UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ALLEN CHEATHAM, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. REGENERON PHARMACEUTICALS, INC., GEORGE D. YANCOPOULOS, ISRAEL LOWY, and RYAN CROWE Defendants.	Case No. 7:26-cv-06026 **COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **CLASS ACTION** Demand for Jury Trial

Plaintiff Allen Cheatham ("Plaintiff"), individually and on behalf of all other persons similarly situated, by her undersigned attorneys, alleges in this Complaint for violations of the federal securities laws (the "Complaint") the following based upon knowledge with respect to her own acts, and upon facts obtained through an investigation conducted by her counsel, which included, *inter alia*: (a) review and analysis of relevant filings made by Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of Regeneron's public documents, conference calls, press releases, and stock chart; (c) review and analysis of securities analysts' reports and advisories concerning the Company; and (d) information readily obtainable on the internet.

Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to the defendants or are exclusively within their control.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Regeneron common stock between August 1, 2025, and May 15, 2026, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws (the "Class").

2. Defendants provided investors with material information concerning Regeneron's Phase III clinical trial of Fianlimab, a LAG-3 inhibitor, in combination with cemiplimab, a PD-1 inhibitor, as a first-line treatment for metastatic or locally advanced melanoma (the "Phase III Fianlimab-Libtayo Study"). Defendants' statements included, among other things, overwhelming confidence in the drug combination's potential for success and a mischaracterization of the additional structural risk imposed on the study by the prolonged slowdown in event accruals.

3. Defendants repeatedly and falsely characterized this slowdown as a likely positive development that reflected the durable efficacy of the active treatment arms, while knowingly or recklessly disregarding that the actual risk of clinical failure had dramatically increased due to the nature of the delay. Defendants' representations regarding the nature and impact of the slowdown mischaracterized the actual risk of failure that the study was facing.

4. Regardless, Defendants provided overwhelmingly positive statements to investors while, at the same time, disseminating materially false and misleading statements and/or concealing material adverse facts concerning the true state of Regeneron's Phase III Fianlimab-Libtayo Study; notably, that its preliminary statistical assumptions were fundamentally flawed, that the active treatment arm was failing to achieve meaningful clinical differentiation over standard therapies, and that the trial would ultimately fail to reach statistical significance on its primary endpoint even without overperformance of the control arm. Such statements absent these

material facts caused Plaintiff and other shareholders to purchase Regeneron's securities at artificially inflated prices.

5. Shareholders began to question the veracity of Defendants' public statements on April 29, 2026, during Regeneron's first quarter earnings call. In pertinent part, Defendants disclosed the Phase III Fianlimab-Libtayo Study had been altered, expanding the number of patients in the study eligible for "analysis of progression-free survival."

6. Investors and analysts reacted immediately to Regeneron's revelation. The price of Regeneron's common stock declined dramatically. From a closing market price of $731.77 per share on April 28, 2026, Regeneron's stock price fell to $686.36 per share on April 29, 2026, a decline of about 6.2% in the span of just a single day.

7. Notwithstanding the April 29 disclosures, Regeneron and the Individual Defendants continued to mislead investors. Defendants continued to develop the false impression that they possessed reliable information pertaining to the likelihood of the Phase III Fianlimab-Libtayo Study to achieve its primary endpoint and the overall risk profile of the study. Despite being forced to issue a last-minute amendment to the study's protocol in order to increase the acceptable patient pool for consideration of the primary endpoint analysis, Defendants continued to suggest that this crawling pace with which the study was reaching event accruals necessary for comparison was a positive development absent the control group doing "something miraculous" to offset the treatment arm's performance.

8. The full truth finally emerged after-market on May 15, 2026, when Regeneron issued a press release announcing that the "Phase 3 Trial of Fianlimab . . . did not reach statistical significance for the primary endpoint of improvement in progression-free survival (PFS)."

9. Investors and analysts again reacted promptly to Regeneron's revelation. The price of Regeneron's common stock declined even further. From a closing market price of $698.25 per share on May 15, 2026, Regeneron's stock price fell to $629.68 per share on May 18, 2026, a decline of about 9.8% in the span of one day.

JURISDICTION AND VENUE

10. Plaintiff brings this action, on behalf of herself and other similarly situated investors, to recover losses sustained in connection with Defendants' fraud.

11. The claims asserted herein arise under and pursuant to §§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).

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

13. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant Regeneron is headquartered in this District and a significant portion of its business, actions, and the subsequent damages to Plaintiff and the Class, took place within this District.

14. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

15. Plaintiff purchased Regeneron common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing her transaction(s) in Regeneron is attached hereto.

16. Regeneron Pharmaceuticals, Inc. is a New York corporation with its principal executive offices located at 777 Old Saw Mill River Road Tarrytown, NY 10591. During the Class Period, the Company's common stock traded on the NASDAQ Stock Market (the "NASDAQ") under the symbol "REGN."

17. Defendant George D. Yancopoulos ("Yancopoulos") was, at all relevant times, the Co-Founder, President, Chief Executive Officer, and Co-Chairman of Regeneron.

18. Israel Lowy ("Lowy") was, at all relevant times, the Senior Vice President and Clinical Development Unit Head of Oncology of Regeneron.

19. Defendant Ryan Crowe ("Crowe") was, at all relevant times, the Senior Vice President of Investor Relations and Strategic Analysis of Regeneron.

20. Defendants Yancopoulos, Lowy, and Crowe are sometimes referred to herein as the "Individual Defendants." Regeneron together with the Individual Defendants are referred to herein as the "Defendants."

21. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Regeneron's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was 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, each of these 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, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

22. Regeneron is liable for the acts of the Individual Defendants, and its employees under the doctrine of respondeat superior and common law principles of agency as all the wrongful acts complained of herein were carried out within the scope of their employment with authorization.

23. The scienter of the Individual Defendants, and other employees and agents of the Company are similarly imputed to Regeneron under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

Company Background

24. Regeneron is a pharmaceutical company that discovers, invents, develops, manufactures, tests, and commercializes medicines to treat various disorders worldwide.

25. During the relevant period, Regeneron was investigating Fianlimab, a human monoclonal antibody targeting the LAG-3 immune checkpoint receptor on T-cells.

26. Fianlimab was pertinently being tested in combination with Libtayo in a phase 3 study to determine whether the drug combination could serve as a first-line treatment for advanced melanoma (the "Phase III Fianlimab-Libtayo Study"). The study had commenced enrollment in mid-2022.

The Defendants Materially Misled Investors Concerning

Their Confidence in the Success of Regeneron's Phase III Fianlimab-Libtayo Study

August 1, 2025

27. On August 1, 2025, Defendants released their second quarter fiscal 2025 results and conducted a same-day shareholder call to discuss them. During the call, Defendant Yancopoulos announced that the Phase III Fianlimab-Libtayo Study's results had been delayed despite completing enrollment as anticipated, stating, in pertinent part:

> Libtayo is being tested in combination with fianlimab, our LAG-3 antibody in a pivotal trial in first-line advanced melanoma, a setting in which this combination has generated compelling preliminary efficacy data when compared cross-trial to PD-1 monotherapy. The primary endpoint for this study is progression-free survival and KEYTRUDA monotherapy as a control. Enrollment for the PFS cohort was completed in January as expected, but ***results are now anticipated in late 2025 or early 2026 as the blinded PFS event rate accrual has slowed in recent months***.

(Emphasis added).

28. During the call, Defendants made no effort to suggest this development would necessitate the alteration of the study protocol and that it implied or otherwise suggested an increased risk of a negative study outcome.

29. Conversely, during the question-and-answer segment of the call, Defendant Yancopoulos only suggested the delayed results as an impact of the slowing event rates:

> <Q: Terence C. Flynn – Morgan Stanley – Equity Analyst> You mentioned in the fianlimab first-line melanoma study that the event rate is slowing. So just wondering if you could speculate on reasons there and just speak to your confidence level in showing a positive readout here and remind us what the efficacy bar is that you're looking for and hoping to show.
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> <A: George D. Yancopoulos> Well, ***I think that you can make a lot of speculations on what it means when you have less events than you might have planned or powered for***. That said, what we're powering for is having minimally the sort of effect that the competitors have shown, of course, with room to show perhaps even a better effect. And as we said, ***because of the slowing of the event rates, it has now delayed when we're going to get these results***.

(Emphasis added).

November 17, 2025

30. On November 17, 2025, Defendant Lowry presented on behalf of Regeneron alongside other members of management at the 7th Annual Wolfe Research Healthcare Conference. To open the dialogue, Defendant Lowry discussed the Phase III Fianlimab-Libtayo Study, the Company's basis for the test, and their confidence level in the treatment, in pertinent part:

> <Q: Alexandria Janet Hammond – Wolfe Research, LLC – Head of Therapeutics Research & Senior Analyst> Thank you. So I guess, looking forward, we think one of the most important readouts for you guys is your PD-1 LAG-3 in melanoma. Can you kind of walk us through the confidence there from a trial readout perspective?
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> <A: Israel Lowy> Sure. Thank you. And first of all, thank you for having us, and it's a pleasure to be here. And before I start, I just -- it's really exciting for us at Regeneron to be, I think, now comfortably viewed as a serious oncology company. What wasn't always the case that I think with the development of Libtayo and its success in a number of different indications, more recent success with some of our bispecifics in hematologic malignancies.
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> ***And as we believe it will be the next big thing for us will be the readout of our LAG-3 PD-1 combination study. So when we set out to develop our LAG-3 antibody, did a number of clinical trials in first-in-human studies and we're struck to find a very high response rate in a cohort of PD-1 naive patients.***
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> And so we repeated it twice. And we basically -- it is at the end of the day, it's a single-arm 3-part cohort of 98 patients enrolled separately. And over time, what we've seen was a superior response rate coming up to close to 60% with a PFS that over time, as we've continued to follow has certainly outperformed with the competition that was available.
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> ***So we decided to embark on a Phase III study to actually really test it. And the study is designed to be testing 2 different doses as part of our obligation to satisfy the Optimus requirement of the FDA to demonstrate contribution of dosing. And since cemiplimab, Libtayo is not approved, as a monotherapy in melanoma, we needed to go up against another one, and we chose pembrolizumab, because basically, it was a Q3 regimen fit basically with our study and would facilitate blinding across the study, so we could do it properly.***

So it also -- the study contains a calibrator arm for cemiplimab so that we know so we can demonstrate contribution of components and it's basically testing 2 different doses of fianlimab, 1,600 milligrams every 3 weeks, 400 milligrams every 3 weeks, both of them in combination with cemiplimab Libtayo versus pembrolizumab KEYTRUDA at the standard dose.

When I've seen a lot of stuff percolating out in the literature review saying, ***oh, they're worried that there might be an unexpectedly long PFS for the control arm.*** And basically, what we can tell you is that although the label for the PFS for pembrolizumab is in the order of 4 to 5 months, and that was the expectation across multiple different trials. And certainly, that was also the area of where -- how nivolumab performed in the relativity study, we took a conservative approach and ***it set up our study so that we are actually powered to win if pembro surprises and is in the high mid-teens, mid-single digits in terms of of PFS.***

We do believe that certainly compared to nivolumab, we are very well poised to beat what we saw in -- what was seen in that study. And I think there also, I'll just proactively comment that I've seen some comments about recent studies where the PFS on pembrolizumab was in the teens. But I'd point out that, that study, the IO biotech study, in particular, was one in which we feel that the patients were very cherry-picked.

They had a much lower, for example, rate of brain metastases and adverse base characteristics compared to what is in our study compared to what was in RELATIVITY-047. And compared to what was in actually the most recent study conducted, which was the LEAP study, which was a trial of pembrolizumab and lenvatinib versus pembrolizumab, where the blinded independent review of PFS for pembro was 4.5 months -- 4.6 months, something like that.

So ***we are waiting for events to come in. We believe that this is because the test arms are performing well.*** But we won't know until we know. So we think that the way the events are coming in now, we should get a readout by the end of the first half of next year. And what is also important about our study is that when we set it up, we set it up so that we could also get a survival readout in this that would be powered for that even if we were just relatlimab like.

So we think we are in as strong as position as possible within the realm of dice of clinical trials to be set up for success. And we are just adjusting to events as they come in. It's not the first time studies have had slow amounts of -- slowing of events that ultimately proved to be a good sign. And so that's kind of where we stand. I don't know if there's other specific questions you want me to address on it, I mean why . . .

<Q: Alexandria Janet Hammond> You made a lot of ground.

> <A: Israel Lowy> Yes, I did. I usually do. I would also just say why do we think -- people ask us also why do we think fianlimab is different, okay? So one thing is that we were able -- ***there are differences in terms of the molecule and that our molecule does have an Fc that was engineered to be inactive in terms of engaging antibody-dependent cellular cytotoxicity and cellular phagocytosis***.
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> And ***we've seen in preclinically that there are clear differences between that and the competition***. Whether or not this has -- we've also noticed that we've been able to dose higher doses, particularly in combination with chemotherapy, which is particularly important in some of the other indications we're testing and not encounter toxicity.
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> So is that the reason? I'm not 100% sure, but it is a phenomenon that we're seeing. And as it turns out, because the timing is such that we will probably read out in the first half of next year. We also expect to have a potential for a substantial readout in our adjuvant study during that period of time as well. It will be an interim analysis, may not be mature enough, but we will certainly have some initial analysis. So we -- I can't -- it's like a pregnancy***. I can't make it go any faster. But we'll -- we're sticking with it and trying to get through to the end and cautiously optimistic***.

(Emphasis added).

31. Speaking further on the development of Libtayo combinations, Defendant Lowry touted the company's "waves" of potential compounds that could "ultimately combine" with the Libtayo-fianlimab combination, evidencing further Regeneron's confidence in a drug combination that had yet to be proven to the public, in pertinent part:

> <Q: Alexandria Janet Hammond> . . . I guess any last comments on the combination before we maybe move to just Libtayo as a monotherapy.
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> <A: Israel Lowy> I would add that one of the things that we set out to develop -- when we got into immuno-oncology quite a while ago, was to be able to have a toolbox of agents that we can combine. And ***we have other agents in clinical development that we think could ultimately combine with Libtayo-fianlimab combination***. So -- to be honest, when we started with -- as a segue to Libtayo, we decided we needed a PD-1 to enable our entire strategy, and we made sure that, that PD-1 would stand tall and be second to no one.
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> And as -- and as you've seen, that's been true, and it's -- that's the case, and it's actually commercially doing reasonably well and probably surprising some of the people that were originally said, you really want to get another PD-1. So with fianlimab, it's the same story. We have another combination, but we're not done.

> We have other things behind it. So these things will come in waves. So we're building always building for the future.

(Emphasis added).

December 2, 2025

32. On December 2, 2025, Defendant Crowe presented on behalf of Regeneron at the Evercore 8th Annual Healthcare Conference. During the call, Defendant Crowe reiterated the Company's goals and its expectations for the outcome of the Phase III Fianlimab-Libtayo Study:

> <Q: Cory William Kasimov – Evercore ISI Institutional Equities – Research Analyst> . . . moving on to LAG-3. What do you believe you need to see in fianlimab? It's always been a mouthful. The frontline metastatic melanoma Phase III trial for this product some point next year to become a commercial success? I guess what's the ideal outcome here?
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> <A: Ryan Crowe> The ideal outcome would be ***replicating the data that we saw in the Phase I*** pooled cohorts where we had 3 independent cohorts that in total was around -- was 98 patients and produced a response rate of, I believe, 57% and a pooled median PFS of 24 months. That would be fantastic to replicate in a Phase III setting. I think ***the bar for being differentiated, of course, starts with beating pembrolizumab***, which is the control arm of our Phase III study. But beyond that, looking across trial at the approved LAG-3 agent from Bristol, where the response rate was 43% and had a median PFS of 10 months. I think ***improvement from there would be potentially practice changing depending on the magnitude***. So we're clearly focusing on a result that not only beats pembro, but is competitive across the field and think that something in the low to mid-teens in terms of median PFS would achieve that. ***Of course, we aspire for more***, but we'll get that data in the first half of 2026 and eagerly await those results along with you.

(Emphasis added).

December 3, 2025

33. The following day, on December 3, 2025, Defendant Crowe again presented on behalf of Regeneron, this time at the Citi Annual Global Healthcare Conference. During the call, Defendant Crowe again reiterated the ongoing status of the Phase III Fianlimab-Libtayo Study, as well as Regeneron's projections for its outcome, highlighting a significant amount of "hope and confidence" in the study's success, stating, in pertinent part:

<Q: Geoffrey Christopher Meacham – Citigroup Inc. – Managing Director> . . . Well, let's switch gears to a pipeline. We can talk about Libtayo too, but for LAG-3, the -- maybe just remind us of the timing of when we could see that data? What was -- what does and -- you guys view kind of a win look like in terms of clinical differentiation and maybe just remind folks the assumptions of the study.

<A: Ryan Crowe> Sure. The -- we're conducting a Phase III study that combines fianlimab with Libtayo in first-line advanced melanoma, and we are using KEYTRUDA or pembrolizumab as our control arm. ***This study completed the PFS cohort enrollment in January, and we are awaiting enough events to read out the final endpoint or the primary endpoint, which is median PFS***. ***We pushed out the timing of this readout to the first half of 2026 due to a slowing of event rates. So we continue to wait for events to accrue***. And once we reach the number that has been dictated in our trial protocol, we'll complete the study. ***We have a lot of hope and confidence that fianlimab-plus Libtayo can generate a meaningful differentiation against current standards of care***. We look at PD-1 monotherapies, median PFSs range sort of in the mid-single digits, 4 months or so for pembrolizumab, around 5 months for nivolumab. And clearly, this study powered against KEYTRUDA, you want to have a statistically significant result, first and foremost. But when we look at other competing first-line melanoma therapy such as Opdualag from Bristol-Myers, which is another LAG-3, PD-1 combination product. They were able to generate a 43% response rate and a 10-month median PFS with no benefit to overall survival. In our Phase I/II studies, where we studied fianlimab plus Libtayo in 3 independent cohorts on a pooled basis of about 100 patients, the response rate was 57%, and the median PFS was around 24 months. ***So should we be able to even approach replicating that result, I think we'd have a very meaningful advanced -- for first line advanced melanoma***. So we're excited about the data and hope that we can read it out in the next few months.

I'd add beyond first line advanced melanoma, we're also studying this combination in advanced -- adjuvant melanoma and which is a study that we fully enrolled and would anticipate first interim analyses to perhaps be conducted next year, dependent, of course on event rate accrual. Beyond that and beyond skin cancer, we also are looking at this combination in lung cancer, where we will read out some Phase II results in an all-comers population as well as in a high-expressing PD-L1 high-expressing population sometime in the first half of next year as well. But ***I think it all comes down to this first-line melanoma study showing that we truly have a differentiated combination here, relative to not only pembrolizumab but other standards of care in the setting, and we look forward to the results.***

(Emphasis added).

March 4, 2026

34. On March 4, 2026, Regeneron participated in the TD Cowen 46th Annual Health Care Conference. During the Company's presentation, Defendant Crowe discussed developments in Phase III Fianlimab-Libtayo Study, speaking again to the Company's confidence in the study while addressing the ongoing slowdown in event accrual. In pertinent part, Defendant Crowe suggested it was likely that the patients were responding strongly to the treatment arm, halting disease progression and stalling the eventual accrual rate, stating:

> <Q: Tyler Martin Van Buren – TD Cowen – MD & Senior Equity Research Analyst> Great. Maybe a good segue to the pipeline. So Libtayo-fianlimab, LAG-3, frontline melanoma combo data coming by the end of the first half, maybe if you could just discuss expectations there, what we could see from the top line. And again, the delay, is it the active or the control arm outperforming or both? What are your latest thoughts?
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> <A: Ryan Crowe> So I'll start with we are totally blinded to the data. We don't know what it is. The data is not mature yet. We continue to watch events accrue. And once we get to the magic number that's defined in the clinical trial protocol, we'll lock the database, analyze the data and then rate it out.
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> We ***obviously have high hopes for this opportunity***. We saw very compelling results across 3 independent cohorts in Phase I where, on a pooled basis across approximately 100 patients, we demonstrated a 57% objective response rate and a 24-month median PFS, which compares very favorably to the approved agents for this disease. If we're able to even approach replicating those results, I think we'll have the opportunity to really change the standard of care in advanced melanoma.
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> ***Why the events have slowed,*** that's the really big question we don't know the answer to yet. ***We hope that similar to the Phase I results, there was a high level of response and those response are very durable. And therefore, they're not seeing an accrual of events once these patients respond because they're not progressing.*** Of course, there is an ***outside chance that pembrolizumab is outperforming its historical analogs,*** which has been something in the order of 4 to 5 months in the population that we enrolled.
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> So that could happen as well. It's unclear at this time. We think we have got 2 differentiated antibodies. ***We've designed the study with statistical powering that we're very confident will demonstrate this result***. And on overall survival, an endpoint that the incumbent LAG-3 therapy failed to achieve, we've actually powered it even further with additional patients. So there's a real opportunity to

> differentiate not only on response rate in PFS at this initial readout, but eventually on overall survival as well.
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> And then further on LAG-3, we also have an interim analysis to be performed in the adjuvant setting for melanoma. I think the base case for that should be that the trial continues as uninterrupted adjuvant melanoma is a much harder bar, I would say, and we have no data in Phase I to support it. But we're going to see what we have here at the interim analysis in the near term as well.

(Emphasis added).

March 11, 2026

35. A week later, on March 11, 2026, Defendant Crowe presented on behalf of Regeneron at yet another healthcare conference, the Leerink Global Healthcare Conference, 2026. Once again, Defendant Crowe spoke to the Phase III Fianlimab-Libtayo Study's pending results. Speaking further on the delay, Defendant Crowe presented two theories, either the drug was overperforming by preventing disease progression so effectively that event accrual slowed to a halt, or "something miraculous" is happening to the control group.

36. In pertinent part, Defendant Crowe engaged in the following exchange with the analyst conducting the interview:

> <Q: David Reed Risinger – Leerink Partners LLC – Senior Research Analyst & Senior MD of Biopharma> So could you just talk about fianlimab, -- if you could provide an update. Obviously, the trial has been delayed. We're still awaiting the results. And I know that you've commented before. Obviously, there have been some investor concerns that maybe the pembro arm is performing dramatically better than anticipated. But would love to hear the latest please.
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> <A: Ryan Crowe> Sure. ***Certainly been a lot of scrutiny around this study and the readout has been delayed a couple of times***, and we're now still on track for a first half readout as we await these final PFS events to come in. ***We don't believe we've enrolled a population that would result in an outsized pembrolizumab benefit of above and beyond its historical analogs of, call it, 4 to 5 months***. Some of the inclusion criteria in some of the trials that have been recently conducted, I think, are slightly different than what we enrolled. And as a result, pembrolizumab perhaps did better in those trials than we would expect it to do here. We don't know how pembrolizumab is doing in our study.

> We are totally blinded to the events and where they're occurring. We only know the total number and how they are accruing at the rate in which they're accruing. So we will see. ***I think you can look at it from 2 different ways. On the negative side, pembrolizumab is doing something miraculous and amazing and it's going to have a much higher-than-anticipated median PFS or you could look at it and say, well, the active arms are actually doing quite well and are approaching the activity that we saw in the early human studies where pooled median PFS across 3 independent cohorts was 24 months.***
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> I'd add that we feel that we've conservatively powered this study and actually have assumed pembrolizumab performs at a median PFS of 7 months, which is roughly 50% better than it has in first-line metastatic melanoma in past studies. And so based on that assumption and our assumption of at least Relatlimab/nivolumab [indiscernible] activity from our combination, ***we feel comfortable with the powering of the study even if pembro were to outperform its historical analogs.***

(Emphasis added).

37. The above statements in Paragraphs 27 to 36 were false and/or materially misleading. Defendants created the false impression that they possessed reliable information demonstrating that the Phase III Fianlimab-Libtayo Study was well-poised for success, while minimizing risks to the study's odds of achieving its primary endpoint and its overall statistical validity arising from the prolonged event rate slowdown. In truth, Defendant's optimistic reports of confidence in the study's performance fell short of reality. Rather than reflecting a positive indication of drug durability and treatment arm overperformance, the event accrual rate's slowdown ultimately necessitated Defendants to perform a drastic, last-minute protocol amendment to force a trial readout.

The Truth Begins to Emerge as Defendants Disclose Changes to the Phase III Fianlimab-Libtayo Study Protocol

April 29, 2026

38. On April 29, 2026, Regeneron issued its first quarter fiscal 2026 results. Defendants conducted an earnings call to discuss the results and other recent developments.

39. In pertinent part, Defendant Yancopoulos disclosed that the Phase III Fianlimab-Libtayo Study would expand its patient criteria, stating, in pertinent part:

> Turning to oncology. On fianlimab, our LAG-3 antibody in combination with Libtayo, our Phase III study in metastatic melanoma ***remains on track with results expected later in the second quarter*** of this year. ***The primary analysis of progression-free survival will now consider all patients enrolled in the study with a minimum follow-up of 6 months.***

40. Despite this development, during the question-and-answer segment of the call, Defendant Yancopoulos nevertheless touted the fianlimab Libtayo combination as a "potential blockbuster," while claiming the "melanoma opportunity" was the core source of excitement for the drug program, during the following pertinent exchanges:

> <Q: David Reed Risinger – Leerink Partners LLC – Senior Research Analyst & Senior MD of Biopharma>
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> . . .
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> <A: George D. Yancopoulos> Can I just say, I mean I want to comment that past performance should be the strongest indicator of future performance. There's only one company in recent history that have its own labs produced two $10 billion-plus blockbusters. And let me remind you that I think you and probably a lot of other investors never saw those coming or ignored what we were saying about them.
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> So I think that investor confidence, I think, should in large part be reflecting historical performance and the recognition that where blockbusters come from sometimes for the investor community can't be directly anticipated. And the best way of producing very important big drugs is by having very exciting molecules across all stages of development that have enormous opportunity.
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> And if you ***just look at our oncology programs, whether it's the fianlimab Libtayo***, whether you look at Lynozyfic, whether you also look at odronextamab in follicular lymphoma, ***these are all potential blockbusters***. The C5 franchise is a pipeline in a franchise, multiple blockbuster opportunities there. Our Factor XI customized approaches are looking more and more exciting, especially based on competitor data using, we think, inferior and less convenient approaches. And we just covered the obesity opportunity, which arguably could become the preferred obesity approach that not only addresses obesity, but more aggressively addresses cardiovascular morbidity. So I don't know, it's hard to think of a more exciting pipeline in the entire industry.

> . . .
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> <Q: Geoffrey Christopher Meacham – Citigroup Inc. – Managing Director> On fianlimab and lung, I just wanted to see if you guys can give us a bit more context for not moving to Phase III, maybe what was observed in the data, and from a tolerability perspective, is there any read-through to melanoma or broader solid tumor in terms of strategy?
>
> <A: George D. Yancopoulos> Yes. I think that we've been talking about this for a long time. I mean ***we never indicated that we were excited about this opportunity***. ***Our data from earlier-stage studies was always pointing us to the melanoma opportunity***. Once we see that data, it will certainly guide our thinking forward and in terms of going into additional cancer settings as well. But as we've been saying for a while, ***we never had any reason to really believe that this was going to be a game changer in the lung cancer space***.

(Emphasis added).

41. The aforementioned press releases and statements made by the Individual Defendants are in direct contrast to statements they made during the above-referenced earnings calls, releases, and shareholder presentations. On those calls, Defendants continually praised the Phase III Fianlimab-Libtayo Study's progress, highlighting a high level of "hope and confidence" and explicitly attributing the trial's delay to the purported overperformance and durability of the active treatment arms. In doing so, Defendants repeatedly minimized the structural and statistical risks associated with the prolonged slowdown in event accrual, masking the reality that the delay had materially increased the study's risk of failure and would ultimately force a disruptive alteration to the trial's statistical analysis plan.

42. Investors and analysts reacted immediately to Regeneron’s revelation. The price of Regeneron’s common stock declined dramatically. From a closing market price of $731.77 per share on April 28, 2026, Regeneron’s stock price fell to $686.36 per share on April 29, 2026, a decline of about 6.2% in the span of just a single day.

43. A number of well-known analysts who had been following Regeneron commented on the disclosures. For example, Wells Fargo, while cutting their price target 3%, highlighted a "robust" quarter that was overshadowed by management's Lag-3 commentary. In pertinent part, the Analyst summarized:

> We believe REGN's shares are down today primarily due to co's decision to expand PFS cohort to include all enrolled pts (N=1590) raising investors' concerns that such move could suggest underlying PFS benefit may be insufficient to show statistical significance

44. Evercore ISI, while reiterating on the strong quarter, highlighted how "it took [Regeneron] a protocol amendment changing the SAP to essentially ensure the timing" for the Phase III Fianlimab-Libtayo Study to read out in line with projections. Evercore elaborated on the Company's rationale, noting that Regeneron's management "felt they needed to change the protocol given the wait for even t accrual kept dragging on."

45. Concluding, the Evercore analysts noted that, while they "don't have a problem with the change … [i]t's the fact that we got to this point that is worrying . . . it is clear that after a ~1.5 yr delay and this last-minute SAP change, REGN's preliminary assumptions were way off . . . [and] this has become more and more inherently unpredictable."

46. The fact that these analysts, and others, discussed Regeneron's decision to amend the Phase III Fianlimab-Libtayo Study suggests the public placed significant weight Defendants' statements of confidence and lack of concern over the ongoing delay in the study. The frequent, in-depth discussion of Regeneron's change to the study protocol confirms that Defendants' statements during the Class Period were material.

47. Notwithstanding Defendants' disclosures, they continued to mislead investors by misrepresenting the structural soundness of the Phase III Fianlimab-Libtayo Study and downplaying the troubling implications of the eleventh-hour protocol amendment. In doing so,

Defendants provided false assurances to investors that the expanded patient pool through the study protocol amendment was, more or less, routine and deceptively claimed continued confidence in the drug combination's efficacy despite the need for such measures.

May 12, 2026

48. On May 12, 2026, Defendant Crowe presented on behalf of Regeneron at the Bank of America Global Healthcare Conference 2026. Defendant Crowe reiterated the significant purported market for fianlimab as a treatment for metastatic melanoma during the following pertinent interaction:

> <Q: Tazeen Ahmad – BofA Securities – MD in Equity Research & Research Analyst> Okay. Perfect. So now let's move on to fianlimab to the LAG-3 study. Maybe, Ryan, can you level set for us metastatic melanoma? What do you think is the rough total addressable market opportunity here? And how does that compare to the products that we just talked about, EYLEA, DUPIXENT for Regeneron?
>
> <A: Ryan Crowe> We believe ***the global metastatic melanoma market opportunity is somewhere in the range of $2 billion to $3 billion***. Obviously, there's standards of care, including PD-1 monotherapy, PD-1 plus CTLA-4 and the incumbent PD-1 LAG-3 product that's out there. ***With fianlimab, Libtayo, we believe that we have a potentially differentiated efficacy profile relative to that incumbent LAG-3 PD-1 product*** and we expect to get our data very near term. We certainly were encouraged by the promising Phase I data that we generated across three independent cohorts that when pooled, generated a median PFS of about 24 months and a complete response rate of 25%. And those compare very favorably to the incumbent LAG 3 product that had around 10 months of median PFS and around 12% or 13% complete response.
>
> And the differentiator against the CTLA-4 PD-1 combination, I think, is going to hopefully be efficacy as well. But certainly, on the safety side, we see a lot of toxicity with that combination. But at 11.7 months, the median PFS has set the highest bar for efficacy in this setting. So we're very encouraged. We are looking forward to getting this data and hopefully sharing with you guys shortly thereafter.

(Emphasis added).

49. Defendant Crowe continued, highlighting the depth of top line results that investors should expect while maintaining confidence in the study's outcome, in pertinent part:

> <Q: Tazeen Ahmad> And what level of top line information should we expect?
>
> <A: Ryan Crowe> That's TBD, but I think ***Regeneron typically errors on the side of providing more detail in our top line press releases*** than most other companies. I think ***it's safe to assume we'll say more than positive study and see a medical conference in 6 months***. I would think providing the medians across all arms would be an appropriate level of disclosure and perhaps more depending on the interim overall survival readout and the objective response rates. So we'll see exactly what we get from the DMC when the data reads out and put together a fulsome disclosure, I'm sure.

(Emphasis added).

50. Defendant Crowe further elaborated on the decision to amend the protocol of the study and the timeline of events that took place during the following pertinent exchange:

> <Q: Tazeen Ahmad> Okay. And maybe we will wrap it up with this last question, which I think you might have gotten a couple of times in the last week or so. You did make that recent change to the statistical analysis plan. So that's going to now include all patients with at least 6 months of follow-up.
>
> Len and George talked about this a little bit, but maybe can you just reiterate what the genesis of that was when it started? When the idea came and why you think it's important to have it be the case as you go into the readout that this change was made?
>
> <A: Ryan Crowe> Yes. Thanks, Tazeen, for the question. I think there's certainly been some confusion out there about what actually happened, what the time lines for the decisions were. So let me kind of start from the beginning.
>
> We ran this study with originally with two cohorts, a PFS cohort, which was to include the first 1,175 patients or so across four arms, and that was going to be the population that contributed to the primary analysis of progression-free survival.
>
> Upon the 1,176 patient, we were going to begin enrolling a 360 patient cohort that was only going to contribute to the overall survival, secondary endpoint. And that enrollment ran from essentially January through late summer of 2025.
>
> ***As we move through 2025, we saw a very slow accumulation of PFS events in the PFS cohort, which went for several consecutive months into the second half of 2025. And we were beginning to get concerned about when exactly the readout would occu***r.
>
> So what we decided to do, and this was ***in the fall of 2025 was to add the patients that were originally only going to contribute to the overall survival, secondary***

> ***endpoint to the primary analysis, without changing the number of events required to trigger the readout.***
>
> We also added the requirement that every patient would have the opportunity for at least 6 months of follow-up. And we did that because we didn't want to drop in those patients from the old OS cohort and then immediately read out the data when some of those patients would have just begun treatment.
>
> So all patients will have at least 6 months of treatment. We need to reach 399 events in high-dose fianlimab plus Libtayo plus pembro. That analysis and then the low-dose fianlimab versus pembrolizumab. Each of those need to equal 399 and the last patient first dose needs to be at least 6 months beyond that first -- that last patient first dose in order for us to lock the database and read it out.
>
> So ***it was done because of slow event rates, we made the protocol amendment towards the end of last year***. I believe we submitted it to all the global regulatory authorities in November, December time frame. ***We had to wait until it was signed off by all of them before we began talking about it.*** And ***the EU member states that are involved in the study only approved this protocol amendment at the beginning -- towards the beginning of April***, so only about a month ago. which is why it only became public then.
>
> So we're now locked and loaded. As I mentioned, we're fast approaching this readout. We're really looking forward to it, certainly have high hopes for this data set and look forward to sharing it with you as soon as we can.

(Emphasis added).

51. The above statements in Paragraphs 38 to 40 and 48 to 50 were additionally false and/or materially misleading. Defendants continued to craft the false impression that they possessed reliable information providing the basis for their confidence in the chances of success for the Phase III Fianlimab-Libtayo Study. In truth, Regeneron's optimistic reports of trial durability and competitive advantage fell short of reality; the investigational arm of the Phase III Fianlimab-Libtayo Study was unequipped or otherwise ill-premised to deliver the practice-changing efficacy profile Defendants had continuously touted to the market and the last-minute protocol expansion ultimately served to dilute the study's hazard ratio, cementing its failure to achieve statistical significance before the readout even occurred. In short, Defendants' optimism

and continued confidence in the "potential blockbuster" drug combination was sorely misplaced and artificially inflated investor expectations and confidence in Regeneron's performance.

The Full Truth Emerged When Regeneron Unveiled

Phase III Fianlimab-Libtayo Study Topline Results

May 15, 2026

52. On May 15, 2026, Defendants published a press release to provide an "Update on Phase 3 Trial of Fianlimab (LAG-3 Inhibitor)." The release conceded that the "trial ***did not reach statistical significance of the primary endpoint*** of improvement in progression-free survival (PFS)" (emphasis added).

53. The aforementioned press releases and statements made by the Individual Defendants are in direct contrast to statements they made during the previous calls and other shareholder correspondence. In those statements, Defendants continually praised the Phase III Fianlimab-Libtayo Study's clinical trial design, enrollment metrics, and anticipated durability, while continually minimizing risks associated with the prolonged event rate slowdown and the potential impact of the late-stage statistical analysis plan changes on the study's overall ability to achieve statistical significance.

54. Investors and analysts again reacted promptly to Regeneron's revelation. The price of Regeneron's common stock declined even further. From a closing market price of $698.25 per share on May 15, 2026, Regeneron's stock price fell to $629.68 per share on May 18, 2026, a decline of about 9.8% in the span of one day.

55. A number of well-known analysts who had been following Regeneron lowered their price targets in response to Regeneron's disclosures. For example, Citi downgraded to Neutral and slashed its price target more than 22% "following disappointing phase 3 data for fianlimab in

metastatic melanoma." The analyst highlighted the significance of the miss, stating: "we do not believe the current dataset supports regulatory filing or warrants any commercial value in our model."

56. Similarly, Bernstein, while cutting their price target more than 6%, highlighted the study's failure, in pertinent part:

> Notably, ***the problem was underwhelming performance of the investigational arm*** (mPFS 11.5) rather than investor concerns about pemrbp outperformance . . . ***The result is strange*** in that the trial was delayed due to reportedly slow event accrual, but the acutal mPFS of each arm ended up being quite similar to the BMS (Breen) RELATIVITY-047 trial. ***We wonder if expansion of the primary analysis set to include patients who were not originally part of the PFS cohort may have diluted the HR by increasing the contribution of the early months where the KM curves had not yet separated.***

(Emphasis added).

57. Wells Fargo slashed its price target 12.5% despite having "always been skeptical around this catalyst." In the May 17, 2026 report, the analyst highlighted that investor "expectations have been coming down post the latest delay after 1Q call," but still expected the stock further "down 5-7% on this news."

58. The fact that these analysts, and others, discussed the failure of the Phase III Fianlimab-Libtayo Study to achieve statistical significance in its primary endpoints suggests the public placed significant weight on Defendants previous claims of confidence and repeated reassurances and risk minimizations related to the ongoing delay. The frequent, in-depth discussion of the trial's failure confirms that Defendants' statements during the Class Period were material.

Additional Scienter Allegations

59. During the Class Period, Defendants acted with scienter in that they knew, should have known, or otherwise were deliberately reckless in not knowing that the public statements

disseminated on behalf of Regeneron were materially false and misleading at the time they were made. Defendants had actual knowledge of, access to, or reckless disregard for non-public information, data, and metrics demonstrating that the prolonged event rate slowdown was a structural risk to the study's statistical validity and the risk profile regarding the achievement of the study's primary endpoint. Rather than reflecting a positive indicator of drug durability and treatment arm overperformance as Defendants publicly claimed, the crawling pace of event accruals increased the clinical risk or otherwise exacerbated an underlying risk that the trial would fail to reach statistical significance on its primary endpoint of progression-free survival.

60. Notwithstanding such, Defendants repeatedly and affirmatively represented to investors that Regeneron was well-positioned to achieve a practice-changing and clinically differentiated efficacy profile to capture the claimed multi-billion-dollar metastatic melanoma market. Defendants further repeatedly claimed strength in their study design, repeatedly affirming to investors that the study was conservatively powered to withstand overperformance by the control arm, while minimizing the known impact of event rate accrual delays on the study's overall odds of success.

61. Yet, Defendants continued to make selective and misleading disclosures in repeated claims of progress and confidence regarding the status of the Phase III Fianlimab-Libtayo Study. Defendants routinely advanced an overly optimistic public theory that the slowing event rate was driven by durable efficacy; that the drug combination was so effective at slowing disease progression that event accrual had drastically slowed. In so doing, Defendants concealed the material reality that their preliminary assumptions were fundamentally flawed.

62. Indeed, Defendants repeatedly claimed the ongoing delay was either the "active arms doing quite well" or the "something miraculous and amazing" was happening in the control

group to offset these results. Defendants, deliberately or recklessly, failed to convey to investors the third scenario that ultimately manifested: the drug combination of fianlimab and libtayo was simply not as effective as Defendants had previously suggested.

63. Defendants' scienter is further evidenced by the contradiction between their public posture as an outside, blind observer against their active management of the trial's parameters. Throughout the Class Period, the Individual Defendants consistently reiterated to investors that they were blind to the trial and just "waiting for events to come in." In reality, while Defendants were maintaining this passive stance to the public, they were actively tracking an ongoing stagnation in event accumulation that had alarmed management. This critical internal concern, which was not outwardly expressed as a risk upon the study or its outcome, forced Defendants to execute a drastic, last-minute amendment to the study protocol to expand the acceptable patient pool for consideration of the primary endpoint analysis simply to force a trial readout.

64. Moreover, Defendants deliberately withheld disclosure of this critical structural alteration from the market for months. Defendants had submitted the change to the global regulatory authorities in the "November, December time frame," but failed to inform investors as to any application, decision, or even risk factor necessitating such change. Defendants only informed investors of the change during the April 29, 2026, earnings call, just days before the readout occurred, and only after the protocol amendment was fully approved.

65. Defendants' scienter is further underscored by Defendant Yancopoulos's aggressive promotions of the drug program immediately ahead of the final readout. On the very same April 29, 2026, call where the protocol expansion was first revealed, Defendant Yancopoulos sought to deflect immediate analyst anxiety by aggressively touting the combination as a "potential

blockbuster" and suggesting that investor confidence reflect his personal historical track record of delivering multi-billion-dollar drugs.

Loss Causation and Economic Loss

66. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Regeneron's common stock and operated as a fraud or deceit on Class Period purchasers of Regeneron's common stock by materially misleading the investing public. Later, Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Regeneron's common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases of Regeneron's common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

67. Regeneron's stock price fell in response to the partial corrective event on April 29, 2026, as alleged *supra*. On April 29, 2026, Defendants disclosed information that was directly related to their prior misrepresentations and material omissions concerning Regeneron's Phase III Fianlimab-Libtayo Study.

68. In particular, on April 29, 2026, Regeneron announced that the protocol of the study had been altered to now consider "all patients enrolled in the study with a minimum follow-up of 6 months," when analyzing the primary endpoint of progression-free survival.

69. Regeneron's stock price fell again in response to the corrective event on May 15, 2026, as alleged *supra*.

70. In particular, on May 15, 2026, Regeneron announced that its Phase III Fianlimab-Libtayo Study had failed to achieve its primary endpoint, confirming that the delay to the study

readout was not due to drug overperformance reducing the accrual of events due to the lack of disease progression.

Presumption of Reliance; Fraud-On-The-Market

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

(a) Regeneron's common stock met the requirements for listing and was listed and actively traded on the NASDAQ during the Class Period, a highly efficient and automated market;

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

(c) Regeneron was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

(d) Unexpected material news about Regeneron was reflected in and incorporated into the Company's stock price during the Class Period.

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

73. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine

74. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint. As alleged above, Defendants' liability stems from the fact that they provided investors with false and misleading assurances regarding the ongoing Phase III Fianlimab-Libtayo Study and its anticipated outcomes, while at the same time failing to maintain, or deliberately disregarding, internal metrics and known impacts that demonstrated the prolonged event rate slowdown had materially increased the study's structural risk of failure or otherwise that the drug was not performing in line with a trajectory to achieve its primary endpoint. To the extent the Defendants did provide the public with statements concerning the trial's timeline and anticipated data readouts, such statements failed to account or otherwise risk any impact from the accrual delays.

75. To the extent certain of the statements alleged to be misleading or inaccurate 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.

76. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Regeneron who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by the defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

77. 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 those who purchased or otherwise acquired Regeneron's common stock during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are defendants herein, 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.

78. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Regeneron's common stock were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. 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. As of April 14, 2026, there were 103 million shares of the Company's common stock outstanding. Upon information and belief, these shares are held by thousands, if not millions, of individuals located throughout the country and possibly the world. Joinder would be highly impracticable.

79. 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.

80. 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. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

81. 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 misrepresented material facts about the business, operations and management of Regeneron;

(c) whether the Individual Defendants caused Regeneron to issue false and misleading public statements and disclosures during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading public statements and disclosures;

(e) whether the prices of Regeneron's common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

82. 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 make 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.

COUNT I

Against All Defendants for Violations of

Section 10(b) and Rule 10b-5 Promulgated Thereunder

83. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

84. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

85. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon. Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout

the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Regeneron common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Regeneron's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

86. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Regeneron's securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company.

87. By virtue of their positions at the Company, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

88. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or

directors of the Company, the Individual Defendants had knowledge of the details of Regeneron's internal affairs.

89. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of the Company. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Regeneron's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Regeneron's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Regeneron's common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock and/or upon statements disseminated by Defendants, and were damaged thereby.

90. During the Class Period, Regeneron's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Regeneron's common stock at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff

and the Class, the true value of Regeneron's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Regeneron's common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

91. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

92. 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, acquisitions and sales of the Company's common stock during the Class Period, upon the disclosure that the Company had been disseminating misrepresentations and misleading statements regarding the status and risks of the Phase III Fianlimab-Libtayo Study to the investing public.

COUNT II

Against the Individual Defendants

for Violations of Section 20(a) of the Exchange Act

93. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

94. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about Regeneron's misstatements.

95. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, and to correct promptly any public statements issued by Regeneron which had become materially false or misleading.

96. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Regeneron disseminated in the marketplace during the Class Period concerning the misrepresentations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Regeneron to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Regeneron's common stock.

97. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause Regeneron to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

98. By reason of the above conduct, the Individual Defendants and/or Regeneron are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demand judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: July 16, 2026

Respectfully submitted,

LEVI & KORSINSKY, LLP

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