

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

, Individually and on
Similarly Situated,

Plaintiff,

v.

REGENERON PHARMACEUTICALS,
INC., LEONARD S. SCHLEIFER,
CHRISTOPHER FENIMORE, and ROBERT
E. LANDRY,

Defendants.

Case No.

**CLASS ACTION COMPLAINT FOR
VIOLATIONS OF THE FEDERAL
SECURITIES LAWS**

DEMAND FOR JURY TRIAL

Plaintiff (“Plaintiff”), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff’s information and belief is based upon, among other things, his counsel’s investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Regeneron Pharmaceuticals, Inc. (“Regeneron” or the “Company”) with the United States (“U.S.”) Securities and Exchange Commission (“SEC”); (b) review and analysis of press releases and media reports issued by and disseminated by Regeneron; and (c) review of other publicly available information concerning Regeneron.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Regeneron securities between November 2, 2023 and October 30, 2024, inclusive (the “Class Period”). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Regeneron is a biotechnology company that designs products for eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, among others. One of the Company’s primary products is Eylea, an injection to treat age-related macular degeneration, among other conditions, by inhibiting anti-vascular endothelial growth factor (“anti-VEGF”). In November 2011, the U.S. Food and Drug Administration (“FDA”) approved Eylea as an anti-VEGF inhibitor for wet age-related macular degeneration, and in August 2023, the FDA approved Eylea HD, a high dose version of Eylea. The Company is “substantially dependent on the success of Eylea [and] Eylea HD.” Sales of the Company’s products, including Eylea and Eylea HD, are, in turn, largely dependent on the availability and extent of reimbursement from third-party payors, including programs such as Medicare and Medicaid.

3. The reimbursement rate for each claim submitted for Eylea and Eylea HD is based on the Average Sales Price (“ASP”) reported by Regeneron to Centers for Medicare and Medicaid Services. In reporting ASP, companies like Regeneron are required to include all price concessions, such as volume discounts, chargebacks, and rebates, as part of their calculation, meaning companies must report the net price received after accounting for these concessions.

4. On April 10, 2024, the U.S. Department of Justice (“DOJ”) announced it had filed a complaint against Regeneron under the False Claims Act. According to the DOJ, the Company failed to report millions of dollars in discounts provided to drug distributors in the form of reimbursed credit card fees. As a result, the DOJ alleges that Eylea’s ASP was inflated, which inappropriately increased Medicare reimbursements. By reimbursing credit card fees, Regeneron subsidized the treatment costs, thereby gaining a competitive advantage over other anti-VEGF treatments.

5. On this news, Regeneron’s stock price declined by \$31.50, or 3.36%, over two consecutive trading days to close at \$904.70 on April 12, 2024, on unusually heavy trading volume.

6. Then, on October 31, 2024, before the market opened, Regeneron released its third quarter 2024 financial results, revealing lagging U.S. net sales for Eylea HD and Eylea. The Company reported sales had only increased 3% versus the third quarter 2023, and quarterly sales of Eylea HD were only \$392 million, missing consensus estimates of \$415 million to \$425 million. The Company also revealed that “[n]et product sales of EYLEA in the third quarter of 2024 were adversely impacted by a lower net selling price compared to the third quarter of 2023.” In the wake of this news, Reuters reported the Company had “reported weaker-than-expected quarterly sales of the higher dose version of its blockbuster eye disease drug Eylea.”

7. On this news, Regeneron's stock price fell \$84.59, or 9.2%, to close at \$838.20 per share on October 31, 2024, on unusually heavy trading volume.

8. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that Regeneron paid credit card fees to distributors on the condition that distributors did not charge Eylea customers more to use a credit card; (2) that these payments subsidized the prices that customers paid when using credit cards to purchase Eylea; (3) that, as a result, Regeneron offered a price concession that lowered Eylea's selling price; (4) that, because retina practices were sensitive to higher prices when using credit cards to purchase anti-VEGF medications, Regeneron's price concessions provided a competitive advantage; (5) that, as a result of the foregoing, Regeneron misleadingly boosted reported Eylea sales; (6) that, by failing to report its payment of credit card fees as price concessions, Regeneron overstated the ASP reported to federal agencies, thereby violating the False Claims Act; and (7) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

10. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

12. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principle executive offices are located in this District.

13. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

14. Plaintiff Jeffrey Radtke, as set forth in the accompanying certification, incorporated by reference herein, purchased Regeneron securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

15. Defendant Regeneron is incorporated under the laws of New York with its principal executive offices located in Tarrytown, New York. Regeneron's common stock trades on the NASDAQ exchange under the symbol "REGN."

16. Defendant Leonard S. Schleifer ("Schleifer") was the Company's Chief Executive Officer ("CEO") at all relevant times.

17. Defendant Christopher Fenimore ("Fenimore") has been the Company's Chief Financial Officer ("CFO") since February 5, 2024.

18. Defendant Robert E. Landry (“Landry”) was the Company’s CFO from September, 2013 until February 5, 2024.

19. Defendants Schleifer, Fenimore, and Landry (together, the “Individual Defendants”), because of their positions with the Company, possessed the power and authority to control the contents of the Company’s reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. The Individual Defendants were provided with copies of the Company’s reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

20. Regeneron is a biotechnology company that designs products for eye diseases, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, among others. One of the Company’s primary products is Eylea, an injection to treat age-related macular degeneration, among other conditions. In November 2011, the FDA approved Eylea as an anti-VEGF inhibitor for wet age-related macular degeneration and, in August 2023, the FDA approved Eylea HD, a high dose version of Eylea. The Company is “substantially dependent on the success of Eylea [and] Eylea HD.” Sales of the Company’s products, including Eylea and Eylea HD, are, in turn, largely dependent on the availability and extent of reimbursement from third-party payors, including programs such as Medicare and Medicaid.

21. The reimbursement rate for each claim submitted for Eylea and Eylea HD is based on the Average Sales Price (“ASP”) reported by Regeneron to federal Centers for Medicare and Medicaid Services. In reporting ASP, companies like Regeneron are required to include all price concessions, such as volume discounts, chargebacks, and rebates, as part of their calculation, meaning companies must report the net price received after accounting for these concessions.

Materially False and Misleading

Statements Issued During the Class Period

22. The Class Period begins on November 2, 2023. On that day, Regeneron announced its third quarter 2023 financial results in a press release for the period ended September 30, 2023. The press release reported the Company’s financial and operating results, including that “[t]hird quarter 2023 revenues increased 15% to \$3.36 billion versus third quarter 2022,” supported by Eylea and Eylea HD sales, reporting “U.S. net sales for EYLEA® and EYLEA HD were \$1.49 billion, including \$43 million from EYLEA HD.” Specifically the press release stated the following, in relevant part: ¹

Third quarter 2023 revenues increased 15% to \$3.36 billion versus third quarter 2022

* * *

Third quarter 2023 U.S. net sales for EYLEA® and EYLEA HD were \$1.49 billion, including \$43 million from EYLEA HD

* * *

Third quarter 2023 GAAP diluted EPS of \$8.89 and non-GAAP diluted EPS(a) of \$11.59; includes unfavorable \$0.77 impact from acquired IPR&D charge

¹ Unless otherwise stated, all emphasis in bold and italics hereinafter is added, and all footnotes are omitted.

	*	*	*
	Q3 2023	Q3 2022	% Change
<i>(\$ in millions, except per share data)</i>			
Total revenues	\$ 3,363	\$ 2,936	15 %
GAAP net income	\$ 1,008	\$ 1,316	(23 %)
GAAP net income per share - diluted	\$ 8.89	\$ 11.66	(24 %)
Non-GAAP net income ^(a)	\$ 1,329	\$ 1,270	5 %
Non-GAAP net income per share - diluted ^(a)	\$ 11.59	\$ 11.14	4 %

	*	*	*
	Q3 2023	Q3 2022	% Change
<i>(\$ in millions)</i>			
Net product sales:			
EYLEA - U.S.	\$ 1,448	\$ 1,629	(11 %)
EYLEA HD - U.S.	43	—	*
Libtayo - Global**	232	126	84 %
Praluent [®] - U.S.	40	30	33 %
Evkeeza [®] - U.S.	19	13	46 %
Inmazole [®] - U.S.	4	3	33 %
Total net product sales	1,786	1,801	(1 %)
Collaboration revenue:			
Sanofi	1,065	711	50 %
Bayer	377	333	13 %
Other	(3)	6	*
Other revenue	138	85	62 %
Total revenues	\$ 3,363	\$ 2,936	15 %

23. On November 2, 2023, the Company submitted its quarterly report for the period ended September 30, 2023 on a Form 10-Q filed with the SEC, affirming the previously reported financial results (the “3Q23 10-Q”). The 3Q23 10-Q purported to warn of risks to the Company, including that the Company may be exposed in the future to False Claims Act charges for alleged promotional and marketing activities. Specifically, the 3Q23 10-Q stated the following, in relevant part:

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.

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 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.

* * *

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.

* * *

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.

* * *

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.

24. The 3Q23 10-Q further purported to warn of additional risks to the Company, including that “*if*” the Company fails to comply with its reporting obligations under governmental pricing and reimbursement programs, the Company could be subject to sanctions and fines, which could have a material adverse effect on the Company. Specifically, the 3Q23 10-Q stated the following, in relevant part:

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

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

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

25. On January 8, 2024, at the 42nd Annual J.P. Morgan Healthcare Conference, Defendant Schleifer provided a presentation and corporate update on the Company. The presentation included information regarding the Company's preliminary fourth quarter 2023 results, including reporting approximately \$123 million in U.S. net product sales of Eylea HD and \$1.34 billion in U.S. net product sales of Eylea. Specifically the presentation reported the following, in relevant part:

EYLEA HD approved by FDA for wAMD, DME, and DR

EYLEA HD
has the potential to become the next-generation standard-of-care anti-VEGF treatment

4Q 2023 U.S. Net Product Sales*:
\$123 million
achieved in first full quarter following launch

4Q 2023 combined EYLEA HD + EYLEA U.S. net product sales of **\$1.46 billion***

- ✓ FDA approval for wAMD, DME and DR received in August 2023
- ✓ Early indicators suggest **broad initial uptake** across treatment landscape
- ✓ **Strong 2-year data** from pivotal PULSAR and PHOTON studies presented in 2H 2023, supporting **best-in-class** efficacy, safety, and durability profile
- ✓ **~2/3 of eligible lives have coverage**; vast majority of covered lives have **first-line or single-step-edit access** to Eylea HD
- ✓ **100% of Medicare jurisdictions** have confirmed paid claims
- ✓ Remain on track for **permanent J-Code** on April 1, 2024

6 * Based on preliminary, unaudited results. Preliminary U.S. net product sales for Eylea in 4Q 2023 were \$1.34 billion.

REGENERON*

26. On February 2, 2024, the Company announced its fourth quarter and full year 2023 financial results in a press release for the period ended December 31, 2023. The press release reported the Company’s financial and operating results, including that “[f]ull year 2023 revenues increased 8% to \$13.12 billion versus full year 2022;” supported by Eylea and Eyelea HD sales, reporting “full year 2023 U.S. net sales for EYLEA HD and EYLEA were \$5.89 billion.” Specifically the press release stated the following, in relevant part:

- *Fourth quarter 2023 revenues increased 1% to \$3.43 billion versus fourth quarter 2022; excluding Ronapreve™(a)(b), revenues increased 14%*

- *Full year 2023 revenues increased 8% to \$13.12 billion versus full year 2022; excluding Ronapreve(a), revenues increased 12%*

* * *

- *Fourth quarter 2023 U.S. net sales for EYLEA® HD and EYLEA® were \$1.46 billion, including \$123 million from EYLEA HD; full year 2023 U.S. net sales for EYLEA HD and EYLEA were \$5.89 billion, including \$166 million from EYLEA HD following its August 2023 FDA approval*

* * *

	Three Months Ended December 31,			Year Ended December 31,		
	2023	2022	% Change	2023	2022	% Change
<i>(\$ in millions, except per share data)</i>						
Total revenues	\$ 3,434	\$ 3,414	1 %	\$ 13,117	\$ 12,173	8 %
Total revenues excluding Ronapreve ^{(a)(b)}	\$ 3,436	\$ 3,018	14%	\$ 12,906	\$ 11,546	12%
GAAP net income	\$ 1,160	\$ 1,197	(3 %)	\$ 3,954	\$ 4,338	(9 %)
GAAP net income per share - diluted	\$ 10.19	\$ 10.50	(3 %)	\$ 34.77	\$ 38.22	(9 %)
Non-GAAP net income ^(a)	\$ 1,366	\$ 1,449	(6 %)	\$ 5,045	\$ 5,164	(2 %)
Non-GAAP net income per share - diluted ^(a)	\$ 11.86	\$ 12.56	(6 %)	\$ 43.79	\$ 44.98	(3 %)

* * *

	Q4 2023	Q4 2022	% Change	FY 2023	FY 2022	% Change
<i>(\$ in millions)</i>						
Net product sales:						
EYLEA HD - U.S.	\$ 123	\$ —	*	\$ 166	\$ —	*
EYLEA - U.S.	1,338	1,496	(11 %)	5,720	6,265	(9 %)
Total EYLEA HD and EYLEA - U.S.	1,461	1,496	(2 %)	5,886	6,265	(6 %)
Libtayo - Global**	244	152	61 %	863	448	93 %
Praluent [®] - U.S.	61	36	69 %	182	130	40 %
Evkeeza - U.S.	24	15	60 %	77	48	60 %
Inmazole [®] - U.S.	62	—	*	70	3	*
Total net product sales	1,852	1,699	9 %	7,078	6,894	3 %
Collaboration revenue:						
Sanofi	993	836	19 %	3,800	2,856	33 %
Bayer	377	355	6 %	1,487	1,431	4 %
Other	—	396	(100 %)	216	627	(66 %)
Other revenue	212	128	66 %	536	365	47 %
Total revenues	\$ 3,434	\$ 3,414	1 %	\$ 13,117	\$ 12,173	8 %

27. On February 5, 2024, the Company submitted its annual report for the fiscal year ended December 31, 2023 on a Form 10-K filed with the SEC, affirming the previously reported financial results (the “FY23 10-K”). The FY23 10-K purported to warn of risks to the Company, including that the Company may be exposed in the future to False Claims Act charges for alleged promotional and marketing activities in substantially the same terms as the 3Q23 10-Q. Specifically, the FY23 10-K stated the following, in relevant part:

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.

* * *

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 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.

* * *

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.

* * *

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.

* * *

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.

28. The FY23 10-K further purported to warn of additional risks to the Company, including that “*if*” the Company fails to comply with its reporting obligations under governmental pricing and reimbursement programs, the Company could be subject to sanctions and fines, which could have a material adverse effect on the Company. Specifically, the FY23 10-K stated the following, in relevant part:

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 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.

29. The above statements identified in ¶¶ 22-28 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that Regeneron paid credit card fees to distributors on the condition that distributors did not charge Eylea customers more to use a credit card; (2) that these payments subsidized the prices that customers paid when using credit cards to purchase Eylea; (3) that, as a result, Regeneron offered a price concession that lowered Eylea's selling price; (4) that, because retina practices were sensitive to higher prices when using credit cards to purchase anti-VEGF medications, Regeneron's price concessions provided a competitive advantage; (5) that, as a result of the foregoing, Regeneron misleadingly boosted reported Eylea sales; (6) that, by failing to report its payment of credit card fees as price concessions, Regeneron overstated the ASP reported to federal agencies, thereby violating the False Claims Act; and (7) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

30. The truth began to emerge on April 10, 2024, when the U.S. Department of Justice announced it had filed a complaint against Regeneron under the False Claims Act. In that complaint, the Department of Justice accuses the Company of failing to report millions of dollars in discounts provided to drug distributors in the form of reimbursed credit card fees. As a result, the DOJ alleges that the average selling price of Regeneron’s Eylea drug was inflated, which inappropriately increased Medicare reimbursements. Specifically, the Department of Justice complaint stated the following, in relevant part:

Regeneron knew that distributors incurred processing fees if retina practices used credit cards to purchase expensive drugs like Eylea, and that, accordingly, distributors would charge retina practices a higher amount to use credit cards for Eylea purchases, unless Regeneron reimbursed those fees. Regeneron also knew that most customers wanted to use credit cards for their expensive drug purchases, in part because of the lucrative cash back rewards. ***Regeneron thus agreed to, and did pay, the credit card processing fees for retina practices’ Eylea purchases.***

* * *

An unwritten, but well-understood and followed, component of Regeneron’s agreements with distributors was that Regeneron paid credit card processing fees for customers’ Eylea purchases on the condition that the distributors did not charge Eylea customers more to use a credit card—which Regeneron knew they otherwise would in the absence of Regeneron’s payments.

* * *

Before and after Eylea’s launch, Regeneron understood the competitive nature of the Wet AMD market, including that retina practices were sensitive to the higher prices they faced when they used credit cards to purchase Anti-VEGF medications. In July 2011, a Regeneron “Reimbursement Business Manager” sent an internal email describing this dynamic and noting that it was a “big deal” for certain customers to be able to use credit cards without incurring an additional expense: “Lucentis [D]irect does not charge the providers any more for paying with a credit card, however ***the distributors (Besse) do charge more for a credit card payment. This also was a big deal for several accounts.***” Ex. 28 (emphasis added). Robert Davis, then Regeneron’s Senior Director of Trade, Reimbursement and Managed Markets, responded “Good feedback and pretty consistent ***We will pay pass thru fees so the 3 distributors [(Besse, McKesson, and CuraScript)] will not charge extra to offices.***” *Id.* (emphasis added).

Regeneron marketed to customers that they could use credit cards to purchase Eylea from distributors without paying more—and that customers could not do so for Lucentis—as a “Key Takeaway” in its messaging:

Key Takeaways:

- EYLEA is contracted with three distributors
- Credit cards are accepted by all 3 distributors and not for Lucentis orders

* * *

Thus, Regeneron’s reimbursement of credit card fees was functionally no different than if Regeneron or distributors directly paid customers to cover the higher costs they would otherwise have incurred, or if distributors credited customers for those amounts on their invoices, based on Regeneron’s payments. Regeneron knew its payments were passed on to customers in two ways: (1) the lower, subsidized prices customers paid when they used credit cards to purchase Eylea from distributors, and (2) the “cash back” and credit card rewards Eylea customers received from those purchases

* * *

By purporting not to offer price concessions on Eylea, Regeneron could market Eylea’s stable ASP (and stable reimbursement) as a competitive advantage for retina practices when compared to Lucentis.

* * *

Regeneron knew that its payment of credit card processing fees on behalf of customers was a price concession for many customers, and because Regeneron did not report them as price concessions, had the further benefit of not eroding Eylea’s ASP.

31. On this news, Regeneron’s stock price declined by \$31.50, or 3.36%, over two consecutive trading days to close at \$904.70 on April 12, 2024, on unusually heavy trading volume.

32. On May 2, 2024, the Company announced its first quarter 2024 financial results in a press release for the period ended March 31, 2024. The press release reported the Company’s financial and operating results, including that “excluding RonapreveTM, revenues increased 7%” to \$3.15 billion, supported by Eylea and Eyelea HD sales, reporting “U.S. net sales for EYLEA®

HD and EYLEA® were \$1.40 billion, including \$200 million from EYLEA HD.” Specifically the press release stated the following, in relevant part:

First quarter 2024 revenues decreased 1% to \$3.15 billion versus first quarter 2023; excluding Ronapreve™^[1], revenues increased 7%

* * *

First quarter 2024 U.S. net sales for EYLEA® HD and EYLEA® were \$1.40 billion, including \$200 million from EYLEA HD

* * *

First quarter 2024 GAAP diluted EPS of \$6.27 and non-GAAP diluted EPS(a) of \$9.55

* * *

<i>(\$ in millions, except per share data)</i>	Q1 2024	Q1 2023	% Change
Total revenues	\$ 3,145	\$ 3,162	(1 %)
Total revenues excluding Ronapreve ^{(a)(b)}	\$ 3,145	\$ 2,940	7 %
GAAP net income	\$ 722	\$ 818	(12 %)
GAAP net income per share - diluted	\$ 6.27	\$ 7.17	(13 %)
Non-GAAP net income ^(a)	\$ 1,116	\$ 1,168	(4 %)
Non-GAAP net income per share - diluted ^(a)	\$ 9.55	\$ 10.09	(5 %)

* * *

<i>(\$ in millions)</i>	Q1 2024	Q1 2023	% Change
Net product sales:			
EYLEA HD - U.S.	\$ 200	\$ —	*
EYLEA - U.S.	1,202	1,434	(16 %)
Total EYLEA HD and EYLEA - U.S.	1,402	1,434	(2 %)
Libtayo - Global	264	177	49 %
Praluent - U.S.	70	40	75 %
Evkeeza® - U.S.	24	15	60 %
Inmazole® - Global	1	2	*
Total net product sales	1,761	1,668	6 %
Collaboration revenue:			
Sanofi	910	798	14 %
Bayer	356	357	— %
Other	1	223	(100 %)
Other revenue	117	116	1 %
Total revenues	\$ 3,145	\$ 3,162	(1 %)

33. On May 2, 2024, the Company submitted its quarterly report for the period ended March 31, 2024 on a Form 10-Q filed with the SEC, affirming the previously reported financial results (the “1Q24 10-Q”). The 1Q24 10-Q purported to warn of risks to the Company, including

that the Company may be exposed in the future to False Claims Act charges for alleged promotional and marketing activities in substantially the same terms as the 3Q23 10-Q and the FY23 10-K. Specifically, the 1Q24 10-Q stated the following, in relevant part:

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.

* * *

In addition to FDA and related regulatory requirements, we are subject to healthcare "fraud and abuse" laws, such as the federal civil False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations.

* * *

The 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.

* * *

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.

* * *

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.

* * *

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.

34. The 1Q24 10-Q further purported to warn of additional risks to the Company, including that “*if*” the Company fails to comply with its reporting obligations under governmental pricing and reimbursement programs, the it could be subject to sanctions and fines, which could have a material adverse effect on the Company. Specifically, the 1Q24 10-Q stated the following, in relevant part:

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

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

35. On August 1, 2024, the Company announced its second quarter 2024 financial results in a press release for the period ended June 30, 2024. The press release reported the Company’s financial and operating results, including that “revenues increased 12% to \$3.55 billion” supported by Eylea and Eyelea HD sales, reporting “U.S. net sales for EYLEA®

HD and EYLEA® increased 2% to \$1.53 billion versus second quarter 2023, including \$304 million from EYLEA HD.” Specifically the press release stated the following, in relevant part:

Second quarter 2024 revenues increased 12% to \$3.55 billion versus second quarter 2023

* * *

Second quarter 2024 U.S. net sales for EYLEA® HD and EYLEA® increased 2% to \$1.53 billion versus second quarter 2023, including \$304 million from EYLEA HD

* * *

Second quarter 2024 GAAP diluted EPS increased 46% to \$12.41 and non-GAAP diluted EPS(a) increased 13% to \$11.56 versus second quarter 2023

* * *

(\$ in millions, except per share data)	Q2 2024	Q2 2023	% Change
Total revenues	\$ 3,547	\$ 3,158	12 %
GAAP net income	\$ 1,432	\$ 968	48 %
GAAP net income per share - diluted	\$ 12.41	\$ 8.50	46 %
Non-GAAP net income ^(a)	\$ 1,351	\$ 1,182	14 %
Non-GAAP net income per share - diluted ^(a)	\$ 11.56	\$ 10.24	13 %

* * *

(\$ in millions)	Q2 2024	Q2 2023	% Change
Net product sales:			
EYLEA HD - U.S.	\$ 304	\$ —	*
EYLEA - U.S.	1,231	1,500	(18 %)
Total EYLEA HD and EYLEA - U.S.	1,535	1,500	2 %
Libtayo - Global	297	210	41 %
Praluent - U.S.	56	41	37 %
Evkeeza® - U.S.	31	19	63 %
Inmazoleb® - Global	—	2	(100 %)
Total net product sales	1,919	1,772	8 %
Collaboration revenue:			
Sanofi	1,146	944	21 %
Bayer	375	377	(1 %)
Other	3	(4)	*
Other revenue	104	69	51 %
Total revenues	\$ 3,547	\$ 3,158	12 %

Total EYLEA HD and EYLEA net product sales in the U.S. increased 2% in the second quarter of 2024 compared to the second quarter of 2023. EYLEA HD was approved by the FDA in August 2023 and EYLEA HD net product sales in the second quarter of 2024 were driven by the transition of patients from other anti-VEGF products, including EYLEA, to EYLEA HD, as well as new patients naïve to anti-VEGF therapy.

36. On August 1, 2024, the Company submitted its quarterly report for the period ended June 30, 2024 on a Form 10-Q filed with the SEC, affirming the previously reported financial results (the “2Q24 10-Q”). The 2Q24 10-Q purported to warn of risks to the Company, including that the Company may be exposed in the future to False Claims Act charges for alleged promotional and marketing activities in substantially the same terms as the 3Q23 10-Q, FY23 10-K, and 1Q24 10-Q. Specifically, the 2Q24 10-Q stated the following, in relevant part:

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.

* * *

In addition to FDA and related regulatory requirements, we are subject to healthcare "fraud and abuse" laws, such as the federal civil False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations.

* * *

The 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.

* * *

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.

* * *

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.

* * *

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.

37. The 2Q24 10-Q further purported to warn of additional risks to the Company, including that “*if*” the Company fails to comply with its reporting obligations under governmental pricing and reimbursement programs, the Company could be subject to sanctions and fines, which could have a material adverse effect on the Company in substantially the same terms as the 1Q24 10-Q. Specifically, the 2Q24 10-Q stated the following, in relevant part:

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

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

38. The above statements identified in ¶¶ 32-37 were materially false and/or misleading, and failed to disclose material adverse facts about the Company’s business, operations,

and prospects. Specifically, Defendants failed to disclose to investors: (1) that, because retina practices were sensitive to higher prices when using credit cards to purchase anti-VEGF medications, Regeneron’s price concessions provided a competitive advantage; and (2) that, as a result of the foregoing, Regeneron misleadingly boosted reported Eylea sales; and (3) that, as a result of the foregoing, Defendants’ positive statements about the Company’s business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

Disclosures at the End of the Class Period

39. On October 31, 2024, before the market opened, Regeneron released its third quarter 2024 financial results in a press release for the quarter ended September 30, 2024. The press release revealed lagging U.S. net sales for Eylea HD and Eylea. The Company reported sales had only increased 3% versus the third quarter 2023, and quarterly sales of Eylea HD were only \$392 million, missing consensus estimates of \$415 million to \$425 million. The Company also revealed that “[n]et product sales of EYLEA in the third quarter of 2024 were adversely impacted by a lower net selling price compared to the third quarter of 2023.” In the wake of this news, Reuters reported the Company had “reported weaker-than-expected quarterly sales of the higher dose version of its blockbuster eye disease drug Eylea.” Specifically, the press release stated, in relevant part:

Third quarter 2024 U.S. net sales for EYLEA HD® and EYLEA® increased 3% versus third quarter 2023 to \$1.54 billion, including \$392 million from EYLEA HD

* * *

(\$ in millions)	Q3 2024	Q3 2023	% Change
Net product sales:			
EYLEA HD - U.S.	\$ 392	\$ 43	*
EYLEA - U.S.	1,145	1,448	(21 %)
Total EYLEA HD and EYLEA - U.S.	1,537	1,491	3 %
Libtayo - Global	289	232	25 %
Praluent® - U.S.	53	40	33 %
Evkeeza® - U.S.	32	19	68 %
Inmazoleb® - Global	35	4	*
Total net product sales	1,946	1,786	9 %
Collaboration revenue:			
Sanofi	1,263	1,065	19 %
Bayer	391	377	4 %
Other	6	(3)	*
Other revenue	114	138	(17 %)
Total revenues	\$ 3,720	\$ 3,363	11 %

Total EYLEA HD and EYLEA net product sales in the U.S. increased 3% in the third quarter of 2024 compared to the third quarter of 2023. EYLEA HD was approved by the FDA in August 2023 and net product sales in the third quarter of 2024 were driven by the transition of patients from other anti-VEGF products, including EYLEA, as well as new patients naïve to anti-VEGF therapy. ***Net product sales of EYLEA in the third quarter of 2024 were adversely impacted by a lower net selling price compared to the third quarter of 2023.*** In addition, third quarter 2024 total EYLEA HD and EYLEA net product sales were favorably impacted by approximately \$40 million as a result of higher wholesaler inventory levels for EYLEA HD at the end of the third quarter of 2024 compared to the end of the second quarter of 2024, partially offset by lower wholesaler inventory levels for EYLEA.

40. On this news, Regeneron’s stock price fell \$84.59, or 9.2%, to close at \$838.20 per share on October 31, 2024, on unusually heavy trading volume.

CLASS ACTION ALLEGATIONS

41. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Regeneron securities between November 2, 2023 and October 30, 2024, inclusive, and who were damaged thereby (the “Class”). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

42. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Regeneron's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Regeneron shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Regeneron or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

43. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

44. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

45. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Regeneron; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

46. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

47. The market for Regeneron's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Regeneron's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Regeneron's securities relying upon the integrity of the market price of the Company's securities and market information relating to Regeneron, and have been damaged thereby.

48. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Regeneron's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Regeneron's business, operations, and prospects as alleged herein.

49. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading

statements about Regeneron's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

50. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

51. During the Class Period, Plaintiff and the Class purchased Regeneron's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

52. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Regeneron, their control over, and/or receipt and/or modification of Regeneron's allegedly materially misleading misstatements

and/or their associations with the Company which made them privy to confidential proprietary information concerning Regeneron, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE

(FRAUD-ON-THE-MARKET DOCTRINE)

53. The market for Regeneron's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Regeneron's securities traded at artificially inflated prices during the Class Period. On August 27, 2024, the Company's share price closed at a Class Period high of \$1,201.76 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Regeneron's securities and market information relating to Regeneron, and have been damaged thereby.

54. During the Class Period, the artificial inflation of Regeneron's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Regeneron's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Regeneron and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

55. At all relevant times, the market for Regeneron's securities was an efficient market for the following reasons, among others:

(a) Regeneron shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Regeneron filed periodic public reports with the SEC and/or the NASDAQ;

(c) Regeneron regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Regeneron was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

56. As a result of the foregoing, the market for Regeneron's securities promptly digested current information regarding Regeneron from all publicly available sources and reflected such information in Regeneron's share price. Under these circumstances, all purchasers of Regeneron's securities during the Class Period suffered similar injury through their purchase of Regeneron's securities at artificially inflated prices and a presumption of reliance applies.

57. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to

recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

58. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as “forward-looking statements” when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Regeneron who knew that the statement was false when made.

FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and

Rule 10b-5 Promulgated Thereunder

Against All Defendants

59. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

60. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Regeneron's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

61. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Regeneron's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

62. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Regeneron's financial well-being and prospects, as specified herein.

63. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Regeneron's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Regeneron and its business operations and future prospects in

light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

64. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

65. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Regeneron's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual

knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

66. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Regeneron's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Regeneron's securities during the Class Period at artificially high prices and were damaged thereby.

67. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Regeneron was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Regeneron securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

68. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

69. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM

Violation of Section 20(a) of The Exchange Act

Against the Individual Defendants

70. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

71. Individual Defendants acted as controlling persons of Regeneron within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

72. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

73. As set forth above, Regeneron and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

- (a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;
- (b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- (c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and
- (d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: January 7, 2025