-offs and reserves were \$102.3 million in 2023 compared to \$258.7 million in 2022. The inventory write-offs and reserves in 2022 were primarily related to REGEN-COV.

Cost of Collaboration and Contract Manufacturing

Cost of collaboration and contract manufacturing increased in 2023, compared to 2022, primarily due to the recognition of costs in connection with manufacturing commercial supplies for Sanofi related to Praluent outside the United States and for Bayer related to EYLEA outside the United States. This increase was partly offset by lower Dupixent manufacturing costs as a result of the transition to a higher-yielding manufacturing process.

Other Operating (Income) Expense

Other operating (income) expense, net, in 2022 included the recognition of amounts previously deferred in connection with up-front and development milestone payments, as applicable, received in connection with our Sanofi IO, Teva, and Mitsubishi Tanabe Pharma Corporation ("MTPC") collaborative arrangements. As we discontinued further clinical development of fasinumab (for which we had collaborative arrangements with Teva and MTPC) during 2022, and the A&R IO LCA with Sanofi became effective July 1, 2022, no such amounts were recognized in connection with these collaborative arrangements during 2023.

Other Income (Expense)

Other income (expense) consists of the following:

<i>(In millions)</i>	Year Ended December 31,		
	2023	2022	2021
Unrealized (losses) gains on equity securities, net	\$ (237.8)	\$ (39.8)	\$ 386.1
Interest income	495.9	160.1	45.8
Foreign currency (losses) gains	(12.9)	50.2	0.4
Other	(20.0)	8.8	4.0
Other income (expense), net	225.2	179.3	436.3
Interest expense	(73.0)	(59.4)	(57.3)
Total other income (expense)	<u>\$ 152.2</u>	<u>\$ 119.9</u>	<u>\$ 379.0</u>

The increase in interest income in 2023, compared to 2022, was primarily driven by higher interest rates.

Income Taxes

<i>(In millions, except effective tax rate)</i>	Year Ended December 31,		
	2023	2022	2021
Income tax expense	\$ 245.7	\$ 520.4	\$ 1,250.5
Effective tax rate	5.9%	10.7%	13.4%

The Company's effective tax rate for 2023, compared to 2022, included a higher benefit from stock-based compensation, federal tax credits for research activities, and the proportion of income earned in foreign jurisdictions with tax rates lower than the U.S. federal statutory rate.

Certain countries in which we have operations, including Ireland, have adopted legislation influenced by the OECD Pillar Two rules, including a minimum tax rate of 15%. It is uncertain whether the United States will enact legislation to adopt the Pillar Two framework. While we do not expect the adoption of the Pillar Two framework to have a material impact on our effective tax rate, we are continuing to evaluate additional guidance released by the OECD, along with the pending legislative adoption by additional individual countries.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

<i>(In millions)</i>	As of December 31,		\$ Change
	2023	2022	
Financial assets:			
Cash and cash equivalents	\$ 2,730.0	\$ 3,105.9	\$ (375.9)
Marketable securities - current	8,114.8	4,636.4	3,478.4
Marketable securities - noncurrent	5,396.5	6,591.8	(1,195.3)
	<u>\$ 16,241.3</u>	<u>\$ 14,334.1</u>	<u>\$ 1,907.2</u>
Working capital:			
Current assets	\$ 19,479.2	\$ 15,884.1	\$ 3,595.1
Current liabilities	3,423.4	3,141.3	282.1
	<u>\$ 16,055.8</u>	<u>\$ 12,742.8</u>	<u>\$ 3,313.0</u>
Borrowings and finance lease liabilities:			
Long-term debt	\$ 1,982.9	\$ 1,981.4	\$ 1.5
Finance lease liabilities	\$ 720.0	\$ 720.0	\$ —

As of December 31, 2023, 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, 2023, 2022, and 2021

<i>(In millions)</i>	Year Ended December 31,			\$ Change	
	2023	2022	2021	2023 vs. 2022	2022 vs. 2021
Cash flows provided by operating activities	\$ 4,594.0	\$ 5,014.9	\$ 7,081.3	\$ (420.9)	\$ (2,066.4)
Cash flows used in investing activities	\$ (3,185.1)	\$ (3,784.6)	\$ (5,384.7)	\$ 599.5	\$ 1,600.1
Cash flows used in financing activities	\$ (1,790.1)	\$ (1,009.0)	\$ (1,005.8)	\$ (781.1)	\$ (3.2)

Cash Flows from Operating Activities

As of December 31, 2023 and 2022, deferred tax assets increased by \$837.8 million and \$746.4 million, respectively, primarily related to the impact of the Tax Cuts and Jobs Act of 2017, which requires, for tax purposes, the capitalization and amortization of research and development expenses effective for years beginning after December 31, 2021.

As of December 31, 2021, Accounts receivable increased by \$1.927 billion, compared to December 31, 2020, primarily due to REGEN-COV sales in connection with our September 2021 agreement to supply drug product to the U.S. government. As of December 31, 2022, Accounts receivable had decreased by \$707.8 million, compared to December 31, 2021, driven by the Company's collection of amounts due from the U.S. government in connection with such sales in the fourth quarter of 2021.

Other non-cash items, net, in 2022 and 2021 included inventory write-offs and reserves primarily related to REGEN-COV.

Cash Flows from Investing Activities

Capital expenditures in 2023 included costs incurred in connection with the expansion of our Tarrytown, New York location, as well as costs associated with the expansion of our manufacturing facilities in Rensselaer, New York (including the ongoing construction of a fill/finish facility and related equipment). Additionally, capital expenditures in 2023 is net of grant proceeds of \$60.0 million primarily related to the expansion of our facilities in New York. We expect to incur capital expenditures of \$825 million to \$950 million in 2024 primarily in connection with the continued expansion of our research, preclinical manufacturing, and support facilities at our Tarrytown, New York campus and our manufacturing facilities. We expect continued significant capital expenditures over the next several years in connection with the planned expansion of our Tarrytown, New York campus.

Payments for the Libtayo intangible asset of \$207.8 million and \$1.027 billion in 2023 and 2022, respectively, were related to our acquisition (including contingent consideration paid) of the exclusive right to develop, commercialize, and manufacture Libtayo worldwide (as described in Part I, Item 1. "Collaboration, License, and Other Agreements - *Sanofi - Immuno-Oncology*" above).

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 \$1.146 billion during 2023, compared to \$1.520 billion during 2022 and \$1.672 billion during 2021. For information related to repurchases of Common Stock, see "*Share Repurchase Programs*" section below.

Credit Facility

In December 2022, we entered into an agreement with a syndicate of lenders (the "2022 Credit Agreement") which provides for a \$750.0 million senior unsecured five-year revolving credit facility (the "2022 Credit Facility") and replaced the then-existing credit agreement, which was contemporaneously terminated. The 2022 Credit Agreement includes an option for the Company to elect to increase the commitments under the 2022 Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to \$500.0 million, subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. The 2022 Credit Agreement also provides a \$50.0 million sublimit for letters of credit.

As set forth in the 2022 Credit Agreement, we have the option to amend the 2022 Credit Agreement to establish environmental, social, and governance targets which will be used to adjust pricing under the 2022 Credit Facility, subject to parameters to be provided in the 2022 Credit Agreement.

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

We had no borrowings outstanding under the 2022 Credit Facility as of December 31, 2023.

The 2022 Credit Agreement contains operating covenants and a maximum total leverage ratio financial covenant. We were in compliance with all covenants of the 2022 Credit Agreement as of December 31, 2023.

Share Repurchase Programs

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

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

In January 2023, our board of directors authorized an additional share repurchase program to repurchase up to \$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. As of December 31, 2023, \$1.531 billion remained available for share repurchases under the program.

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

<i>(In millions)</i>	Year Ended December 31,		
	2023	2022	2021
Number of shares	2.9	3.3	3.0
Total cost of shares	\$ 2,214.6	\$ 2,099.8	\$ 1,655.0

Tarrytown, New York Lease

We are party to a Third Amended and Restated Lease and Remedies Agreement, dated March 27, 2023 (the "Third Amended and Restated Lease") with BA Leasing BSC, LLC, an affiliate of Banc of America Leasing & Capital, LLC ("BAL"), as lessor, which relates to our lease of laboratory and office facilities in Tarrytown, New York (the "Facility"); and a Third Amended and Restated Participation Agreement, dated March 27, 2023 (the "Third Amended and Restated Participation Agreement") with Bank of America, N.A., as administrative agent (the "Administrative Agent"), and a syndicate of lenders (collectively with BAL, the "Participants"), as rent assignees. The Third Amended and Restated Lease and Third Amended and Restated Participation Agreement provide for a March 2027 maturity date of the \$720.0 million 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) and the end of the term of our lease of the Facility from BAL, at which time all amounts outstanding thereunder will become due and payable in full.

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

The Third Amended and Restated Lease is classified as a finance lease as we have the option to purchase the Facility under terms that make it reasonably certain to be exercised. The agreements governing the Third Amended and Restated Lease financing contain financial and operating covenants. Such financial covenants and certain of the operating covenants are substantially similar to the covenants set forth in our 2022 Credit Agreement. The Company was in compliance with all such covenants as of December 31, 2023.

Additional Funding Requirements

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

We expect 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 \$696.4 million as of December 31, 2023. Due to their nature, there is a high degree of uncertainty regarding the period and amounts of potential future cash settlement with tax authorities. See Note 15 to our Consolidated Financial Statements.

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

As described in Part I, Item 1. "Collaboration, License, and Other Agreements," under our collaborations with Bayer and Sanofi, 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 Bayer and Sanofi for a defined percentage (generally 50%) of agreed-upon development expenses funded by Bayer and Sanofi (i.e., "development balance"). These reimbursements are deducted each quarter, in accordance with a formula, from our share of the collaboration profits otherwise payable to us, unless, in the case of Bayer, we elect to reimburse these expenses at a faster rate. As of December 31, 2023, our contingent reimbursement obligation to Bayer was approximately \$293 million and our contingent reimbursement obligation to Sanofi in connection with the companies' Antibody Collaboration was approximately \$2.330 billion. Therefore, we continue to expect that a portion of our share of profits from sales under our collaborations with Bayer and Sanofi will be used to reimburse our collaborators for these obligations.

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 \$98.7 million and \$102.7 million decrease in the fair value of our investment portfolio as of December 31, 2023 and 2022, respectively.

We have exposure to market risk for changes in interest rates, including the interest rate risk relating to our variable rate Tarrytown, New York lease (as described in Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources - *Tarrytown, New York Leases*"). Our interest rate exposure is 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 2023, 2022, and 2021, we did not record any charges for credit-related impairments of our available-for-sale debt securities.

We are subject to credit risk associated with the receivables due from our collaborators, including Bayer and Sanofi. We are also subject to credit risk in connection with trade accounts receivable due from our customers from our product sales. We have contractual payment terms with each of our collaborators and customers. We also monitor financial performance and credit worthiness so that we can properly assess and respond to any changes in collaborator and/or customer credit profiles. In 2023, 2022, and 2021, we did not recognize any charges for write-offs and allowances of accounts receivable related to credit risk for our collaborators or customers. As of December 31, 2023, two customers accounted on a combined basis for 83% of our net trade accounts receivables.

Foreign Exchange Risk

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

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

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

Market Price Risk

We are exposed to price risk on equity securities included in our investment portfolio. Our investments include equity securities of companies with which we have entered into collaboration arrangements. Changes in the fair value of our equity investments are included in Other income (expense), net on the Statements of Operations. We recorded \$237.8 million and \$39.8 million of net unrealized losses on equity securities in Other income (expense), net in 2023 and 2022, 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, 2023 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, 2023. The effectiveness of the Company's internal control over financial reporting as of December 31, 2023 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, 2023 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, 2023, 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
Robert E. Landry	Executive Vice President, Finance and Chief Financial Officer	11/9/2023	5/6/2024	14,337

^(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 2024 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 2024 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 2024 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 2024 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 2024 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

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

- 10.3.3 + 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).
- 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).
- 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 + Offer Letter for Robert E. Landry effective September 9, 2013. (Incorporated by reference from the Form 8-K for the Registrant, filed September 12, 2013.)
- 10.6 + 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.)
- 10.7 + Regeneron Pharmaceuticals, Inc. Cash Incentive Bonus Plan. (Incorporated by reference from the Form 8-K for the Registrant, filed June 17, 2015.)
- 10.7.1 + 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.)
- 10.8* 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.)
- 10.9* 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.)
- 10.9.1* Restated Amendment Agreement, dated December 30, 2014 and entered into effective as of May 7, 2012, by and between Bayer HealthCare LLC and the Registrant. (Incorporated by reference from the Form 10-K for the Registrant, for the year ended December 31, 2014, filed February 12, 2015.)
- 10.9.2** 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.)
- 10.10* 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.)
- 10.10.1** 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.)
- 10.10.2* 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.)
- 10.10.3** 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.)

10.10.4**	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.)
10.10.5**	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.)
10.11**	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.)
10.12	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.)
10.12.1	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.)
10.13***	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.)
10.14**	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.)
10.15*	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.)
10.16***	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.)
10.17***	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.)
10.18***	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.)
10.19**	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.)
10.19.1**	Form of Co-Co Collaboration Agreement (Exhibit B to Master Agreement contained in Exhibit 10.19).
10.19.2**	Form of License Agreement (Exhibit C to Master Agreement contained in Exhibit 10.19).
10.19.3**	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.)
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.
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, 2023 and 2022; (ii) the Registrant's Consolidated Statements of Operations and Comprehensive Income for the years ended December 31, 2023, 2022, and 2021; (iii) the Registrant's Consolidated Statements of Stockholders' Equity for the years ended December 31, 2023, 2022, and 2021; (iv) the Registrant's Consolidated Statements of Cash Flows for the years ended December 31, 2023, 2022, and 2021; and (v) the notes to the Registrant's Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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- * Portions of this document have been omitted and filed separately with the 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, 2024

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:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ LEONARD S. SCHLEIFER</u> Leonard S. Schleifer, M.D., Ph.D.	<i>Board Co-Chair, President and Chief Executive Officer (Principal Executive Officer)</i>	February 5, 2024
<u>/s/ ROBERT E. LANDRY</u> Robert E. Landry	<i>Executive Vice President, Finance and Chief Financial Officer (Principal Financial Officer)</i>	February 5, 2024
<u>/s/ CHRISTOPHER FENIMORE</u> Christopher Fenimore	<i>Senior Vice President, Controller (Principal Accounting Officer)</i>	February 5, 2024
<u>/s/ GEORGE D. YANCOPOULOS</u> George D. Yancopoulos, M.D., Ph.D.	<i>Board Co-Chair, President and Chief Scientific Officer</i>	February 5, 2024
<u>/s/ BONNIE L. BASSLER</u> Bonnie L. Bassler, Ph.D.	<i>Director</i>	February 5, 2024
<u>/s/ MICHAEL S. BROWN</u> Michael S. Brown, M.D.	<i>Director</i>	February 5, 2024
<u>/s/ N. ANTHONY COLES</u> N. Anthony Coles, M.D.	<i>Director</i>	February 5, 2024
<u>/s/ JOSEPH L. GOLDSTEIN</u> Joseph L. Goldstein, M.D.	<i>Director</i>	February 5, 2024
<u>/s/ KATHRYN GUARINI</u> Kathryn Guarini, Ph.D.	<i>Director</i>	February 5, 2024
<u>/s/ CHRISTINE A. POON</u> Christine A. Poon	<i>Director</i>	February 5, 2024
<u>/s/ ARTHUR F. RYAN</u> Arthur F. Ryan	<i>Director</i>	February 5, 2024
<u>/s/ DAVID P. SCHENKEIN</u> David P. Schenkein, M.D.	<i>Director</i>	February 5, 2024
<u>/s/ GEORGE L. SING</u> George L. Sing	<i>Director</i>	February 5, 2024
<u>/s/ CRAIG B. THOMPSON</u> Craig B. Thompson, M.D.	<i>Director</i>	February 5, 2024
<u>/s/ HUDA Y. ZOGHBI</u> Huda Y. Zoghbi, M.D.	<i>Director</i>	February 5, 2024

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, 2023 and 2022, 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, 2023, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023 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, 2023, 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.

Reserve for an Uncertain Tax Position

As described in Notes 1 and 15 to the consolidated financial statements, the Company's reserves for uncertain tax positions were \$696.4 million as of December 31, 2023. A reserve for an individual uncertain tax position represents a 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 the reserve for an uncertain tax position is a critical audit matter are (i) the significant judgment by management when determining the reserve for the uncertain tax position; (ii) a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's determination of the reserve for the uncertain tax position; (iii) the assessment and evaluation of audit evidence available to support the reserve for the uncertain tax position 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 the reserve for the individual uncertain tax position, such as international and federal filing positions, and the related final tax returns; (ii) testing the calculation of the reserve for the uncertain tax position; and (iii) evaluating management's assessment of the technical merits of tax positions and estimates of the amount of tax benefit expected to be sustained, as well as the likelihood of the possible outcome. Professionals with specialized skills and knowledge were used to assist in evaluating the technical merits and the tax benefit expected to be sustained and the application of relevant tax laws.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
February 5, 2024

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

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

	December 31,	
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,730.0	\$ 3,105.9
Marketable securities	8,114.8	4,636.4
Accounts receivable, net	5,667.3	5,328.7
Inventories	2,580.5	2,401.9
Prepaid expenses and other current assets	386.6	411.2
Total current assets	19,479.2	15,884.1
Marketable securities	5,396.5	6,591.8
Property, plant, and equipment, net	4,146.4	3,763.0
Intangible assets, net	1,038.6	915.5
Deferred tax assets	2,575.4	1,723.7
Other noncurrent assets	444.1	336.4
Total assets	\$ 33,080.2	\$ 29,214.5
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 606.6	\$ 589.2
Accrued expenses and other current liabilities	2,357.9	2,074.2
Deferred revenue	458.9	477.9
Total current liabilities	3,423.4	3,141.3
Long-term debt	1,982.9	1,981.4
Finance lease liabilities	720.0	720.0
Deferred revenue	126.7	69.8
Other noncurrent liabilities	854.1	638.0
Total liabilities	7,107.1	6,550.5
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 2023 and 2022	—	—
Common Stock, par value \$.001 per share; 320.0 shares authorized; shares issued - 133.1 in 2023 and 130.4 in 2022	0.1	0.1
Additional paid-in capital	11,354.0	9,949.3
Retained earnings	27,260.3	23,306.7
Accumulated other comprehensive loss	(80.9)	(238.8)
Treasury Stock, at cost; 25.5 shares in 2023 and 22.6 shares in 2022	(12,560.4)	(10,353.3)
Total stockholders' equity	25,973.1	22,664.0
Total liabilities and stockholders' equity	\$ 33,080.2	\$ 29,214.5

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,		
	2023	2022	2021
Statements of Operations			
Revenues:			
Net product sales	\$ 7,078.0	\$ 6,893.7	\$ 12,117.2
Collaboration revenue	5,503.1	4,914.1	3,673.3
Other revenue	536.1	365.1	281.2
	<u>13,117.2</u>	<u>12,172.9</u>	<u>16,071.7</u>
Expenses:			
Research and development	4,439.0	3,592.5	2,860.1
Acquired in-process research and development	186.1	255.1	48.0
Selling, general, and administrative	2,631.3	2,115.9	1,824.9
Cost of goods sold	932.1	800.0	1,773.1
Cost of collaboration and contract manufacturing	883.7	760.4	664.4
Other operating (income) expense, net	(2.1)	(89.9)	(45.6)
	<u>9,070.1</u>	<u>7,434.0</u>	<u>7,124.9</u>
Income from operations	<u>4,047.1</u>	<u>4,738.9</u>	<u>8,946.8</u>
Other income (expense):			
Other income (expense), net	225.2	179.3	436.3
Interest expense	(73.0)	(59.4)	(57.3)
	<u>152.2</u>	<u>119.9</u>	<u>379.0</u>
Income before income taxes	4,199.3	4,858.8	9,325.8
Income tax expense	245.7	520.4	1,250.5
Net income	<u>\$ 3,953.6</u>	<u>\$ 4,338.4</u>	<u>\$ 8,075.3</u>
Net income per share - basic	\$ 37.05	\$ 40.51	\$ 76.40
Net income per share - diluted	\$ 34.77	\$ 38.22	\$ 71.97
Weighted average shares outstanding - basic	106.7	107.1	105.7
Weighted average shares outstanding - diluted	113.7	113.5	112.2
Statements of Comprehensive Income			
Net income	\$ 3,953.6	\$ 4,338.4	\$ 8,075.3
Other comprehensive income (loss), net of tax:			
Unrealized gain (loss) on debt securities	158.2	(213.6)	(56.4)
Loss on foreign currency translation	(0.3)	—	—
Unrealized gain on cash flow hedges	—	1.0	0.9
Comprehensive income	<u>\$ 4,111.5</u>	<u>\$ 4,125.8</u>	<u>\$ 8,019.8</u>

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

REGENERON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In millions)

	<u>Class A Stock</u>		<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Retained Earnings</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Treasury Stock</u>		<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				<u>Shares</u>	<u>Amount</u>	
Balance, December 31, 2020	1.8	\$ —	121.5	\$ 0.1	\$ 6,716.2	\$ 10,893.0	\$ 29.3	(16.4)	\$ (6,613.3)	\$ 11,025.3
Issuance of Common Stock for equity awards granted under long-term incentive plans	—	—	6.2	—	1,676.0	—	—	—	—	1,676.0
Common Stock tendered upon exercise of stock options and vesting of restricted stock for employee tax obligations	—	—	(1.5)	—	(944.6)	—	—	—	—	(944.6)
Issuance/distribution of Common Stock for 401(k) Savings Plan	—	—	—	—	40.7	—	—	0.1	7.4	48.1
Repurchases of Common Stock	—	—	—	—	—	—	—	(3.1)	(1,655.0)	(1,655.0)
Stock-based compensation charges	—	—	—	—	599.2	—	—	—	—	599.2
Net income	—	—	—	—	—	8,075.3	—	—	—	8,075.3
Other comprehensive loss, net of tax	—	—	—	—	—	—	(55.5)	—	—	(55.5)
Balance, December 31, 2021	1.8	—	126.2	0.1	8,087.5	18,968.3	(26.2)	(19.4)	(8,260.9)	18,768.8
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

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	—	—	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	<u>1.8</u>	<u>\$ —</u>	<u>133.1</u>	<u>\$ 0.1</u>	<u>\$ 11,354.0</u>	<u>\$ 27,260.3</u>	<u>\$ (80.9)</u>	<u>(25.5)</u>	<u>\$(12,560.4)</u>	<u>\$ 25,973.1</u>

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,		
	2023	2022	2021
Cash flows from operating activities:			
Net income	\$ 3,953.6	\$ 4,338.4	\$ 8,075.3
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	421.0	341.4	286.2
Stock-based compensation expense	885.0	725.0	601.7
Losses (gains) on marketable and other securities, net	266.4	36.8	(387.0)
Other non-cash items, net	(0.1)	368.0	568.7
Deferred income taxes	(837.8)	(746.4)	(147.1)
Acquired in-process research and development in connection with asset acquisition	—	195.0	—
Changes in assets and liabilities:			
(Increase) decrease in accounts receivable	(338.8)	707.8	(1,927.4)
Increase in inventories	(271.7)	(696.5)	(494.3)
Increase in prepaid expenses and other assets	(120.1)	(148.6)	(240.7)
Increase (decrease) in deferred revenue	37.9	32.4	(120.2)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	598.6	(138.4)	866.1
Total adjustments	640.4	676.5	(994.0)
Net cash provided by operating activities	<u>4,594.0</u>	<u>5,014.9</u>	<u>7,081.3</u>
Cash flows from investing activities:			
Purchases of marketable and other securities	(11,646.0)	(7,487.9)	(7,048.1)
Sales or maturities of marketable and other securities	9,442.2	5,550.5	2,215.3
Capital expenditures	(718.6)	(590.1)	(551.9)
Payments for Libtayo intangible asset	(207.8)	(1,026.8)	—
Acquisitions, net of cash acquired	(54.9)	(230.3)	—
Net cash used in investing activities	<u>(3,185.1)</u>	<u>(3,784.6)</u>	<u>(5,384.7)</u>
Cash flows from financing activities:			
Proceeds from issuance of Common Stock	1,145.5	1,519.5	1,672.3
Payments in connection with Common Stock tendered for employee tax obligations	(700.6)	(445.7)	(1,032.7)
Repurchases of Common Stock	(2,235.0)	(2,082.8)	(1,645.4)
Net cash used in financing activities	<u>(1,790.1)</u>	<u>(1,009.0)</u>	<u>(1,005.8)</u>
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(0.4)	—	—
Net (decrease) increase in cash, cash equivalents, and restricted cash	(381.6)	221.3	690.8
Cash, cash equivalents, and restricted cash at beginning of period	<u>3,119.4</u>	<u>2,898.1</u>	<u>2,207.3</u>
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 2,737.8</u>	<u>\$ 3,119.4</u>	<u>\$ 2,898.1</u>
Supplemental disclosure of cash flow information			
Cash paid for interest (net of amounts capitalized)	\$ 73.1	\$ 53.7	\$ 55.8
Cash paid for income taxes	\$ 870.3	\$ 1,502.4	\$ 1,218.4

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, hematologic conditions, infectious diseases, and rare diseases. The Company's research and development efforts have led to eleven products that have received marketing approval by the U.S. Food and Drug Administration ("FDA"). In addition, REGEN-COV[®] was authorized under an Emergency Use Authorization ("EUA") from November 2020 until January 2022 when the EUA was revised to exclude its use in geographic regions where infection or exposure is likely due to a variant that is not susceptible to the treatment; as a result, REGEN-COV is not currently authorized for use in any U.S. states, territories, or jurisdictions. The Company is a party to collaboration agreements to develop and commercialize, as applicable, certain products and product candidates (see Note 3).

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

Basis of Presentation

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

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 collaborator (see Note 3) and customer accounts receivable are significant. As of December 31, 2023 and 2022, two individual customers accounted for 83% and 86% 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 December 31, 2023 and 2022, there were no write-offs and allowances of accounts receivable related to credit risk for the Company's collaborators or customers.

Significant Accounting Policies

Cash and Cash Equivalents

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

Debt and Equity Securities

The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and diversification. The Company invests its cash primarily in debt securities. The Company considers its investments in debt securities to be "available-for-sale," as defined by authoritative guidance issued by the Financial Accounting Standards Board ("FASB"). These assets are carried at fair value and the unrealized gains and losses are included in accumulated other comprehensive income (loss). Realized gains and losses on available-for-sale debt securities are included in other income

(expense), net. The Company reviews its portfolio of available-for-sale debt securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost have resulted from a credit-related loss or other factors. If the decline in fair value is due to credit-related factors, a loss is recognized in net income, whereas if the decline in fair value is not due to credit-related factors, the loss is recorded in other comprehensive income (loss).

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

Accounts Receivable

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

Inventories

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

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

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

Property, Plant, and Equipment

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

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

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

Leases

The Company determines if an arrangement is a lease considering whether there is an identified asset and the contract conveys the right to control its use. Leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company 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. In a business combination, 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, 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 expenses
Regeneron's obligation for its share of collaborator's research and development expenses	Research and development expense
Up-front/opt-in and development milestone payments to collaborators	Acquired in-process research and development expense
Reimbursement of Regeneron's commercialization-related expenses	Reduction to Selling, general, and administrative expense
Regeneron's obligation for its share of collaborator's commercialization-related expenses	Selling, general, and administrative expense
Regeneron's obligation to pay collaborator for its share of gross profits when Regeneron is deemed to be the principal	Cost of goods sold
Up-front and development milestones earned (when there is a combined unit of account which includes a license and providing research and development services)	Other operating income

In agreements involving multiple goods or services promised to be transferred to the Company's collaborator, the Company 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.

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. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In addition, the Company reassesses its forfeiture rate assumptions at least annually, considering both historical forfeiture experience and an estimate of future forfeitures for currently outstanding unvested awards.

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

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

Income Taxes

The provision for income taxes includes U.S. federal, state, local, and foreign taxes. Income taxes are accounted for under the liability method. Deferred tax assets and liabilities 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

In November 2023, the FASB issued Accounting Standards Update No. 2023-07, *Segment Reporting - Improvements to Reportable Segment Disclosures*. The amendments require disclosure of incremental segment information on an annual and interim basis. The amendments also require companies with a single reportable segment to provide all disclosures required by this amendment and all existing segment disclosures in Accounting Standards Codification 280, *Segment Reporting*. The amendments are effective for fiscal years beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The Company does not expect the adoption of the amendments to have a significant impact on its financial statements.

In December 2023, the FASB issued Accounting Standards Update No. 2023-09, *Income Taxes - Improvements to Income Tax Disclosures*. The amendments require (i) enhanced disclosures in connection with an entity's effective tax rate reconciliation and (ii) income taxes paid disaggregated by jurisdiction. The amendments are effective for annual periods beginning after December 15, 2024. The Company does not expect the adoption of the amendments to have a significant impact on its financial statements.

2. Product Sales

Net product sales consist of the following:

(In millions)		Year Ended December 31,		
		2023	2022	2021
EYLEA [®] HD	U.S.	\$ 165.8	\$ —	\$ —
EYLEA [®]	U.S.	5,719.6	6,264.6	5,792.3
Total EYLEA HD and EYLEA	U.S.	5,885.4	6,264.6	5,792.3
Libtayo ^{®(a)}	U.S.	538.8	374.5	306.3
Libtayo ^(a)	ROW ^(b)	324.3	73.0	—
Total Libtayo	Global	863.1	447.5	306.3
Praluent [®]	U.S.	182.4	130.0	170.0
REGEN-COV ^{®(c)}	U.S.	—	—	5,828.0
Evkeeza [®]	U.S.	77.3	48.6	18.4
Inmazoleb [®]	U.S.	69.8	3.0	—
ARCALYST ^{®(d)}	U.S.	—	—	2.2
		<u>\$ 7,078.0</u>	<u>\$ 6,893.7</u>	<u>\$ 12,117.2</u>

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

(b) Rest of world ("ROW")

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

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

As of December 31, 2023 and 2022, the Company had \$3.888 billion and \$3.586 billion, respectively, of trade accounts receivable that were recorded within Accounts receivable, net.

The Company had product sales to certain customers that accounted for more than 10% of total gross product revenue for each of the years ended December 31, 2023, 2022, and 2021. Sales to each of these customers as a percentage of the Company's total gross product revenue are as follows:

	Year Ended December 31,		
	2023	2022	2021
Besse Medical, a subsidiary of Cencora, Inc.	51 %	55 %	30 %
McKesson Corporation	25 %	28 %	18 %
U.S. government	*	*	43 %

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

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

<i>(In millions)</i>	Rebates, Chargebacks, and Discounts	Distribution- Related Fees	Other Sales- Related Deductions	Total
Balance as of December 31, 2020	\$ 202.2	\$ 77.2	\$ 44.8	\$ 324.2
Provisions	1,047.1	363.6	150.4	1,561.1
Credits/payments	(1,034.7)	(360.8)	(127.6)	(1,523.1)
Balance as of December 31, 2021	214.6	80.0	67.6	362.2
Provisions	1,537.3	431.1	141.1	2,109.5
Credits/payments	(1,398.0)	(399.7)	(127.2)	(1,924.9)
Balance as of December 31, 2022	353.9	111.4	81.5	546.8
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	<u>\$ 455.7</u>	<u>\$ 162.3</u>	<u>\$ 79.3</u>	<u>\$ 697.3</u>

3. Collaboration, License, and Other Agreements

a. Sanofi

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

(In millions)	Statement of Operations Classification	Year Ended December 31,		
		2023	2022	2021
Antibody:				
Regeneron's share of profits in connection with commercialization of antibodies	Collaboration revenue	\$ 3,136.5	\$ 2,082.0 *	\$ 1,363.0
Sales-based milestones earned	Collaboration revenue	\$ 50.0	\$ 100.0	\$ 50.0
Reimbursement for manufacturing of commercial supplies	Collaboration revenue	\$ 613.0	\$ 633.7	\$ 488.8
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	\$ (83.7)	\$ 43.0	\$ 129.2
Reimbursement of commercialization-related expenses	Reduction of SG&A expense	\$ 534.4	\$ 437.4	\$ 320.5
Immuno-oncology^(a):				
Regeneron's share of profits (losses) in connection with commercialization of Libtayo outside the United States	Collaboration revenue	\$ —	\$ 6.7	\$ (13.6)
Reimbursement for manufacturing of ex-U.S. commercial supplies	Collaboration revenue	\$ —	\$ 4.6	\$ 14.0
Reimbursement of R&D expenses	Reduction of R&D expense	\$ —	\$ 42.7	\$ 85.1
Reimbursement of commercialization-related expenses	Reduction of SG&A expense	\$ —	\$ 41.4	\$ 89.6
Regeneron's obligation for its share of Sanofi commercial expenses	SG&A expense	\$ —	\$ (19.9)	\$ (36.3)
Regeneron's obligation for Sanofi's share of Libtayo U.S. gross profits	Cost of goods sold	\$ —	\$ (70.1)	\$ (133.0)
Amounts recognized in connection with up-front payments received	Other operating income	\$ —	\$ 35.1	\$ 6.1

* 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, pursuant to which the percentage of the Company's share of profits used to reimburse Sanofi for such development costs increased from 10% to 20%. A portion of the value associated with the increase in reimbursement percentage was deemed to be contingent consideration attributable to the Company's acquisition of the Libtayo (cemiplimab) 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 to Sanofi under the Antibody Collaboration was approximately \$2.330 billion as of December 31, 2023.

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 (including Praluent, which was previously included in the LCA) 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 (including Praluent) exceeding \$2.0 billion and \$2.5 billion, respectively, on a rolling twelve-month basis. In 2021, the Company earned a \$50.0 million sales-based milestone from Sanofi, upon aggregate annual sales of antibodies outside the United States (including Praluent) exceeding \$1.5 billion, on a rolling twelve-month basis.

The Company's significant promised goods and services in connection with the Antibody Collaboration consist of providing research and development services, including the manufacturing of clinical supplies, and providing commercial-related services, including the manufacturing of commercial supplies. The Company recognizes amounts in connection with the Antibody Collaboration based on the amount it has the right to invoice and such amount corresponds directly with the Company's performance to date.

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

<i>(In millions)</i>	As of December 31,	
	2023	2022
Accounts receivable, net	\$ 1,029.1	\$ 692.3
Deferred revenue	\$ 427.7	\$ 415.8

Immuno-Oncology

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

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

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

Recognition of the up-front payments received from Sanofi had been deferred (recorded within Other liabilities), and such amounts were being recognized over the remaining period in which the Company was obligated to perform development activities. During 2021, the Company updated its estimate of the total research and development costs expected to be incurred (which resulted in a change to the estimate of the stage of completion) in connection with the IO Collaboration, and, as a result, recorded a cumulative catch-up adjustment of \$66.9 million as a reduction to other operating income.

In connection with the Amended and Restated Immuno-oncology License and Collaboration Agreement with Sanofi (the "A&R IO LCA") described below, the remaining IO Collaboration Other liabilities balance of \$241.0 million as of July 1, 2022 was recognized as a reduction to the intangible asset recorded in connection with the transaction during 2022.

Effective July 1, 2022, the Company obtained the exclusive right to develop, commercialize, and manufacture Libtayo worldwide under the A&R IO LCA. In connection with the A&R IO LCA, in 2022, the Company made a \$900.0 million up-front payment to Sanofi, as well as a \$100.0 million regulatory milestone payment. In addition, Sanofi was eligible to earn an aggregate of \$100.0 million in Libtayo sales-based milestones under the terms of the A&R IO LCA, of which they 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.

In accordance with the Amended IO Discovery Agreement, the Company was obligated to reimburse Sanofi for half of the development costs it funded that were attributable to clinical development of product candidates from the Company's share of profits from commercialized IO Collaboration products. Under the A&R IO LCA, the amount of development costs incurred under the IO Collaboration for which the Company was obligated to reimburse Sanofi was \$35.0 million as of the effective date of the A&R IO LCA, and the Company pays Sanofi a 0.5% royalty on net product sales of Libtayo until all such development costs have been reimbursed by Regeneron. The Company's contingent reimbursement obligation to Sanofi under the A&R IO LCA was approximately \$28 million as of December 31, 2023.

b. Bayer

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

Within the United States, the Company is responsible for commercialization and retains profits from such sales. Bayer is responsible for commercialization activities outside the United States, and the companies share equally in profits from such sales. In Japan, the Company was entitled to receive a tiered percentage of between 33.5% and 40.0% of EYLEA net product sales through 2021, and effective January 1, 2022, the companies share equally in profits from sales in Japan. The Company is obligated to reimburse Bayer out of its share of the collaboration profits for 50% of the agreed-upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option. The Company's contingent reimbursement obligation to Bayer was approximately \$293 million as of December 31, 2023.

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

<i>(In millions)</i>	Statement of Operations Classification	Year Ended December 31,		
		2023	2022	2021
Regeneron's share of profits in connection with commercialization of EYLEA outside the United States	Collaboration revenue	\$ 1,376.4	\$ 1,317.4	\$ 1,349.2
Reimbursement for manufacturing of ex-U.S. commercial supplies	Collaboration revenue	\$ 111.1	\$ 91.4	\$ 60.1
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	\$ (44.0)	\$ 16.7	\$ 5.2

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

<i>(In millions)</i>	As of December 31,	
	2023	2022
Accounts receivable, net	\$ 381.7	\$ 348.2
Deferred revenue	\$ 138.2	\$ 131.9

c. Alnylam

In 2019, the Company and Alnylam Pharmaceuticals, Inc. entered into a global, strategic collaboration to discover, develop, and commercialize RNA interference ("RNAi") therapeutics for a broad range of diseases by addressing therapeutic disease targets expressed in the eye and central nervous system ("CNS"), in addition to a select number of targets expressed in the liver. In connection with entering into the collaboration, the Company made an up-front payment of \$400.0 million to Alnylam, and also purchased shares of Alnylam common stock for \$400.0 million. For each program, the Company provides Alnylam with a specified amount of funding at program initiation and at lead candidate designation. 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 (under which the parties are advancing ALN-APP and ALN-PNP, which are currently in clinical development) or a license agreement.

The initial target nomination and discovery period is five years (which may under certain situations automatically be extended for up to seven years in the aggregate) (the "Research Term"). In addition, the Company has the option to extend the Research Term for an additional five-year period for a research extension fee of \$300.0 million.

During 2023, the Company paid a \$100.0 million development milestone to Alnylam, which was recorded to Acquired in-process research and development expense, upon the achievement of specified proof-of-principle criteria for the ALN-APP program. Alnylam is eligible to receive an additional \$100.0 million clinical proof-of-principle milestone in connection with an eye program.

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

<i>(In millions)</i>	Statement of Operations Classification	Year Ended December 31,		
		2023	2022	2021
Regeneron's obligation for its share of Alnylam R&D expenses, net of reimbursement of R&D expenses	(R&D expense)	\$ (74.1)	\$ (55.8)	\$ (60.5)
Development milestone	Acquired in-process research and development	\$ (100.0)	\$ —	\$ —

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

<i>(In millions)</i>	As of December 31,	
	2023	2022
Accrued expenses and other current liabilities	\$ 22.6	\$ 7.4

d. 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 parties jointly fund certain studies, and 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, depending on the amount of manufactured product supplied by each party to the market.

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,		
		2023	2022	2021
Global gross profit payment from Roche in connection with sales of REGEN-COV and Ronapreve	Collaboration revenue	\$ 224.3	\$ 627.3	\$ 361.8
Other	Collaboration revenue	\$ (13.3)	\$ —	\$ —
Reimbursement of R&D expenses	(R&D expense)/Reduction of R&D expense	\$ (1.5)	\$ 6.8	\$ 128.1
Global gross profit payment to Roche in connection with sales of REGEN-COV and Ronapreve	Cost of goods sold	\$ —	\$ —	\$ 259.6

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

(In millions)	As of December 31,	
	2023	2022
Accounts receivable, net	\$ —	\$ 396.6

e. Intellia

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

Under the terms of the 2016 agreement, the parties agreed to a target selection process, whereby the Company may obtain exclusive rights in up to 10 targets to be chosen by the Company during the collaboration term, subject to various adjustments and limitations set forth in the agreement. Certain targets that either the Company or Intellia selects may be subject to a co-development and co-commercialization arrangement at the Company's option or Intellia's option, as applicable. NTLA-2001, which is in clinical development, is subject to a co-development and co-commercialization arrangement pursuant to which Intellia will lead development and commercialization activities and the parties share an agreed-upon percentage of development expenses and profits (if commercialized).

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

In September 2023, the Company further expanded its existing collaboration 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, the Company 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 October 2023, the Company elected to extend the period for selecting targets under the 2016 license and collaboration agreement for an additional two years until April 2026; as a result, the Company became obligated to make a \$30.0 million extension payment to Intellia (which was recorded to Acquired in-process research and development expense in 2023).

Amounts recognized in the Company's Statements of Operations in connection with research and development activities co-funded under the Intellia agreements were not material for the years ended December 31, 2023, 2022, and 2021. In addition, contract balances in the Company's Balance Sheets in connection with the Intellia agreements were not material as of December 31, 2023 and 2022.

f. Sonoma

In March 2023, the Company and Sonoma Biotherapeutics, Inc. entered into a license and collaboration agreement to bring together the Company's *VelociSuite*[®] technologies with Sonoma's technology platform for the discovery, development, and commercialization of novel regulatory T cell ("Treg") therapies for autoimmune diseases. In connection with the agreement, the Company made a \$45.0 million up-front payment (which was recorded to Acquired in-process research and development expense in 2023) and, in April 2023, the Company purchased an aggregate of \$30.0 million of Sonoma preferred stock. Sonoma is also eligible to receive a \$45.0 million development milestone payment. The Company and Sonoma will co-fund research and development activities and share equally any future commercial expenses and profits. The Company will have the option to lead late-stage development and commercialization on all products globally, with Sonoma retaining rights to co-promote all such products in the United States.

Amounts recognized in the Company's Statements of Operations in connection with research and development activities co-funded under the Sonoma agreement were not material for the year ended December 31, 2023. In addition, contract balances in the Company's Balance Sheets in connection with the Sonoma agreement were not material as of December 31, 2023.

g. U.S. Government

In 2021, the Company entered into agreements with the U.S. Department of Defense and the U.S. Department of Health and Human Services ("HHS") to manufacture and deliver filled and finished drug product of REGEN-COV to the U.S. government. Roche supplied a portion of the doses to Regeneron to fulfill the Company's agreement with the U.S. government (see "Roche" above for further details regarding the Company's collaboration agreement with Roche). As of December 31, 2021, the Company had completed its final deliveries of drug product under these agreements. See Note 2 for REGEN-COV net product sales recognized during the year ended December 31, 2021 in connection with these agreements.

In August 2023, the Company expanded its Other Transaction Agreement ("OTA") with the Biomedical Advanced Research and Development Authority ("BARDA"), pursuant to which the HHS is obligated to fund up to 70% of the Company's costs incurred for certain development activities related to a next-generation COVID-19 monoclonal antibody therapy for the prevention of SARS-CoV-2 infection. Pursuant to the terms of the expanded agreement, the Company could receive payments of up to approximately \$326 million in the aggregate to support clinical development, clinical manufacturing, and the regulatory licensure process.

Amounts recognized within Other revenue in the Company's Statements of Operations in connection with the expanded BARDA agreement were \$50.4 million for the year ended December 31, 2023.

The following table summarizes the Company's contract balances in connection with this BARDA agreement:

	As of December 31,	
<i>(In millions)</i>	2023	
Accounts receivable, net	\$	18.5

h. Decibel

In 2017, the Company 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 connection with the agreement, the Company also purchased shares of Decibel stock.

In August 2023, the Company entered into an Agreement and Plan of Merger to acquire Decibel, and in September 2023, the Company completed its acquisition of Decibel (which was accounted for as a business combination). The Company paid \$101.3 million in cash (or \$4.00 per share of Decibel common stock), of which \$6.6 million was attributed to post-combination services to be rendered by Decibel equity award holders, and as a result, was excluded from the amount of consideration transferred for purchase accounting. In addition, Decibel shareholders received one non-tradeable contingent value right ("CVR") per share of Decibel common stock, which entitles the holder to receive up to \$3.50 per share in cash upon achievement of certain clinical development and regulatory milestones for DB-OTO within specified time periods. At closing, the Company recorded a liability related to the fair value of the CVRs of \$43.7 million (see Note 5). The maximum aggregate amount that holders of the CVRs may be entitled to receive if all the milestones contemplated by the CVRs are achieved is approximately \$97 million.

The fair value of the Company's investment in Decibel stock immediately before the acquisition date was \$10.3 million.

The following table summarizes the amounts recognized for assets acquired and liabilities assumed based on their estimated fair values as of the acquisition date:

<i>(In millions)</i>	September 25, 2023
Cash and cash equivalents	\$ 42.2
Marketable securities	12.1
Deferred tax assets, net	58.1
Indefinite-lived intangible asset related to in-process research and development	42.5
Goodwill	5.2
Other assets and liabilities, net	(11.4)
	<u>\$ 148.7</u>

The final determination of fair values of assets acquired, liabilities assumed, and tax-related items will be completed no later than one year from the acquisition date.

i. Checkmate

In 2022, the Company completed its acquisition of Checkmate Pharmaceuticals, Inc. for a total equity value of approximately \$250 million. As a result of the transaction, which was accounted for as an asset acquisition, the Company recorded, during 2022, (i) a charge of \$195.0 million to Acquired in-process research and development and (ii) net assets of \$61.7 million, including \$26.4 million of cash and cash equivalents acquired, related to the assets acquired (including deferred tax assets and investments) and liabilities assumed.

j. Other

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

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. Prior to July 1, 2022, royalties on such sales were shared equally by the Company and Sanofi.

For the years ended December 31, 2023, 2022, and 2021, the Company recorded royalty expense (net of reimbursements from collaborators, as applicable) in its Statements of Operations of \$117.6 million, \$84.5 million, and \$66.9 million, respectively, based on product sales under various licensing agreements.

4. Marketable Securities

Marketable securities as of December 31, 2023 and 2022 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:

<i>(In millions)</i>	Amortized	Unrealized		Fair
		Cost Basis	Gains	
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
Sovereign bonds	58.1	—	(0.9)	57.2
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
	<u>\$ 12,636.0</u>	<u>\$ 13.7</u>	<u>\$ (115.8)</u>	<u>\$ 12,533.9</u>
As of December 31, 2022				
Corporate bonds	\$ 6,975.5	\$ —	\$ (291.1)	\$ 6,684.4
U.S. government and government agency obligations	2,945.4	0.9	(6.9)	2,939.4
Sovereign bonds	67.1	—	(3.0)	64.1
Commercial paper	121.1	—	—	121.1
Certificates of deposit	182.1	—	(0.1)	182.0
Asset-backed securities	28.9	—	(1.7)	27.2
	<u>\$ 10,320.1</u>	<u>\$ 0.9</u>	<u>\$ (302.8)</u>	<u>\$ 10,018.2</u>

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, 2023 mature at various dates through April 2029. The fair values of available-for-sale debt securities by contractual maturity consist of the following:

<i>(In millions)</i>	As of December 31,	
	2023	2022
Maturities within one year	\$ 8,114.8	\$ 4,636.4
Maturities after one year through five years	4,414.5	5,381.4
Maturities after five years	4.6	0.4
	<u>\$ 12,533.9</u>	<u>\$ 10,018.2</u>

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

<i>(In millions)</i> As of December 31, 2023	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
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)
	<u>\$ 7,854.9</u>	<u>\$ (9.0)</u>	<u>\$ 4,157.5</u>	<u>\$ (106.8)</u>	<u>\$ 12,012.4</u>	<u>\$ (115.8)</u>
As of December 31, 2022						
Corporate bonds	\$ 2,445.4	\$ (73.1)	\$ 4,200.4	\$ (218.0)	\$ 6,645.8	\$ (291.1)
U.S. government and government agency obligations	785.2	(2.0)	71.0	(4.9)	856.2	(6.9)
Sovereign bonds	18.6	(1.1)	45.6	(1.9)	64.2	(3.0)
Certificates of deposit	40.2	(0.1)	—	—	40.2	(0.1)
Asset-backed securities	11.5	(0.6)	15.2	(1.1)	26.7	(1.7)
	<u>\$ 3,300.9</u>	<u>\$ (76.9)</u>	<u>\$ 4,332.2</u>	<u>\$ (225.9)</u>	<u>\$ 7,633.1</u>	<u>\$ (302.8)</u>

The unrealized losses on corporate bonds as of December 31, 2023 and 2022 were primarily driven by increased 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, 2023, 2022, and 2021, 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. Realized gains and losses on sales of marketable securities were not material for the years ended December 31, 2023, 2022, and 2021.

The Company recognized interest income of \$495.9 million, \$160.1 million, and \$45.8 million for the years ended December 31, 2023, 2022, and 2021, 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)

As of December 31, 2023	Fair Value	Fair Value Measurements at Reporting Date		
		Level 1	Level 2	Level 3
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	—
Sovereign bonds	57.2	—	57.2	—
Commercial paper	636.8	—	636.8	—
Certificates of deposit	521.4	—	521.4	—
Asset-backed securities	87.1	—	87.1	—
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 - CVRs	\$ 43.7	\$ —	\$ —	\$ 43.7

As of December 31, 2022

Assets:				
Cash equivalents	\$ 1,662.8	\$ 88.3	\$ 1,574.5	\$ —
Available-for-sale debt securities:				
Corporate bonds	6,684.4	—	6,684.4	—
U.S. government and government agency obligations	2,939.4	—	2,939.4	—
Sovereign bonds	64.1	—	64.1	—
Commercial paper	121.1	—	121.1	—
Certificates of deposit	182.0	—	182.0	—
Asset-backed securities	27.2	—	27.2	—
Equity securities (unrestricted)	24.6	24.6	—	—
Equity securities (restricted)	1,185.4	1,185.4	—	—
Total assets	\$ 12,891.0	\$ 1,298.3	\$ 11,592.7	\$ —

The Company held certain restricted equity securities as of December 31, 2023 which are subject to transfer restrictions that expire at various dates through 2024.

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. During the year ended December 31, 2021, the Company recorded \$386.1 million of net unrealized gains 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.

In addition to the investments summarized in the table above, as of December 31, 2023 and 2022, the Company had \$74.3 million and \$48.3 million, respectively, in equity investments that do not have a readily determinable fair value. These investments are recorded within Other noncurrent assets.

As described in Note 3, in September 2023, the Company acquired Decibel and recorded a liability for the CVRs within other liabilities. The fair value of the CVR liability is determined based on the probability of achieving certain clinical development and regulatory milestones and estimated discount rates. Through December 31, 2023, there were no changes in the fair value of the CVRs subsequent to the date of acquisition.

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 \$1.528 billion and \$1.443 billion as of December 31, 2023 and 2022, respectively.

6. Inventories

Inventories consist of the following:

<i>(In millions)</i>	As of December 31,	
	2023	2022
Raw materials	\$ 789.3	\$ 818.4
Work-in-process	1,121.8	963.1
Finished goods	147.3	98.6
Deferred costs	522.1	521.8
	<u>\$ 2,580.5</u>	<u>\$ 2,401.9</u>

Deferred costs represent the costs of product manufactured and shipped to the Company's collaborators for which recognition of revenue has been deferred.

Inventory balances in the table above are net of reserves of \$705.9 million and \$720.7 million as of December 31, 2023 and 2022, respectively. For the years ended December 31, 2023, 2022, and 2021, Cost of goods sold included inventory write-offs and reserves of \$102.3 million, \$258.7 million, and \$457.1 million, respectively. Inventory write-offs and reserves for the years ended 2022 and 2021 primarily related to REGEN-COV.

7. Property, Plant, and Equipment

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

<i>(In millions)</i>	As of December 31,	
	2023	2022
Building and improvements	\$ 2,423.1	\$ 2,270.0
Leasehold improvements	133.9	114.3
Laboratory equipment	1,384.5	1,315.3
Computer equipment and software	389.7	337.4
Furniture, office equipment, and other	165.9	150.2
Land	283.1	264.5
Construction in progress	1,345.0	980.5
	6,125.2	5,432.2
Accumulated depreciation and amortization	(1,978.8)	(1,669.2)
	<u>\$ 4,146.4</u>	<u>\$ 3,763.0</u>

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

Depreciation and amortization expense on property, plant, and equipment was \$328.8 million, \$303.9 million, and \$281.1 million for the years ended December 31, 2023, 2022, and 2021, respectively.

As of December 31, 2023 and 2022, \$3.375 billion and \$2.960 billion, respectively, of the Company's net property, plant, and equipment was located in the United States and \$771.4 million and \$803.0 million, respectively, was located outside the United States (primarily in Ireland).

8. Intangible Assets

Intangible assets, net consist of the following:

<i>(In millions)</i>	Estimated Useful Life	As of December 31,					
		2023			2022		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquired product rights - Libtayo	13 years	\$ 1,119.1	\$ (126.7)	\$ 992.4	\$ 946.3	\$ (35.7)	\$ 910.6
Other intangibles	8 years	10.0	(6.3)	3.7	10.0	(5.1)	4.9
Acquired in-process research and development	Indefinite	42.5	—	42.5	—	—	—
		<u>\$ 1,171.6</u>	<u>\$ (133.0)</u>	<u>\$ 1,038.6</u>	<u>\$ 956.3</u>	<u>\$ (40.8)</u>	<u>\$ 915.5</u>

As described in Note 3, during the year ended December 31, 2023, the Company recorded an indefinite-lived intangible asset of \$42.5 million in connection with its acquisition of Decibel.

During the year ended December 31, 2022, the Company recorded an intangible asset in connection with obtaining the exclusive right to develop, commercialize, and manufacture Libtayo worldwide. The intangible asset recognized upon the effective date of the A&R IO LCA primarily consisted of the \$900.0 million up-front payment, offset by the remaining IO Collaboration other liabilities balance of \$241.0 million. Additionally, during the years ended December 31, 2023 and 2022, the Company recorded additions to the Libtayo intangible asset related to contingent consideration (including regulatory and sales-based milestones) due to Sanofi. See Note 3.

Amortization expense on intangible assets was \$92.2 million and \$37.6 million for the years ended December 31, 2023 and 2022, respectively. Amortization expense for the year ended December 31, 2021 was not material.

As of December 31, 2023, assuming no changes in the gross carrying amount of intangible assets, amortization expense is estimated to be approximately \$85 million for each of the years ending December 31, 2024 through December 31, 2028.

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

<i>(In millions)</i>	As of December 31,	
	2023	2022
Accrued payroll and related costs	\$ 618.2	\$ 497.3
Accrued clinical expenses	292.2	295.0
Accrued sales-related costs	780.8	633.6
Other accrued expenses and liabilities	666.7	648.3
	<u>\$ 2,357.9</u>	<u>\$ 2,074.2</u>

10. Debt

Credit Facility

In December 2022, the Company entered into an agreement with a syndicate of lenders (the "2022 Credit Agreement") which provides for a \$750.0 million senior unsecured five-year revolving credit facility (the "2022 Credit Facility") and replaced the Company's then-existing credit agreement, which was contemporaneously terminated. The 2022 Credit Agreement includes an option for the Company to elect to increase the commitments under the 2022 Credit Facility and/or to enter into one or more tranches of term loans in the aggregate principal amount of up to \$500.0 million, subject to the consent of the lenders providing the additional commitments or term loans, as applicable, and certain other conditions. The 2022 Credit Agreement also provides a \$50.0 million sublimit for letters of credit.

Proceeds of the loans under the 2022 Credit Facility may be used to finance working capital needs, and for general corporate or other lawful purposes, of Regeneron and its subsidiaries. Regeneron Pharmaceuticals, Inc. has guaranteed all obligations under the 2022 Credit Facility. The 2022 Credit Agreement includes an option for the Company to elect to extend the maturity date of the 2022 Credit Facility beyond December 2027, subject to the consent of the extending lenders and certain other conditions.

The Company had no borrowings outstanding under the 2022 Credit Facility as of December 31, 2023.

The 2022 Credit Agreement contains operating covenants and a maximum total leverage ratio financial covenant. The Company was in compliance with all covenants of the 2022 Credit Agreement as of December 31, 2023.

Senior Notes

In 2020, the Company issued and sold \$1.250 billion aggregate principal amount of senior unsecured notes due 2030 and \$750 million aggregate principal amount of senior unsecured notes due 2050 (collectively, the "Notes"). The underwriting discounts and offering expenses are being amortized as additional interest expense over the period from issuance through maturity.

Long-term debt in connection with the Notes, net of underwriting discounts and offering expenses, consists of the following:

<i>(In millions)</i>	As of December 31,	
	2023	2022
1.750% Senior Notes due September 2030	\$ 1,242.2	\$ 1,241.0
2.800% Senior Notes due September 2050	740.7	740.4
	<u>\$ 1,982.9</u>	<u>\$ 1,981.4</u>

Interest on each series of Notes is payable semi-annually in arrears on March 15 and September 15 of each year until their respective maturity dates. Interest expense related to the Notes was \$44.4 million in each of the years ended December 31, 2023, 2022, and 2021.

The Notes may be redeemed at the Company's option at any time at 100% of the principal amount plus accrued and unpaid interest, and, until a specified period before maturity, a specified make-whole amount. The Notes contain a change-of-control provision that, under certain circumstances, may require the Company to offer to repurchase the Notes at a price equal to 101% of the principal amount plus accrued and unpaid interest. The Notes also contain certain limitations on the Company's ability to incur liens and enter into sale and leaseback transactions, as well as customary events of default.

11. 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 Lease

The Company is party to a Third Amended and Restated Lease and Remedies Agreement (the "Third Amended and Restated Lease") with BA Leasing BSC, LLC, an affiliate of Banc of America Leasing & Capital, LLC ("BAL"), as lessor, which relates to the Company's lease of laboratory and office facilities in Tarrytown, New York (the "Facility"); and a Third Amended and Restated Participation Agreement (the "Third Amended and Restated Participation Agreement") with Bank of America, N.A., as administrative agent (the "Administrative Agent"), and a syndicate of lenders (collectively with BAL, the "Participants"), as rent assignees. The Third Amended and Restated Lease and Third Amended and Restated Participation Agreement provide for a March 2027 maturity date of the \$720.0 million 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) and the end of the term

of the Company's lease of the Facility from BAL, at which time all amounts outstanding thereunder will become due and payable in full.

In accordance with the terms of the Third Amended and Restated 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 during the remaining term of the Third Amended and Restated Lease to satisfy the yield payable to the Participants on their outstanding advances under the Third Amended and Restated 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 Third Amended and Restated Participation Agreement and Third Amended and Restated Lease include an option for the Company to elect to further extend the maturity date of the Third Amended and Restated Participation Agreement and the term of the Third Amended and Restated Lease for an additional five-year period, subject to the consent of all the Participants and certain other conditions. The Company also has the option prior to the end of the term of the Third Amended and Restated Lease to (a) purchase the Facility by paying an amount equal to the outstanding principal amount of the Participants' advances under the Third Amended and Restated Participation Agreement, all accrued and unpaid yield thereon, and all other outstanding amounts under the Third Amended and Restated Participation Agreement, Third Amended and Restated Lease, and certain related documents or (b) sell the Facility to a third party on behalf of BAL.

The Third Amended and Restated 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 Third Amended and Restated Lease financing contain financial and operating covenants. Such financial covenants and certain of the operating covenants are substantially similar to the covenants set forth in the 2022 Credit Agreement. The Company was in compliance with all such covenants as of December 31, 2023.

Aggregate Lease Information

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

<i>(In millions)</i>	Classification	As of December 31,	
		2023	2022
Assets:			
Finance lease right-of-use assets	Property, plant, and equipment, net ^(a)	\$ 605.7	\$ 620.3
Operating lease right-of-use assets	Other noncurrent assets ^(b)	78.0	71.2
		<u>\$ 683.7</u>	<u>\$ 691.5</u>
Liabilities:			
Finance lease liabilities - noncurrent	Finance lease liabilities	\$ 720.0	\$ 720.0
Operating lease liabilities - current	Accrued expenses and other current liabilities	19.0	12.4
Operating lease liabilities - noncurrent	Other noncurrent liabilities	68.7	55.8
		<u>\$ 807.7</u>	<u>\$ 788.2</u>

^(a) Finance lease right-of-use assets were recorded net of accumulated amortization of \$133.9 million and \$119.4 million as of December 31, 2023 and 2022, respectively.

^(b) Operating lease right-of-use assets were recorded net of accumulated amortization of \$44.6 million and \$31.0 million as of December 31, 2023 and 2022, respectively.

Lease costs consist of the following:

<i>(In millions)</i>	Year Ended December 31,		
	2023	2022	2021
Operating lease costs	\$ 19.2	\$ 12.4	\$ 10.3
Finance lease costs:			
Amortization of finance lease right-of-use assets	14.5	14.5	14.4
Interest on finance lease liabilities	45.0	21.6	11.9
Total finance lease costs	59.5	36.1	26.3
Total lease costs	<u>\$ 78.7</u>	<u>\$ 48.5</u>	<u>\$ 36.6</u>

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

	As of December 31,	
	2023	2022
Weighted-average remaining lease term (in years):		
Finance leases	3.2	4.2
Operating leases	7.4	7.2
Weighted-average discount rate:		
Finance leases	5.08%	4.84%
Operating leases	5.38%	5.20%

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

<i>(In millions)</i>	Year Ended December 31,		
	2023	2022	2021
Cash paid for amounts included in the measurement of operating lease liabilities (included within cash flows from operating activities)	\$ 22.5	\$ 7.7	\$ 10.2
Right-of-use assets obtained in exchange for operating lease liabilities	\$ 31.9	\$ 35.1	\$ 0.2

The following is a maturity analysis of the Company's lease liabilities as of December 31, 2023:

<i>(In millions)</i>	Finance Leases	Operating Leases	Total
2024	\$ 44.8	\$ 24.1	\$ 68.9
2025	39.5	20.1	59.6
2026	30.9	15.6	46.5
2027	728.4	12.4	740.8
2028	—	11.0	11.0
Thereafter	—	20.1	20.1
Total undiscounted lease payments	843.6	103.3	946.9
Imputed interest	(123.6)	(15.6)	(139.2)
Total lease liabilities	<u>\$ 720.0</u>	<u>\$ 87.7</u>	<u>\$ 807.7</u>

12. Stockholders' Equity

The Company's Restated Certificate of Incorporation, as amended, provides for the issuance of up to 40 million shares of Class A Stock, par value \$0.001 per share, and 320 million shares of Common Stock, par value \$0.001 per share. Shares of Class A Stock are convertible, at any time, at the option of the holder into shares of Common Stock on a share-for-share basis. Holders of Class A Stock have rights and privileges identical to Common Stockholders except that each share of Class A is entitled to ten votes per share, while each share of Common Stock is entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. Under the Company's Restated Certificate of Incorporation, the Company's board of directors is authorized to issue up to 30 million shares of Preferred Stock, in series, with rights, privileges, and qualifications of each series determined by the board of directors.

Share Repurchase Programs

In January 2021, the Company's board of directors authorized a share repurchase program to repurchase up to \$1.5 billion of the Company's Common Stock. As of December 31, 2021, the Company had repurchased the entire \$1.5 billion of its Common Stock that it was authorized to repurchase under the program.

In November 2021, the Company's board of directors authorized 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 that it was authorized to repurchase under the program.

In January 2023, the Company's board of directors authorized an additional share repurchase program to repurchase up to \$3.0 billion of the Company's Common Stock. The share repurchase program 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. As of December 31, 2023, \$1.531 billion remained available for share repurchases under the program.

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

<i>(In millions)</i>	Year Ended December 31,		
	2023	2022	2021
Number of shares	2.9	3.3	3.0
Total cost of shares	\$ 2,214.6	\$ 2,099.8	\$ 1,655.0

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 or allow Participants to purchase such shares at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). Should employment terminate, as specified in the Incentive Plans, except as determined by the Committee in its discretion and subject to the applicable Incentive Plan documents, the ownership of any unvested restricted stock awards will be transferred to the Company.

Phantom stock awards provide the Participant the right to receive Common Stock or an amount of cash based on the value of the Common Stock at a future date. The award is subject to such restrictions, if any, as the Committee may impose at the date of grant or thereafter, including a specified period of employment or the achievement of performance goals. Time-based restricted stock units and performance-based restricted stock units are each a type of phantom stock award permitted under the Second Amended and Restated 2014 Incentive Plan.

The Incentive Plans contain provisions that allow for the Committee to provide for the immediate vesting of awards upon a change in control of the Company, as defined in the Incentive Plans.

As of December 31, 2023, there were 14.6 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 2023.

	Number of Shares (In millions)	Weighted -Average Exercise Price	Weighted- Average Remaining Contractual Term	Intrinsic Value (In millions)
Outstanding as of December 31, 2022	15.6	\$ 481.62		
2023: Granted	1.6	\$ 835.91		
Forfeited	(0.2)	\$ 580.17		
Exercised	(2.8)	\$ 412.05		
Outstanding as of December 31, 2023	<u>14.2</u>	\$ 534.13	6.0 years	\$ 4,918.6
Vested and expected to vest as of December 31, 2023	13.8	\$ 526.95	5.9 years	\$ 4,852.2
Exercisable as of December 31, 2023	9.6	\$ 450.01	4.7 years	\$ 4,118.0

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 2023, 2022, and 2021 was \$1.096 billion, \$1.214 billion, and \$1.707 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, 2023, 2022, and 2021.

	Number of Options Granted <i>(In millions)</i>	Weighted- Average Exercise Price	Weighted- Average Fair Value
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
2021:			
Exercise price equal to Market Price	2.3	\$ 628.43	\$ 174.20

For the years ended December 31, 2023, 2022, and 2021, the Company recognized \$357.1 million, \$341.9 million, and \$328.7 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, 2023, there was \$589.6 million of stock-based compensation cost related to unvested stock options, net of estimated forfeitures, which had not yet been recognized. The Company expects to recognize this compensation cost over a weighted-average period of 1.8 years.

Fair Value Assumptions:

The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2023, 2022, and 2021.

	2023	2022	2021
Expected volatility	26 %	28 %	27 %
Expected lives from grant date	5.1 years	5.2 years	5.5 years
Expected dividend yield	0 %	0 %	0 %
Risk-free interest rate	4.29 %	3.50 %	1.22 %

Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's historical exercise experience with previously issued employee and board of directors' option grants. The expected dividend yield is zero as the Company has never paid dividends and does not currently have plans to do so. 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 2023 is summarized below.

	Number of Shares/Units <i>(In millions)</i>	Weighted- Average Grant Date Fair Value
Unvested as of December 31, 2022	2.6	\$ 571.19
2023: Granted	0.8	\$ 838.11
Vested	(1.0)	\$ 458.49
Forfeited	(0.1)	\$ 585.23
Unvested as of December 31, 2023	<u>2.3</u>	<u>\$ 705.37</u>

For the years ended December 31, 2023, 2022, and 2021, the Company recognized \$475.9 million, \$331.1 million, and \$221.0 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, 2023, there was \$1.023 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 2.2 years.

c. Performance-based Restricted Stock Units

Performance-based restricted stock units ("PSUs") have been granted to certain members of senior management of the Company. PSUs may be earned based upon the attainment of pre-established performance criteria, which may include a market and/or performance condition. Depending on the terms of the PSUs and the outcome of the pre-established performance criteria, a recipient may ultimately earn the target number of PSUs granted or a specified multiple thereof at the end of a 4–6 year vesting period, as applicable.

The table below summarizes activity related to PSUs during 2023. The number of unvested PSUs represents the maximum number of units that are eligible to be earned.

	Number of Shares/Units <i>(In millions)</i>	Weighted- Average Grant Date Fair Value
Unvested as of December 31, 2022	1.5	\$ 245.94
2023: Vested	(0.1)	\$ 198.10
Unvested as of December 31, 2023	<u>1.4</u>	<u>\$ 247.91</u>

For each of the years ended December 31, 2023, 2022, and 2021 the Company recognized \$52.0 million of stock-based compensation expense related to PSUs. As of December 31, 2023, there was \$104.1 million of stock-based compensation cost related to unvested PSUs which had not yet been recognized. The Company expects to recognize this compensation cost on a straight-line basis over a weighted average period of 2.3 years.

Fair Value Assumptions:

The following table summarizes the weighted average values of the assumptions used in computing the fair value of PSUs that were granted during 2022. The Company did not grant PSUs during 2023 and 2021.

	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 \$84.7 million, \$67.6 million, and \$55.5 million for the years ended December 31, 2023, 2022, and 2021, 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:

<i>(In millions)</i>	Year Ended December 31,		
	2023	2022	2021
United States	\$ (362.3)	\$ 839.9	\$ 5,944.7
Foreign	4,561.6	4,018.9	3,381.1
	<u>\$ 4,199.3</u>	<u>\$ 4,858.8</u>	<u>\$ 9,325.8</u>

Components of income tax expense consist of the following:

<i>(In millions)</i>	Year Ended December 31,		
	2023	2022	2021
Current:			
Federal	\$ 667.9	\$ 968.5	\$ 1,429.8
State	7.7	7.4	6.2
Foreign	407.9	290.9	(38.4)
Total current tax expense	<u>1,083.5</u>	<u>1,266.8</u>	<u>1,397.6</u>
Deferred:			
Federal	(834.5)	(797.7)	(423.2)
State	(6.5)	(2.7)	(0.6)
Foreign	3.2	54.0	276.7
Total deferred tax benefit	<u>(837.8)</u>	<u>(746.4)</u>	<u>(147.1)</u>
	<u>\$ 245.7</u>	<u>\$ 520.4</u>	<u>\$ 1,250.5</u>

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,		
	2023	2022	2021
U.S. federal statutory tax rate	21.0 %	21.0 %	21.0 %
Taxation of non-U.S. operations	(6.6)	(5.5)	(2.8)
Stock-based compensation	(4.6)	(2.9)	(2.4)
Income tax credits	(3.2)	(2.0)	(1.0)
Foreign-derived intangible income deduction	(0.3)	(1.0)	(1.4)
Other permanent differences	(0.4)	1.1	—
Effective income tax rate	<u>5.9 %</u>	<u>10.7 %</u>	<u>13.4 %</u>

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:

<i>(In millions)</i>	As of December 31,	
	2023	2022
Deferred tax assets:		
Capitalized research and development expenses	\$ 1,728.2	\$ 845.3
Deferred compensation	413.6	416.2
Accrued expenses	214.1	235.6
Fixed assets and intangible assets	154.8	227.6
Tax attribute carryforwards	88.7	41.3
Other	26.4	15.9
Total deferred tax assets	2,625.8	1,781.9
Deferred tax liabilities:		
Unrealized gains on investments	(50.4)	(58.2)
Net deferred tax assets	<u>\$ 2,575.4</u>	<u>\$ 1,723.7</u>

The Company's federal income tax returns for 2017 through 2022 remain open to examination by the IRS. The Company's 2017 and 2018 federal income tax returns are currently under audit by the IRS. In general, the Company's state income tax returns from 2018 to 2022 remain open to examination. The Company's income tax returns outside the United States remain open to examination from 2018 to 2022. 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:

<i>(In millions)</i>	2023	2022	2021
Balance as of January 1	\$ 542.8	\$ 410.9	\$ 267.0
Gross increases related to current year tax positions	153.4	136.9	182.3
Gross increases (decreases) related to prior year tax positions	3.2	(5.0)	2.9
Gross decreases due to settlements and lapse of statutes of limitations	(3.0)	—	(41.3)
Balance as of December 31	<u>\$ 696.4</u>	<u>\$ 542.8</u>	<u>\$ 410.9</u>

In 2023, 2022, and 2021, 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. In 2021, the decrease in unrecognized tax benefits due to settlements and lapse of statutes of limitations was related to the closing of audits for the Company's federal income tax returns for 2015 and 2016. Interest expense related to unrecognized tax benefits was not material in 2023, 2022, and 2021. The Company does not believe that it is reasonably possible that the resolution of tax exposures within the next twelve months would have a material impact on the consolidated financial statements as of December 31, 2023.

The amount of net unrecognized tax benefits that, if settled, would impact the effective tax rate is \$442.5 million, \$373.7 million, and \$321.1 million as of December 31, 2023, 2022, and 2021, respectively.

In August 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law in the United States. The IRA created a new corporate alternative minimum tax of 15% on adjusted financial statement income and an excise tax of 1% of the value of certain stock repurchases. The provisions of the IRA became effective for periods beginning after December 31, 2022. The IRA did not have a material impact on the Company's financial statements as of and for the periods ended December 31, 2023 and 2022.

16. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The outcome of any such proceedings, regardless of the merits, is inherently uncertain. If the Company were unable to prevail in any such proceedings, its consolidated financial position, results of operations, and future cash flows may be materially impacted. Costs associated with the Company's involvement in legal proceedings are expensed as incurred. The Company recognizes accruals for loss contingencies associated with such proceedings when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. As of December 31, 2023 and 2022, the Company's accruals for loss contingencies were not material. There are certain loss contingencies that the Company deems reasonably possible for which the possible loss or range of possible loss is not estimable at this time.

Proceedings Relating to Praluent (alirocumab) Injection

As described below, the Company is currently a party to patent infringement actions initiated by Amgen Inc. (and/or its affiliated entities) against the Company and/or Sanofi (and/or the Company's and Sanofi's respective affiliated entities) in a number of jurisdictions relating to Praluent. In addition, as described below, the Company filed a lawsuit against Amgen alleging that Amgen engaged in an anticompetitive bundling scheme which was designed to exclude Praluent from the market in violation of U.S. federal and state laws.

United States

In the United States, Amgen asserted claims of U.S. Patent Nos. 8,829,165 (the "'165 Patent") and 8,859,741 (the "'741 Patent"), and sought a permanent injunction to prevent the Company and the Sanofi defendants from commercial manufacturing, using, offering to sell, or selling within the United States (as well as importing into the United States) Praluent. Amgen also sought a judgment of patent infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuits, and attorneys' fees. As previously reported, on February 11, 2021, the United States Court of Appeals for the Federal Circuit (the "Federal Circuit") affirmed the lower court's decision that certain of Amgen's asserted patent claims are invalid based on lack of enablement. On April 14, 2021, Amgen filed a petition for a rehearing en banc with the Federal Circuit, which was denied on June 21, 2021. On November 4, 2022, the United States Supreme Court granted Amgen's petition for writ of certiorari. An oral hearing was held on March 27, 2023. On May 28, 2023, the United States Supreme Court affirmed the Federal Circuit's decision that certain of Amgen's asserted patent claims are invalid based on lack of enablement.

On May 27, 2022, the Company filed a lawsuit against Amgen in the United States District Court for the District of Delaware, alleging that, beginning in 2020, Amgen engaged in an anticompetitive bundling scheme which was designed to exclude Praluent from the market in violation of federal and state laws. The lawsuit seeks damages for harm caused by the alleged scheme, as well as injunctive relief restraining Amgen from continuing its alleged anticompetitive conduct. On August 1, 2022, Amgen filed a motion to dismiss the complaint. On August 11, 2022, Amgen filed a motion to stay these proceedings pending resolution of the patent litigation described in the preceding paragraph. An oral hearing on Amgen's motion to dismiss and motion to stay was held on January 6, 2023. 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. A trial has been scheduled to begin in November 2024.

Europe

Amgen has asserted European Patent No. 2,215,124 (the "'124 Patent"), which pertains to PCSK9 monoclonal antibodies, in certain countries in Europe. In October 2020, the '124 Patent claims directed to compositions of matter and medical use relevant to Praluent were ruled invalid based on a lack of inventive step by the Technical Board of Appeal (the "TBA") of the European Patent Office (the "EPO"). Following the EPO's decision, each of the '124 Patent infringement proceedings initiated by Amgen against the Company and certain of Sanofi's affiliated entities in these countries was dismissed, including in Germany. The dismissal in Germany followed an earlier finding of infringement and granting of an injunction, both of which were subsequently overturned. As a result of the overturned injunction in Germany, the Company and/or certain of Sanofi's affiliated entities are seeking damages caused by Amgen's enforcement of the injunction. An oral hearing has been scheduled for February 28, 2024. As part of its opposition to these damages claims, on March 23, 2022, Amgen filed a counterclaim that asserted the German designation of European Patent No. 2,641,917 (the "'917 Patent") and seeks, among other things, a judgment of patent infringement, injunctive relief, and monetary damages. The '917 Patent is a divisional patent of the '124 Patent discussed above (i.e., a patent that shares the same priority date, disclosure, and patent term of the parent '124 Patent but contains claims to a different invention). An oral hearing before the Munich Regional Court was held on November 29, 2023, at which Amgen's counterclaim was dismissed. The '917 Patent is also subject to opposition proceedings in the EPO, which were initiated by Sanofi on May 5, 2021. An oral hearing before the EPO was held on February 21, 2023, at which the '917 Patent was revoked. Amgen filed a notice to appeal to the TBA of the EPO on February 27, 2023.

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 Unified Patent Court (the "UPC") alleging infringement of Amgen's European Patent No. 3,666,797 (the "'797 Patent"). The lawsuit seeks, among other things, a permanent injunction in several countries in Europe and monetary damages. The '797 Patent is a divisional patent of the '124 Patent discussed above. A trial has been scheduled for October 16–17, 2024. Also on June 1, 2023, Sanofi filed an action in the Munich Central Division of the UPC seeking revocation of the '797 Patent. A trial has been scheduled for June 4–5, 2024.

Proceedings Relating to EYLEA (afibercept) Injection

Certain of the Company's patents pertaining to EYLEA are subject to post-grant proceedings before the United States Patent and Trademark Office ("USPTO"), EPO, or other comparable foreign authorities, including those described in greater detail below. In addition, the Company has filed patent infringement lawsuits in several jurisdictions alleging infringement of certain Company patents pertaining to EYLEA, including those described in greater detail below.

United States

Post-Grant Proceedings Before USPTO

<u>Company Patent(s)</u>	<u>Challenger(s)</u>	<u>Type of Challenge</u>	<u>Date of Challenge</u>	<u>Latest Events/Current Status</u>
U.S. Patent Nos. 10,406,226 (the "'226 Patent") and 10,464,992 (the "'992 Patent")	Anonymous parties	<i>Ex parte</i> reexamination	February 11, 2020	<p>On September 11, 2023, the USPTO dismissed the '226 Patent reexamination proceedings following the Company's filing of a Notice of Disclaimer, disclaiming all claims of the '226 Patent.</p> <p>On September 8, 2023, the '992 Patent reexamination proceedings were stayed by the USPTO pending resolution of the <i>inter partes</i> review ("IPR") of the '992 Patent initiated by Celltrion, Inc., as discussed further below. On January 17, 2024, the Company filed a Notice of Disclaimer with the USPTO, disclaiming all claims of the '992 Patent.</p>

Company Patent(s) <i>(continued)</i>	Challenger(s)	Type of Challenge	Date of Challenge	Latest Events/Current Status
U.S. Patent Nos. 9,254,338 (the "'338 Patent") and 9,669,069 (the "'069 Patent")	Mylan Pharmaceuticals Inc., joined by Apotex Inc. and Celltrion	IPR petitions seeking declarations of invalidity	May 5, 2021	On November 9, 2022, the USPTO issued final written decisions finding that the challenged claims of the '338 and '069 Patents are unpatentable and, therefore, invalid. On January 10, 2023, the Company filed notices of appeal of the USPTO written decisions concerning the '338 and '069 Patents with the Federal Circuit.
U.S. Patent Nos. 10,130,681 (the "'681 Patent"), 10,888,601 (the "'601 Patent"), and 10,857,205 (the "'205 Patent")	Mylan, joined by Celltrion ('601 and '681 Patents) and Samsung Bioepis Co., Ltd. ('601 Patent)	IPR petitions seeking declarations of invalidity	July 1, 2022 ('681 Patent and '601 Patent) October 28, 2022 ('205 Patent)	On January 9, 2024, the USPTO issued final written decisions finding that the challenged claims of the '681 and '601 Patents are unpatentable and, therefore, invalid. On March 1, 2023, the USPTO denied institution of Mylan's IPR petition against the '205 Patent following the Company's filing of a Notice of Disclaimer with the USPTO, disclaiming all claims of the '205 Patent.
'681 Patent and '601 Patent	Samsung Bioepis, joined by Biocon Biologics Inc. ('601 Patent)	IPR petitions seeking declarations of invalidity	January 6, 2023 ('681 Patent) March 26, 2023 ('601 Patent)	On July 19, 2023 and October 20, 2023, the USPTO instituted IPR proceedings concerning the '681 Patent and the '601 Patent, respectively.
U.S. Patent No. 11,253,572 (the "'572 Patent")	Apotex Samsung Bioepis	IPR petition seeking declaration of invalidity IPR petition seeking declaration of invalidity	September 9, 2022 April 27, 2023	On March 10, 2023, the USPTO declined to institute an IPR proceeding based on the Apotex IPR petition. On November 17, 2023, the USPTO instituted IPR proceedings concerning the '572 Patent based on the Samsung IPR petition.
'992 Patent and '226 Patent	Celltrion, joined by Samsung Bioepis ('992 Patent)	IPR petitions seeking declarations of invalidity	January 17, 2023 ('992 Patent) February 28, 2023 ('226 Patent)	On July 20, 2023, the USPTO instituted an IPR proceeding concerning the '992 Patent. On January 17, 2024, the Company filed a Notice of Disclaimer with the USPTO, disclaiming all claims of the '992 Patent. On September 1, 2023, the USPTO denied institution of Celltrion's IPR petition against the '226 Patent following the Company's filing of a Notice of Disclaimer with the USPTO, disclaiming all claims of the '226 Patent.

U.S. Patent Litigation

On August 2, 2022, the Company filed a patent infringement lawsuit against Mylan, a wholly-owned subsidiary of Viatrix Inc., in the United States District Court for the Northern District of West Virginia alleging that Mylan's filing for FDA approval of an aflibercept 2 mg biosimilar infringes certain Company patents. On April 20, 2023, Mylan filed a motion for summary judgment or partial summary judgment concerning four of the asserted patents. On April 26, 2023, the Company filed a stipulation accepting summary judgment of noninfringement of all asserted claims of the Company's U.S. Patent No. 11,104,715. 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"). Closing arguments were presented on August 3, 2023. 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 (ii) the asserted claims of the '601 and '572 Patents were infringed by Mylan but were invalid as obvious.

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. A preliminary injunction hearing concerning each of these lawsuits has been scheduled for May 2, 2024.

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 January 11, 2024, the Company filed a motion with the United States Judicial Panel on Multidistrict Litigation seeking to transfer this lawsuit to the United States District Court for the Northern District of West Virginia for coordinated pretrial proceedings with the lawsuits described in the preceding paragraph. A hearing on the motion to transfer has been scheduled for March 28, 2024.

Europe

Post-Grant Proceedings

Authority/Court	Company Patent(s)	Challenger(s)	Type of Challenge	Date of Challenge	Latest Events/ Current Status
EPO	European Patent No. 2,944,306 (the "'306 Patent")	Anonymous parties	Opposition proceedings	October 26 and October 27, 2021	Oral hearing to be scheduled.
EPO	European Patent No. 3,716,992 (the "EP '992 Patent")	Amgen and three anonymous parties	Opposition proceedings	May 5-10, 2023	Oral hearing to be scheduled.
German Federal Patent Court	German designation of European Patent No. 2,364,691 (the "'691 Patent")	Samsung Bioepis NL B.V.	Invalidation proceedings	June 22, 2023	Trial has been scheduled to begin in June 2025.

Canada

On June 15, July 15, August 30, and October 4, 2022, the Company and Bayer Inc. filed patent infringement lawsuits against BGP Pharma ULC d.b.a Viatrix Canada ("Viatrix 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. 2,654,510 (the "'510 Patent") and 3,007,276 (the "'276 Patent") (in the lawsuit filed on June 15, 2022); the Company's Canadian Patent No. 2,965,495 (the "'495 Patent") (in the lawsuit filed on July 15, 2022); the Company's Canadian Patent No. 2,906,768 (the "'768 Patent") (in the lawsuit filed on August 30, 2022, which has been joined with the lawsuit filed on July 15, 2022); and the Company's Canadian Patent No. 3,129,193 (the "'193 Patent") (in the lawsuit filed on October 4, 2022). A trial for the lawsuit concerning the '510 Patent and the '276 Patent (the "Viatrix Canada 510/276 Lawsuit") has been scheduled for March 2024; a trial for the lawsuit concerning the '193 Patent has been scheduled for May 2024; and a trial for the lawsuit concerning the '495 Patent and the '768 Patent has been scheduled for November/December 2024. The filing of the Viatrix Canada 510/276 Lawsuit resulted in a statutory 24-month stay of regulatory approval of Viatrix Canada's aflibercept 2 mg

biosimilar in Canada unless the lawsuit is resolved earlier. On March 27, 2023, in light of the transfer of Viatris Canada's New Drug Submission ("NDS") of its aflibercept 2 mg biosimilar to Biosimilar Collaborations Ireland Limited ("BCIL"), the Company filed a motion in the Federal Court of Canada seeking termination of the Viatris Canada 510/276 Lawsuit. On June 5, 2023, BCIL was added as a defendant in the Viatris Canada 510/276 Lawsuit.

On March 23, 2023 and June 14, 2023, the Company and Bayer Inc. filed patent infringement lawsuits against BCIL 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 and '276 Patents. The June 14, 2023 lawsuit was filed after BCIL served Bayer Inc. with a statutory notification in relation to the NDS on May 23, 2023. On September 14, 2023, the Company, Bayer Inc., and Bayer Healthcare LLC filed patent infringement lawsuits against Viatris Canada and BCIL 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 May 9, 2023, Amgen Canada Inc. ("Amgen Canada") filed invalidation proceedings against the Company in the Federal Court of Canada seeking revocation of the '510 Patent and 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 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 '193 Patent, '495 Patent, and '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. A trial for the lawsuits concerning the '510 Patent and the '276 Patent has been scheduled for May 2025.

On January 15, 2024, the Company and Bayer Inc. filed patent infringement lawsuits against Celltrion, Inc., Celltrion Healthcare Co, Ltd., Celltrion Pharma Inc., and Celltrion Healthcare Canada Ltd. 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, and the '315 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 against the Company's Korean Patent Nos. 1131429 and 1406811, respectively, seeking revocation of each of such patents in its entirety.

On January 16, 2023, the Company filed patent infringement lawsuits against Samsung Bioepis Co., Ltd. and its parent company Samsung Biologics Co., Ltd. before the Seoul Central District Court seeking a declaration that the making, constructing, using, or selling of an aflibercept 2 mg biosimilar would infringe one or more claims of the Company's Korean Patent No. 659477 (the "'477 Patent"). On July 20, 2023, the Company filed a preliminary injunction petition against Samsung Bioepis Co., Ltd. and its parent company Samsung Biologics Co., Ltd. before the Seoul Central District Court seeking a court order enjoining the manufacture, use, and assignment of an aflibercept 2 mg biosimilar that infringes one or more claims of the '477 Patent; and on December 20, 2023, the Seoul Central District Court granted a preliminary injunction. On January 10, 2024, the injunction was lifted against the Samsung entities following the expiration of the '477 Patent.

On March 2, 2023, the Company filed an affirmative scope confirmation action against Samsung Bioepis Co., Ltd. before the Intellectual Property Tribunal and Appeal Board of the Korean Intellectual Property Office seeking a ruling that Samsung Bioepis's aflibercept 2 mg biosimilar is covered by the claims of the '477 Patent. On March 7, 2023, the action was designated for expedited proceedings.

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") and seeking preliminary and permanent injunctions to prevent the Company from continuing to infringe the '631 Patent. Novartis also seeks a judgment of patent infringement of the '631 Patent, monetary damages (together with interest), an order of willful infringement of the '631 Patent (which would allow the court in its discretion to award damages up to three times the amount assessed), costs and expenses of the

lawsuits, and attorneys' fees. On November 7, 2022, the Company and Novartis entered into a stipulation staying the lawsuit in light of the decision in the IPR proceeding discussed below.

On July 16, 2020, the Company initiated two IPR petitions in the USPTO seeking a declaration of invalidity of the '631 Patent on two separate grounds. On October 26, 2021, the USPTO issued a decision instituting the IPR proceeding. An oral hearing was held on July 21, 2022. On October 25, 2022, the Patent Trial and Appeal Board ("PTAB") of the USPTO issued a final written decision invalidating all claims of the '631 Patent. On December 23, 2022, Novartis filed a notice of appeal of the PTAB's decision to the Federal Circuit.

On July 17, 2020, the Company filed an antitrust lawsuit against Novartis and Vetter Pharma International GmbH ("Vetter") in the United States District Court for the Southern District of New York seeking a declaration that the '631 Patent is unenforceable and a judgment that the defendants' conduct violates Sections 1 and 2 of the Sherman Antitrust Act of 1890, as amended (the "Sherman Antitrust Act"). The Company is also seeking injunctive relief and treble damages. On September 4, 2020, Novartis filed, and Vetter moved to join, a motion to dismiss the complaint, to transfer the lawsuit to the Northern District of New York, or to stay the suit; and on October 19, 2020, Novartis filed, and Vetter moved to join, a second motion to dismiss the complaint on different grounds. On January 25, 2021, the Company filed an amended complaint seeking a judgment that Novartis's conduct violates Section 2 of the Sherman Antitrust Act based on additional grounds, as well as a judgment of tortious interference with contract. On February 22, 2021, Novartis filed, and Vetter moved to join, a motion to dismiss the amended complaint. On September 21, 2021, the court granted Novartis and Vetter's motion to transfer this lawsuit to the Northern District of New York. As a result, this lawsuit was transferred to the same judge that had been assigned to the patent infringement lawsuit discussed above. On November 5, 2021, the Company filed a motion to stay these proceedings in light of the pending IPR proceeding discussed above. On January 31, 2022, the court denied the Company's motion to stay these proceedings and granted Novartis and Vetter's motion to dismiss the amended complaint. On June 10, 2022, the Company filed an appeal of the District Court's decision to dismiss the amended complaint with the U.S. Court of Appeals for the Second Circuit. An oral hearing before the U.S. Court of Appeals for the Second Circuit was held on October 11, 2023.

Proceedings Relating to REGEN-COV (casirivimab and imdevimab)

On October 5, 2020, Allele Biotechnology and Pharmaceuticals, Inc. ("Allele") filed a lawsuit (as amended on April 8, 2021 and December 12, 2022) against the Company in the United States District Court for the Southern District of New York, asserting infringement of U.S. Patent No. 10,221,221 (the "'221 Patent"). Allele seeks a judgment of patent infringement of the '221 Patent, an award of monetary damages (together with interest), an order of willful infringement of the '221 Patent (which would allow the court in its discretion to award damages up to three times the amount assessed), costs and expenses of the lawsuit, and attorneys' fees. On July 16, 2021, the Company filed a motion to dismiss the complaint, which motion was denied on March 2, 2022. On September 18, 2023, the parties entered into a stipulation that narrowed the case to (i) whether any safe harbor defense under federal law applies to Regeneron's use of the invention covered, based on the court's claim construction, by the '221 Patent; (ii) damages for any use by Regeneron found to not be covered by such safe harbor defense; and (iii) whether any use referred to in clause (ii) above was willful.

Department of Justice Matters

In January 2017, the Company received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents relating to its support of 501(c)(3) organizations that provide financial assistance to patients; documents concerning its provision of financial assistance to patients with respect to products sold or developed by Regeneron (including EYLEA, Praluent, ARCALYST, and ZALTRAP®); and certain other related documents and communications. On June 24, 2020, the U.S. Attorney's Office for the District of Massachusetts filed a civil complaint in the U.S. District Court for the District of Massachusetts alleging violations of the federal Anti-Kickback Statute, and asserting causes of action under the federal False Claims Act and state law. On August 24, 2020, the Company filed a motion to dismiss the complaint in its entirety. On December 4, 2020, the court denied the motion to dismiss. On December 28, 2022, the U.S. Attorney's Office for the District of Massachusetts filed a motion for partial summary judgment. On January 31, 2023, the Company filed a motion for summary judgment. 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 the court's September 27, 2023 order.

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 in part granted and in part denied 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. A trial has been scheduled for April 2025.

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. The Company is cooperating with this investigation. 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.

California Department of Insurance Subpoena

In September 2022, the Company received a subpoena from the Insurance Commissioner for the State of California pursuant to the California Insurance Code. The subpoena seeks information relating to the marketing, sale, and distribution of EYLEA, including (i) discounts, rebates, credit card fees, and inventory management systems; (ii) Regeneron's relationships with distributors; (iii) price reporting; (iv) speaker programs; and (v) patient support programs. The subpoena covers the period from January 1, 2014 through August 1, 2021. The Company is cooperating with this investigation.

Proceedings Initiated by Other Payors Relating to Patient Assistance Organization Support

The Company is party to several lawsuits relating to the conduct alleged in the civil complaint filed by the U.S. Attorney's Office for the District of Massachusetts discussed under "Department of Justice Matters" above. These lawsuits were filed by UnitedHealthcare Insurance Company and United Healthcare Services, Inc. (collectively, "UHC") and Humana Inc. ("Humana") in the United States District Court for the Southern District of New York on December 17, 2020 and July 22, 2021, respectively; and by Blue Cross and Blue Shield of Massachusetts, Inc. and Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc. (collectively, "BCBS"), Medical Mutual of Ohio ("MMO"), Horizon Healthcare Services, Inc. d/b/a Horizon Blue Cross Blue Shield of New Jersey ("Horizon"), and Local 464A United Food and Commercial Workers Union Welfare Service Benefit Fund ("Local 464A") in the U.S. District Court for the District of Massachusetts on December 20, 2021, February 23, 2022, April 4, 2022, and June 17, 2022, respectively. These lawsuits allege causes of action under state law and the federal Racketeer Influenced and Corrupt Organizations Act and seek monetary damages and equitable relief. The MMO and Local 464A lawsuits are putative class action lawsuits. On December 29, 2021, the lawsuits filed by UHC and Humana were stayed by the United States District Court for the Southern District of New York pending resolution of the proceedings before the U.S. District Court for the District of Massachusetts discussed under "Department of Justice Matters" above. On September 27, 2022, the lawsuits filed by BCBS, MMO, and Horizon were stayed by the U.S. District Court for the District of Massachusetts pending resolution of the proceedings before the same court discussed under "Department of Justice Matters" above; and, in light of these stays, the parties to the Local 464A action have also agreed to stay that matter.

Proceedings Relating to Shareholder Derivative Complaint

On June 29, 2021, an alleged shareholder filed a shareholder derivative complaint in the New York Supreme Court, naming the current and certain former members of the Company's board of directors and certain current and former executive officers of the Company as defendants and Regeneron as a nominal defendant. The complaint asserts that the individual defendants breached their fiduciary duties in relation to the allegations in the civil complaint filed by the U.S. Attorney's Office for the District of Massachusetts discussed under "Department of Justice Matters" above. The complaint seeks an award of damages allegedly sustained by the Company; an order requiring Regeneron to take all necessary actions to reform and improve its corporate governance and internal procedures; disgorgement from the individual defendants of all profits and benefits obtained by them resulting from their sales of Regeneron stock; and costs and disbursements of the action, including attorneys' fees. On July 28, 2021, the defendants filed a notice of removal, removing the case from the New York Supreme Court to the U.S. District Court for the Southern District of New York. On September 23, 2021, the plaintiff moved to remand the case to the New York Supreme Court. Also on September 23, 2021, the individual defendants moved to dismiss the complaint in its entirety. On December 19, 2022, the U.S. District Court for the Southern District of New York denied the plaintiff's motion to remand the case and granted a motion to stay the case pending resolution of the proceedings before the U.S. District Court for the District of Massachusetts discussed under "Department of Justice Matters" above. As a result of the stay, the court also terminated the Company's motion to dismiss the complaint without prejudice. The Company can therefore renew the motion to dismiss upon conclusion of the stay.

17. Net Income Per Share

The calculations of basic and diluted net income per share are as follows:

<i>(In millions, except per share data)</i>	Year Ended December 31,		
	2023	2022	2021
Net income - basic and diluted	\$ 3,953.6	\$ 4,338.4	\$ 8,075.3
Weighted average shares - basic	106.7	107.1	105.7
Effect of dilutive securities:			
Stock options	4.9	4.9	5.4
Restricted stock awards and restricted stock units	2.1	1.5	1.1
Weighted average shares - diluted	<u>113.7</u>	<u>113.5</u>	<u>112.2</u>
Net income per share - basic	\$ 37.05	\$ 40.51	\$ 76.40
Net income per share - diluted	\$ 34.77	\$ 38.22	\$ 71.97

Shares which have been excluded from diluted per share amounts because their effect would have been antidilutive include the following:

<i>(Shares in millions)</i>	Year Ended December 31,		
	2023	2022	2021
Stock options	1.8	2.3	2.9

18. Statement of Cash Flows

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

<i>(In millions)</i>	December 31,		
	2023	2022	2021
Cash and cash equivalents	\$ 2,730.0	\$ 3,105.9	\$ 2,885.6
Restricted cash included in Other noncurrent assets	7.8	13.5	12.5
Total cash, cash equivalents, and restricted cash shown in the Consolidated Statement of Cash Flows	<u>\$ 2,737.8</u>	<u>\$ 3,119.4</u>	<u>\$ 2,898.1</u>

Restricted cash consists of amounts held by financial institutions pursuant to contractual arrangements.

Supplemental disclosure of non-cash investing and financing activities

<i>(In millions)</i>	As of December 31,		
	2023	2022	2021
Accrued capital expenditures	\$ 75.4	\$ 70.8	\$ 74.8
Accrued contingent consideration in connection with acquisitions	\$ 71.6	\$ 135.5	\$ —

DIRECTORS

Bonnie L. Bassler, Ph.D.

Chair of the Department of Molecular Biology and Squibb Professor in Molecular Biology at Princeton University

Michael S. Brown, M.D.

Regental Professor of Molecular Genetics and Internal Medicine and Director of the Jonsson Center for Molecular Genetics at The University of Texas Southwestern Medical Center at Dallas

N. Anthony Coles, M.D.

Chair of the Board and former Chief Executive Officer of Cerevel Therapeutics Holdings, Inc., the parent entity of Cerevel Therapeutics, Inc.

Joseph L. Goldstein, M.D.

Regental Professor of Molecular Genetics and Internal Medicine and the Chair of the Department of Molecular Genetics at the University of Texas Southwestern Medical Center at Dallas

Kathryn Guarini, Ph.D.

Former Chief Information Officer of IBM

Christine A. Poon

Former Vice Chair and Worldwide Chair of Pharmaceuticals at Johnson & Johnson

Arthur F. Ryan

Former Chief Executive Officer and Chair of the Board of Prudential Financial, Inc.

David P. Schenkein, M.D.

General Partner and co-Lead of Life Sciences at GV (formerly Google Ventures)

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

Board co-Chair, President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc.

George L. Sing

Chief Executive Officer of GanD, Inc. and Chair of Grace Science, LLC

Craig B. Thompson, M.D.

Former President and Chief Executive Officer of Memorial Sloan Kettering Cancer Center

George D. Yancopoulos, M.D., Ph.D.

Board co-Chair, President and Chief Scientific Officer of Regeneron Pharmaceuticals, Inc.

Huda Y. Zoghbi, M.D.

Professor in the Departments of Pediatrics, Molecular and Human Genetics, and Neurology and Neuroscience at Baylor College of Medicine

EXECUTIVE OFFICERS

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

Board co-Chair, President and Chief Executive Officer

Joseph J. LaRosa

Executive Vice President, General Counsel and Secretary

Jason Pitofsky

Vice President, Controller

George D. Yancopoulos, M.D., Ph.D.

Board co-Chair, President and Chief Scientific Officer

Marion McCourt

Executive Vice President, Commercial

Neil Stahl, Ph.D.

Executive Vice President, Research and Development

Christopher Fenimore

Senior Vice President, Finance and Chief Financial Officer

Andrew J. Murphy, Ph.D.

Executive Vice President, Research

Daniel P. Van Plew

Executive Vice President and General Manager, Industrial Operations and Product Supply

CORPORATE INFORMATION

Common Stock and Related Matters

Our Common Stock is traded on The NASDAQ Global Select Market under the symbol "REGN." Our Class A Stock is not publicly quoted or traded.

Shareholders' Inquiries

Inquiries relating to stock transfer or lost certificates and notices of changes of address should be directed to our Transfer Agent, Equiniti Trust Company, LLC, 55 Challenger Road, Floor 2, Ridgefield Park, NJ 07660, (800)-937-5449, www.equiniti.com. General information regarding the Company, recent press releases, and filings with the U.S. Securities and Exchange Commission are available on our website at www.regeneron.com, or can be obtained by contacting our Investor Relations Department at (914) 847-7741 or invest@regeneron.com.

Transfer Agent & Registrar

Equiniti Trust Company, LLC
55 Challenger Road, Floor 2
Ridgefield Park, NJ 07660

Corporate Office

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Annual Meeting

The 2024 Annual Meeting of Shareholders will be held virtually via the Internet at www.virtualshareholdermeeting.com/REGN2024 on June 14, 2024 at 10:30 a.m., Eastern Time.

Independent Registered Public Accounting Firm

PricewaterhouseCoopers LLP



REGENERON
SCIENCE TO MEDICINE®