UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PLAINTIFF, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. QUIDELORTHO CORPORATION f/k/a QUIDEL CORPORATION, DOUGLAS BRYANT, JOSEPH BUSKY, and RANDALL STEWARD, Defendants.	Civil Action No. DEMAND FOR JURY TRIAL CLASS ACTION

CLASS ACTION COMPLAINT FOR VIOLATION
OF THE FEDERAL SECURITIES LAWS

Plaintiff, individually and on behalf of all others similarly situated, by and through its counsel, 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 are based upon, *inter alia*, counsel's investigation, which includes review and analysis of: (1) regulatory submissions filed by QuidelOrtho Corporation, formerly known as Quidel Corporation ("QuidelOrtho" or the "Company"), with the U.S. Securities and Exchange Commission ("SEC"); (2) press releases and media reports issued and disseminated by the Company; (3) analyst and media reports concerning the Company; and (4) other public information regarding the Company, including statements made by QuidelOrtho

executives.[1] Plaintiff believes that substantial additional evidentiary support exists for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired QuidelOrtho common stock between February 18, 2022 and April 1, 2024, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws (the "Class"). The claims asserted herein are alleged against QuidelOrtho, Douglas Bryant ("Bryant"), Joseph Busky ("Busky"), and Randall Steward ("Steward" and, collectively with QuidelOrtho, Bryant, and Busky, the "Defendants").

2. QuidelOrtho provides tests for the detection and diagnosis of various respiratory diseases and other medical conditions. The Company's respiratory business has historically been tied to the sale of seasonal flu tests and more recently to COVID-19 detection tests. Since the onset of the COVID-19 pandemic, the Company has generated a significant portion of its revenue through the sale of COVID-19 tests to government customers, healthcare providers (through its authorized distributors), and large retail pharmacy chains. According to Defendant Busky, revenue from the Company's respiratory tests is "very high margin revenue." QuidelOrtho manufactures respiratory tests under various brands, including QuickVue, Sofia, and Savanna.

3. In December 2021, the Company announced that it had agreed to merge with Ortho Clinical Diagnostics Holdings plc ("Ortho") through a transaction valued at approximately $6 billion. The merger closed in May 2022, shortly after the start of the Class Period. Meanwhile, COVID-19 was transitioning from pandemic to "endemic" status (i.e., COVID-19 infections no longer growing exponentially). Despite COVID-19 transitioning into an endemic, Defendants

[1] Emphasis has been added unless otherwise noted.

assured investors that QuidelOrtho was well positioned to maintain a stable high margin revenue stream from its respiratory business. Among other strategies, the Company aimed to launch its "next flagship product," a new test called the Savanna Respiratory Viral Panel-4 (the "Savanna RVP4 Test," which tests for COVID-19 and other respiratory conditions) by utilizing Ortho's commercial distribution network. During the Class Period, the Savanna RVP4 Test was not approved by the U.S. Food and Drug Administration (the "FDA") to be marketed or sold in the United States. Therefore, investors closely monitored the Company's progress in getting the Savanna RVP4 Test approved.

4. Throughout the Class Period, Defendants misled investors by making statements that were false and misleading when made because they knew or deliberately disregarded and failed to disclose the following adverse facts about QuidelOrtho's business, operations, and prospects:

(a) that QuidelOrtho sold more COVID-19 tests to its distributors and pharmacy chain customers than they could resell to healthcare providers and end customers;

(b) that excess inventories of COVID-19 tests existed throughout the supply chain;

(c) that, as a result of (a)-(b) above, QuidelOrtho's distributors and pharmacy chain customers were poised to significantly reduce their COVID-19 test orders;

(d) that undisclosed problems created a heightened risk that the Savanna RVP4 Test would experience a delayed commercial launch in the United States;

(e) that, as a result of (a)-(d) above, Defendants lacked a reasonable basis for their positive statements about QuidelOrtho's business, financials, and growth trajectory.

5. The truth began about these undisclosed issues began to emerge on February 13, 2024, when QuidelOrtho reported underwhelming results for its fourth quarter ended December 31, 2023. Among other things, the Company's Adjusted Earnings Per Share ("Adjusted EPS") was ***46% below*** the midpoint of Wall Street analysts' expectations. This miss was largely attributed to lower endemic COVID-19 revenues during the quarter due to distributor destocking. The Company also slashed its 2024 financial forecasts, including a drastic cut to its COVID-19 revenue guidance. Specifically, QuidelOrtho lowered its annual endemic COVID-19 revenue forecast from the range of $200-$400 million to $200 million. During the related earnings call that day, Defendant Bryant continued to mislead investors about the prospects of the U.S. marketing approval for the Savanna RVP4 Test. Specifically, he stated, "the status of the submission of the 510(k) is on track per my previous comments. Recall that I had said that we expect to get clearance before the end of the first quarter, I think we're still on track for all that."

6. Analysts were shocked by these poor results and weak projections. For example, Craig-Hallum analyst Alexander Nowak downgraded his rating on QuidelOrtho stock from "Buy" to "Hold" stating that "Q4 came in as one of the most surprising results we have seen in diagnostics in some time." Similarly, Raymond James analyst Andrew Cooper downgraded his rating on the Company's stock noting Defendants "fairly deplorable communication and expectation setting both over the course of 2023 and even as recently as [January 2024]." On this news, the price of QuidelOrtho stock dropped $21.50, or more than 32 percent, to close at $45.27 on February 14, 2024.

7. On February 21, 2024, QuidelOrtho announced that its Board of Directors (the "Board") terminated Defendant Bryant from his positions as President and Chief Executive Officer ("CEO") of the Company. Defendant Bryant also resigned from the Company's Board, effective February 21, 2024. According to William Blair analyst Andew Brackmann, "[f]ollowing last week's 2024 guidance debacle and the ensuing calls from many investors advocating for a change in management, we understand why the [B]oard made this move."

8. Then, on April 2, 2024, QuidelOrtho announced that it had withdrawn its FDA 510(k) submission for approval to sell the Savanna RVP4 Test in the United States after recent data did not meet expectations. According to Citi analyst Patrick Donnelly, the Savanna RVP4 Test was "expected to be a key driver of Savanna uptake in the respiratory season." On this news, the price of QuidelOrtho stock dropped $4.85, or more than 10 percent, to close at $42.15 on April 2, 2024.

9. As a result of Defendants' wrongful acts and omissions, and the resulting decline in the market value of QuidelOrtho's stock, Plaintiff and the Class suffered significant losses and damages under the federal securities laws.

JURISDICTION AND VENUE

10. 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).

11. 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.

12. Venue is proper here pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b) because the Company conducts business in this District, and the events and omissions giving rise to the claims asserted herein occurred in substantial part in this District, including the

dissemination of false and misleading statements in this District. The Company's common stock trades in this District on the Nasdaq Global Select Market.

13. 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

14. Plaintiff purchased QuidelOrtho common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing its transactions in QuidelOrtho common stock is attached hereto.

15. QuidelOrtho is a Delaware corporation with its principal executive offices located at 9975 Summers Ridge Road, San Diego, California 92121. The Company's common stock is listed on the NASDAQ under the ticker symbol "QDEL."

16. Defendant Bryant was QuidelOrtho's President and CEO as well as a Director on the Company's Board throughout the Class Period. Defendant Bryant was terminated from his positions as President and CEO and resigned from the Company's Board, effective February 21, 2024.

17. Defendant Busky has been the Chief Financial Officer ("CFO") of QuidelOrtho since May 27, 2022.

18. Defendant Steward was the CFO of QuidelOrtho until May 27, 2022 and served in the role of special advisor to QuidelOrtho relating to the Company's 2022 merger with Ortho Clinical Diagnostics PLC, the CFO transition, and other general matters between May 27, 2022 and March 31, 2024.

19. Defendants Bryant, Busky, and Steward are sometimes referred to herein as the "Individual Defendants." QuidelOrtho together with the Individual Defendants are referred to herein as the "Defendants."

20. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of QuidelOrtho'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.

21. QuidelOrtho 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.

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

SUBSTANTIVE ALLEGATIONS

Company Background

23. Founded in 1981, QuidelOrtho manufactures and sells diagnostic healthcare products in the areas of immunoassay and molecular testing, clinical chemistry, and transfusion medicine. The Company's products and related services are sold worldwide. The Company sells its products through its network of authorized distributors and its direct sales force. QuidelOrtho's main customer groups include governmental health agencies, physician offices, hospitals, universities, retail health clinics, large pharmacy chains, and blood banks.

24. Seasonal flu tests have traditionally been the Company's main diagnostic products in the respiratory category. Since 2020, when COVID-19 became a pandemic, QuidelOrtho's respiratory business began generating substantial revenue from the sale of COVID-19 detection tests. Defendants have repeatedly characterized revenue from the Company's respiratory tests as "high margin revenue." QuidelOrtho manufactures its respiratory tests under various brands, including QuickVue, Sofia, and Savanna.

25. In December 2021, the Company announced that it had agreed to merge with Ortho. Defendants stated that the merger would benefit QuidelOrtho by expanding revenue through cross-selling opportunities. Defendants also touted how the merger would benefit the Company in the form of cost synergies through supply chain optimization and shared administrative functions. The merger closed in May 2022, shortly after the start of the Class Period.

26. Despite COVID-19 transitioning into an endemic during the Class Period, Defendants assured investors that QuidelOrtho was well positioned to maintain a stable high margin revenue stream from its respiratory business. QuidelOrtho highlighted sales of the Savanna RVP4 Test through Ortho's distribution network as a key strategy for its respiratory business. During the Class Period, the Savanna RVP4 Test was not approved by the FDA to be marketed or

sold in the United States. Therefore, investors closely monitored the Company's progress in getting the Savanna RVP4 Test approved.

Materially False and Misleading Statements Issued During the Class Period

Fourth Fiscal Quarter 2021 and Full Year 2021

27. The Class Period begins on February 18, 2022, the day after the Company issued a press release announcing its financial results for its fiscal quarter and year ended December 31, 2021. The Company reported $511.8 million in quarterly revenue for COVID-19 products, versus $405.3 million in its fourth fiscal quarter of 2020. Citing the upcoming merger, management declined to provide guidance for 2022.

28. On an earnings call held after the close of trading on February 17, 2022 to discuss the financial results, Defendant Bryant touted the "strong demand for COVID-19 rapid immunoassay products for both Sofia and QuickVue." Defendant Bryant also stated:

> In January, ***we saw incredibly strong demand for our Sofia COVID-19 antigen test in the professional market as well as demand for our QuickVue At-Home product as a result of elevated COVID-19 case counts***. As we move closer to the end of February, we are seeing demand moderate in the professional and retail markets commensurate with lower COVID-19 positive cases but bolstered by the continued fulfillment of state and U.S. government orders as COVID-19 shifts from a pandemic to what some scientists anticipate as an endemic phase.

29. On February 18, 2022, the Company filed with the SEC its Form 10-K reporting the Company's financial results for the year ended December 31, 2021 (the "2021 10-K") which included the following false and misleading risk factor:

> **Our operating results are heavily dependent on sales of our COVID-19 and influenza diagnostic tests and if sales or revenues of our COVID-19 or influenza tests decline for any reason, our operating results would be materially and adversely affected.**

> A significant percentage of our total revenues come from a limited number of our product families. In particular, revenues from the sale of our COVID-19 and influenza tests represent a significant portion of our total revenues and are expected to remain so for at least the near future. For the years ended December 31, 2021, 2020 and 2019, sales of our COVID-19 products accounted for 75%, 70% and 0% and influenza products accounted for 4%, 8%, and 26%, respectively, of total revenue. In addition, the gross margins derived from sales of our COVID-19 and influenza tests are significantly higher than the gross margins from many of our other core products. As a result, if sales or revenues of our COVID-19 or influenza tests decline for any reason, whether as a result of a waning of the COVID-19 pandemic, a mild flu season, market share loss or price pressure, obsolescence, regulatory matters, such as loss of EUAs for our COVID-19 products, or any other reason, our operating results would be materially and adversely affected on a disproportionate basis.

30. On March 11, 2022, the Company filed a Form 10-K/A amending the 2021 10-K ("2021 10-K Amendment"). Appended as an exhibit to the 2021 10-K Amendment were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendant Bryant and Defendant Steward certified that "[t]he [2021 10-K Amendment] does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

First Fiscal Quarter 2022

31. On May 4, 2022, the Company issued a press release announcing its financial results for its fiscal quarter ended March 31, 2022. The Company reported $836.1 million in quarterly revenue for COVID-19 products, versus $269.1 million in its first fiscal quarter of 2021. Citing the upcoming merger, management declined to provide guidance for 2022.

32. On the related earnings call held the same day, Defendant Bryant stated that, "consistent with the anticipated shift in COVID-19 testing demand, we continue to bolster our

resilience in the post-pandemic future by accelerating assay development and production and further expanding our footprint at the point of care." Defendant Bryant continued:

> Total rapid immunoassay revenue increased by $655 million in the first quarter '22 to $893 million. ***We saw significant sales of QuickVue At-Home OTC COVID-19 tests. And while COVID-19 testing made up the bulk of this heightened demand***, it's noteworthy that non-COVID sales grew 56%.

33. On May 5, 2022, the Company filed with the SEC a Form 10-Q reporting the Company's financial results for the quarter (the "Q1 2022 10-Q"). In the Q1 2022 10-Q, the Company claimed there had been "no material change to the risk factors as previously disclosed in [the 2022 10-K]."

34. Appended as an exhibit to the Q1 2022 10-Q was a signed SOX certification wherein Defendant Bryant and Defendant Steward certified that the information in the Q1 2022 10-Q "fairly presents, in all material respects, the financial condition and results of operations of the Company."

Second Fiscal Quarter 2022

35. On August 4, 2022, the Company issued a press release announcing its financial results for its second fiscal quarter ended July 3, 2022. The Company reported $298 million in quarterly revenue for COVID-19 products, versus $280.3 million in its second fiscal quarter of 2021.

36. During the related earnings call held the same day, Defendant Bryant stated, "In terms of the OTC space, we continue to strengthen our positioning through our QuickVue at-home OTC COVID-19 test." Additionally, Defendant Buskey further assured investors that "we believe that the COVID revenue once it gets into endemic stage, as you move into next year, we'll be in that $150 million to $200 million range annual COVID revenue."

37. On August 5, 2022, the Company filed with the SEC a Form 10-Q reporting the Company's financial results for the quarter (the "Q2 2022 10-Q") which included the following false and misleading risk factor:

> **Fluctuations or a decline in sales of our COVID-19 and influenza diagnostic tests can have a significant impact on our operating results and if sales or revenues of our COVID-19 or influenza tests fluctuate or decline for any reason, our operating results could be materially and adversely affected.**
>
> A significant percentage of our total revenues come from a limited number of our product families. In particular, revenues from the sale of our COVID-19 tests have recently represented a significant portion of our total revenues. Sales of our COVID-19 products accounted for approximately 70% of our total revenue for the six months ended July 3, 2022. Demand for our COVID-19 testing products can fluctuate or decline as a result of a number of factors, including but not limited to the emergence and impact of new variants, the effectiveness of global containment efforts, and increased market supply of COVID-19 tests by our competitors. Similarly, demand for our influenza tests can fluctuate or decline based on the severity of the flu season. The gross margins derived from sales of our COVID-19 and influenza tests are significantly higher than the gross margins from many of our other core products. As a result, if sales or revenues of our COVID-19 or influenza tests fluctuate or decline for any reason, whether as a result of a waning of the COVID-19 pandemic, a mild flu season, market share loss or price pressure, obsolescence, regulatory matters, such as loss of EUAs from the FDA for our COVID-19 products, or any other reason, our operating results would be materially and adversely affected on a disproportionate basis.

38. Appended as an exhibit to the Q2 2022 10-Q was a signed SOX certification wherein Defendant Bryant and Defendant Buskey certified that the information in the Q2 2022 10-Q "fairly presents, in all material respects, the financial condition and results of operations of the Company."

Third Fiscal Quarter 2022

39. On November 2, 2022, the Company released its financial results for its third fiscal quarter ended October 2, 2022. The Company reported $171 million in quarterly revenue for COVID-19 products, versus $402.6 million in its third fiscal quarter of 2021.

40. During the Company's related earnings call, Defendants Bryant and Buskey further assured investors that endemic COVID-19 revenue would be in the $150 million to $200 million range annually. Defendant Buskey further called the $150 million to $200 million range "conservative."

41. On November 4, 2022, the Company filed with the SEC a Form 10-Q reporting the Company's financial results for the quarter (the "Q3 2022 10-Q"). In the Q3 2022 10-Q, the Company claimed there had been "no material change in our risk factors as previously disclosed in [the Q2 2022 10-Q]."

42. Appended as an exhibit to the Q3 2022 10-Q was a signed SOX certification wherein Defendant Bryant and Defendant Buskey certified that the information in the Q3 2022 10-Q "fairly presents, in all material respects, the financial condition and results of operations of the Company."

43. On December 13, 2022, the Company hosted its 2022 Investor Day. During the 2022 Investor Day, Defendant Busky stated:

> The next item on the list again, it's investing back in the business, and this is more an operational excellence area. We will invest CapEx. We are investing. We will continue to invest CapEx into the business to increase the manufacturing capacity. I think Doug said this earlier, too, ***we don't have so much of a demand problem right now. We have a supply problem. We got to get more products***.

Fourth Fiscal Quarter 2022 and Full Year 2022

44. On February 15, 2023, the Company released its financial results for its fourth fiscal quarter and year ended January 1, 2023. The Company reported $132 million in quarterly revenue for COVID-19 products, versus $511.8 million in its fourth fiscal quarter of 2021.

45. During the Company's related earnings call later that day, Defendant Buskey guided "[r]espiratory revenue of $610 million to $875 million, which includes COVID revenue of $300 million to $500 million" for fiscal year 2023. Defendant Buskey continued:

> Going forward, although there may be spikes and no one really knows for sure, we assume COVID-19 transitions to an endemic state. Similar to other seasonal respiratory viruses and we plan to bucket it with those other respiratory viruses in '23 and forward. And while 2022 included a record-setting respiratory season, including flu and COVID-19, we expect '23 to return to a more normal respiratory season. ***We expect to continue to capture and grow our share of the respiratory market underpinned by our large and growing Sofia placements.***

46. On the same call, Defendants Byrant and Busky were asked about what the Company expected in terms of COVID-19 revenue:

> **Analyst Andrew Cooper:** But just to kind of jump into it, one thing I think investors are certainly going to be keyed into is the commentary for 2023 being normal and that $300 million to $500 million of COVID, I think it sounds like it does include those government contracts or at least some contribution from. So can you give us a sense for where you're sort of settling out of what normal might be for COVID? And how that's going to play out through the course of the year kind of in context of Joe, what you just said about some of the seasonality in flu and respiratory in general?
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> **Defendant Bryant:** Yes. Andrew, we did go -- the $300 million to $500 million is still our range. So that's consistent, and we can talk about the government contracts. But that's -- we're not treating that as normal and usual.
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> **Defendant Busky:** Yes. And it is exactly. ***It's consistent with what we said at Investor Day, we were saying $200 to $400 million for endemic state, and it's up $300 million to $500 million because***

you've got this level of government contracts that we know we have in hand. So that's -- there's no change there.

[…]

Analyst Conor McNamara: Okay. So just getting back to the respiratory business, if you just think about kind of all of the moving pieces for this year, including the government contract on COVID, going into next year and not getting into next year's guidance. But just going forward, how should we think about the total respiratory business size wise, including all of that? And then once you do have Savanna, how does that change the size of that business?

Defendant Bryant: Yes, go ahead, Joe.

Defendant Busky: Yes, I can start. And again, breaking it up into the pieces, Conor. I think we would, again, go back to the ***COVID $200 million to $400 million***, and the rapid flu in the $230 million to $270 million. Those are the 2 base numbers. And then the Savanna number, that number is a little bit of a TBD as you move into '24, obviously because it's going to be based on the slope of the ramp or the launch because some of that Savanna revenue is going to be respiratory, the RVP4 and RVP11. And then you've got that other piece I mentioned the RSP and the strep, we call it, $80 million to $100 million. And so those are your pieces as you move forward.

47. On February 23, 2023, the Company filed with the SEC a Form 10-K reporting the Company's financial results for the year (the "2022 10-K") which included the following false and misleading risk factor:

Fluctuations or a decline in sales of our COVID-19 and influenza diagnostic tests can have a significant impact on our operating results and if sales or revenues of our COVID-19 or influenza tests fluctuate or decline for any reason, our operating results could be materially and adversely affected.

A significant percentage of our total revenues is generated from a limited number of our product families. In particular, revenues from the sales of our COVID-19 tests have represented a significant portion of our total revenues. Sales of our COVID-19 products accounted for approximately 44% of our total revenues for the year ended January 1, 2023, which includes the impact of Ortho's operations from the date of the Combinations. Demand for our COVID-19 testing products has and may continue to fluctuate or decline as a result of a number of factors, including but not limited

> to the emergence and impact of new variants or resurgences, the effectiveness of global containment efforts, and the increased market supply of COVID-19 tests by our competitors. Sales of our influenza tests accounted for approximately 11% of our total revenues for the year ended January 1, 2023, which includes the impact of Ortho's operations from the date of the Combinations. Demand for our influenza tests can fluctuate or decline based on the severity of the flu season. The gross margins derived from sales of our COVID-19 and influenza tests are generally significantly higher than the gross margins from many of our other core products. As a result, if sales or revenues of our COVID-19 or influenza tests fluctuate or decline for any reason, whether as a result of a waning of the COVID-19 pandemic, a mild flu season, market share loss or price pressure, obsolescence, regulatory matters, such as loss of EUAs from the FDA for our COVID-19 products, or any other reason, our operating results would be materially and adversely affected on a disproportionate basis.

48. Appended as an exhibit to the 2022 10-K was a signed SOX certification wherein Defendant Bryant and Defendant Buskey certified that the information in the 2022 10-K "fairly presents, in all material respects, the financial condition and results of operations of the Company."

First Fiscal Quarter 2023

49. On March 7, 2023, the Company participated in the Raymond James Institutional Investors Conference. During the conference, Defendant Bryant was asked about the Company's endemic COVID-19 guidance:

> **Analyst Andrew Cooper:** And, I guess while we're on the topic, let's go ahead and kind of hit on respiratory. You're pointing folks to $200 million to $400 million of endemic COVID. First, I feel sorry that you have to put a number out there in the first place because nobody can really nail down what it is. But can you talk to us a little bit about how you arrived at that $200 million to $400 million number in context of sort of where flu was for you, and where are some of the drivers of that being the right range really come from?
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> **Defendant Bryant:** Yes. We—typically, finance organizations will look at it, at least a couple of different ways and one from a top down and what's logical, and looking at historic data in the professional segment. I think, that's a reasonable way. We also rely on marketers

> to more of a bottoms-up approach and almost do an account-by-account analysis.
>
> Now it's a little difficult because when you look at the total number of customers that we have, respiratory customers, it's about -- in the United States, it's about 93,000 and it is a little bit of an overlap. So we're double counting customers that actually run QuickVue and Sofia. But Sofia customers, it's approximately 21,400. QuickVue customers, it's about 72,000. So it's kind of hard to do a complete bottoms-up by name, but ***I think, they do a pretty good job of coming at it from a couple of different ways. And it's a pretty big range to $200 million to $400 million.***

50. On May 3, 2023, the Company released its financial results for its fiscal quarter ended April 2, 2023. The Company reported $265.6 million in quarterly Respiratory revenues, versus $947.3 million in its first fiscal quarter of 2022. During the Company's related earnings call later that day, Defendant Bryant reiterated that "demand for diagnostics across the health care continuum remained strong" and noted the "significant increase in global demand for global testing." During the earnings call, Defendant Bryant was again asked about QuidelOrtho's endemic guidance:

> **Analyst Patrick Donnelly:** And then maybe just a quick one on the respiratory guide, basically put up a pretty nice beat this quarter, maintain the guide for the full year. Was that essentially, Joe, to your point about some pull forward of revs and then maybe wanting to derisk that second half ramp a little bit. There was quite a bit of focus on that post the guidance, as you know, so maybe just talk through how you approach that, given the results in the quarter.
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> **Defendant Bryant:** Let me start and then Joe will provide for more detail. ***But remember, in the endemic state, we had -- assuming that we are now in that pandemic state, we had forecasted that we would be doing $200 million to $400 million per year over the next few years, this year, next year and perhaps beyond that was how we derisked the number.***
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> The 300 to 500 was to take under account federal orders that we knew we had already on hand and assumed that there would be some level of shipment. So all of that was shipped in the first quarter, a small amount, I think a tiny amount, maybe $4 million or so, we shipped in April as well, and now we're done with the fed orders.

> right? So I think that, that coupled with the run rate that we had forecasted plus a little bit of pull forward on the retail segment.
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> As a number of the retail -- the large retailers actually had programs where patients would order product online, and then we go pick on that -- pick the product off stores, that sort of offset. ***So I think we're still very comfortable that moving forward will be in that 200 to 400 range for COVID.*** And this year, obviously, we're forecasting to be slightly higher.

51. On May 4, 2023, the Company filed with the SEC a Form 10-Q reporting the Company's financial results for the quarter (the "Q1 2023 10-Q"). In the Q1 2023 10-Q, the Company claimed there had been "no material change in our risk factors as previously disclosed in [the 2022 10-K]." Appended as an exhibit to the Q1 2023 10-Q was a signed SOX certification wherein Defendant Bryant and Defendant Buskey certified that the information in the Q1 2023 10-Q "fairly presents, in all material respects, the financial condition and results of operations of the Company."

Second Fiscal Quarter 2023

52. On August 8, 2023, the Company announced its financial results for its fiscal quarter ended July 2, 2023. The Company reported $89.0 million in quarterly Respiratory revenues, versus $339.1 million in its second fiscal quarter of 2022.

53. During the Company's related earnings call later that day, Defendant Bryant stated:

> Turning to our Point-of-Care business unit. Respiratory revenue declined, driven by a reduction in our retail business as expected, following the end of the COVID-19 public health emergency in May and the continued transition to an endemic state. With insurance companies no longer supporting free at-home COVID-19 tests including our QuickVue over-the-counter test, our overall COVID-19 business faced a challenging comp on a year-over-year basis.
>
> And as reported by several other diagnostic companies, the end of the public health emergency had a significant dampening effect on molecular COVID test volumes. ***For us, this helped to drive double-digit year-over-year growth of our Point-of-Care COVID business as many customers shifted testing for symptomatic patients back***

> ***to antigen tests and more specifically to our Sofia SARS Antigen assay.***

On the same call, Defendant Busky stated:

> We now expect full year gross margins to be at the low end of our prior expectations of low to mid-50s due to product mix, including higher instrument revenues from the faster-than-expected drilling on the labs instrument open orders. Adjusted EBITDA margin expected of 26.9% to 27.7% in the range of $800 million to $830 million compared to our prior guidance of $815 million to $865 million.
>
> ***And despite the reduction in our guidance for higher-margin COVID-related revenue, we are offsetting the full P&L impact of the revenue drop with expense reductions***. Adjusted diluted EPS is now expected to be in the range of $4.85 to $5.30 compared to our prior guidance of $5.15 to $5.70.

54. On August 9, 2023, the Company filed with the SEC a Form 10-Q reporting the Company's financial results for the quarter (the "Q2 2023 10-Q"). In the Q2 2023 10-Q, the Company claimed there had been "no material change in our risk factors as previously disclosed in [the 2022 10-K]." Appended as an exhibit to the Q2 2023 10-Q was a signed SOX certification wherein Defendant Bryant and Defendant Buskey certified that the information in the Q2 2023 10-Q "fairly presents, in all material respects, the financial condition and results of operations of the Company."

Third Fiscal Quarter 2023

55. On September 12, 2023, Defendants participated in the Morgan Stanley Global Healthcare Conference. During the conference, Defendant Bryant stated:

> What I would say for the back half total guide, though, that this certainly derisks what we said we would do for the back half in terms of respiratory disease testing for both COVID and Influenza. And then further, I would say, it supports the notion what's happening right now supports our assertion that COVID is just another respiratory virus and it is now endemic. ***And we should expect, therefore, moving forward, 2024 and beyond to see $200 million to $400 million in COVID specifically COVID-only sales***. And I would suggest that with the pending launch of the combination

> product in the OTC space that I think that product will be a winner for us. But -- so your question was, are we going to change the guide, I don't think so. I think it's been derisked though.

56. Defendant Bryant was also asked about FDA approval for the Savanna RVP 4 Test:

> **Analyst Tejas Savant:** So -- and what about sort of FDA submission and 510(k) for the instrument? And then I think you had the RVP4 and the HSV panels. What are the timelines for that in terms of U.S. approval?
>
> **Defendant Bryant:** We submitted 510(k)'s at the end of July for HSV/VZV as well as the respiratory panel. We've also submitted an EUA for the respiratory panel. The 510(k)'s both are under active review at the FDA, meaning that they've accepted the package and actually are -- have sent us several series of questions to talk about what's in the package of the data, et cetera. And we have not heard anything back on the EUA, which I would suggest means that the package for the 510(k) must be reasonably suitable because they're pursuing that rather aggressively with us. So I would also point to the fact that in the last month or so, we've had several the FDA clearances, for example, in the lab business for CEA, CA 19-9 both of which are oncology markers. We've also had approval for PTH, all were reviewed and cleared in a very timely manner. ***So it would suggest to me that the FDA is now pretty much back on track in terms of its cadence of review and approval. So I think that portends well for us also***.

57. On November 1, 2023, the Company released its financial results for its fiscal quarter ended October 1, 2023. The Company reported $185.4 million in quarterly Respiratory revenues, versus $236.1 million in its third fiscal quarter of 2022.

58. During the Company's related earnings call, Defendant Bryant stated that:

> First, the ***strong and early respiratory demand in Q3 was mainly driven by high COVID-19 prevalence throughout the United States***. This will potentially be the first real flu season we see where COVID 19 rates immediately precede it, contributing to higher prioritization of our combo assay as disease stages converge. While the high COVID-19 rates were less pronounced than the 2022-2023 season, there is potential for a longer drop-off in overall season duration. If the timing in Australia translates to this hemisphere, the most aggressive growth in flu prevalence could occur early November, with peak prevalence sometime in early January.

Both the overall market for respiratory testing and our respiratory business became significantly larger due to more testing in general, and significant share gains from competitors for us specifically. We have a strong position in this market and our respiratory diagnostic capabilities play an important role in combating both early and seasonal upticks of COVID-19, RSV and influenza, among others. We're also well positioned to manage any seasonal fluctuations, given our operations team's agility to respond to meet customer demand.

[…]

I'd like to leave you with one key takeaway, and that's we are the same successful respiratory company that we were prior to the global pandemic and the acquisition of Ortho Clinical Diagnostics. The key difference is that ***the overall respiratory market, including COVID-19 now in its current endemic state, is significantly larger than it was pre-pandemic, and QuidelOrtho's position in the overall diagnostics market, including respiratory, is much stronger as a combined company than either company was on a stand-alone basis.***

Contrary to some recent opinions, we believe, as evidenced by our results, the market, the diagnostics market is positioned for continued durable growth for many years to come.

59. Defendant Bryant was also asked about FDA approval for the Savanna RVP 4 Test:

Analyst Alexander Nowak: And then so on Savanna, what has been the feedback so far at the FDA? And I'm sure they've had questions around the submission. And I've honestly forgotten, is this going to be a 510(k) or an EUA that we should get the approval at the end of this year?

Defendant Bryant: Thanks for the question, Alex. We're super confident that we'll have approval for the box. And it will be approved by 510(k). We'll pursue CLIA waiver at our earliest opportunity. But it's not going to be in the EUA.

Analyst Alexander Nowak: And that's 510 (k) for the RVP 4 as well, just to confirm.

Defendant Bryant: That's correct. So ***RVP 4 would be cleared***, HSV obviously is under active review as well.

Analyst Alexander Nowak: Okay. Perfect. And then just an update on the high-volume cartridge manufacturing line.

> **Defendant Bryant:** I don't have a further update. ***We're still targeting everything on track for midyear next year***.

60. On November 2, 2023, the Company filed with the SEC a Form 10-Q reporting the Company's financial and operational results for the quarter (the "Q3 2023 10-Q"). In the Q3 2023 10-Q, the Company claimed there had been "no material change in our risk factors as previously disclosed in [the 2022 10-K]." Appended as an exhibit to the Q3 2023 10-Q was a signed SOX certification wherein Defendant Bryant and Defendant Buskey certified that the information in the Q3 2023 10-Q "fairly presents, in all material respects, the financial condition and results of operations of the Company."

61. On November 30, 2023, the Company participated in the Evercore ISI HealthCONx Conference. During the conference, Defendant Bryant was asked about the endemic COVID revenue guidance:

> **Analyst Vijay Kumar:** The -- I think a lot of us are -- actually one high-level question. A lot of your peers look at base business ex COVID and you guys took the path of guiding to respiratory versus non-respiratory. What was the thought process behind clubbing COVID along with respiratory revenues and breaking it out?
>
> **Defendant Bryant:** We group it in respiratory because they're linked. And you would not -- ***so if you take ranges for COVID, and we've said $200 million to $400 million***, and you take a range for flu, we've called it $230 to $270. So we're a little bit tighter there. And you look at RSV and the other and Strep and you look at those ranges, you can't go to the mid across all of them. You can't go to the high or the low across all of them. What we've seen is in years when in the fourth quarter, we saw a lot of COVID, it seemed to have crowded out flu.

62. Additionally, Defendant Busky was asked about the endemic COVID guidance:

> **Analyst Vijay Kumar:** And some of the margin targets that you had laid out at your Analyst Day, I think, annual expansion, 25 to 50 basis points with EBITDA margins of 27% to 29% exiting '23. I know a lot has changed since then -- since deal announcement. What is the right base we should be thinking about margins, right, ex

> COVID? And what should be like the normal margin expansion cadence?
>
> **Defendant Busky:** Well, Vijay, there's no change in the guidance that we provided at that Analyst Day a year ago. We're still in that 27% to 29% range. And as you know, there's some variables that are going to impact the timing of when we get to that 27% to 29%. The biggest of which is going to be the slope and the pace of the Savanna launch and how dilutive those margins are during the launch and when we get the high-volume line up and running, which will make the margins accretive. You've also got the timing of the achievement of synergies that will impact that achievement of that target margin? ***And then you've got the level of endemic COVID and where you end up in that range of 200 to 400***.

63. On January 8, 2024, the Company participated in the 42nd Annual JPMorgan Healthcare Conference. During the conference, Defendant Bryant was asked about QuidelOrtho's endemic COVID guidance:

> **Analyst Casey Woodring:** So you're guiding to 6% to 9% top line growth ex COVID over the longer term. Just want to clarify, since you've been splitting out kind of ex respiratory the last couple of quarters, is that 6% to 9% now ex respiratory? And then will you kind of continue to split out respiratory.
>
> **Defendant Bryant:** No, that's total and those same ranges that we had described, both at our -- excuse me, our Analyst Day, Investor Day, the last 1, they still haven't changed and we've been pretty much been -- we have been in those ranges. A couple of things have caused that to be different. For example, ***we said $200 million to $400 million on COVID. And -- but we didn't anticipate we were going to get that big government order in the first quarter. So we'll be higher than the range there***.

64. On the same call, Defendant Bryant was asked about the status of the Savanna RVP4 Test:

> **Analyst Casey Woodring:** Doug, maybe in the last 2 minutes, we can talk about Savanna, exciting update a couple of weeks ago. Can you give us a sense of when we should expect the RV4 panel, should that be approved during the respiratory season here? And just kind of any update on what you've heard from the agency or anything?

> **Defendant Bryant:** ***Well, we're in good shape. And I would commit to being in market before the end of the quarter***.

65. Defendants statements referenced in ¶¶27-64 above were materially false and misleading when made because they knew or deliberately disregarded and failed to disclose the following adverse facts about QuidelOrtho's business, operations, and prospects:

(a) that QuidelOrtho sold more COVID-19 tests to its distributors and pharmacy chain customers than they could resell to healthcare providers and end customers;

(b) that excess inventories of COVID-19 tests existed throughout the supply chain;

(c) that, as a result of (a)-(b) above, QuidelOrtho's distributors and pharmacy chain customers were poised to significantly reduce their COVID-19 test orders;

(d) that undisclosed problems created a heightened risk that the Savanna RVP4 Test would experience a delayed commercial launch in the United States;

(e) that, as a result of (a)-(d) above, Defendants lacked a reasonable basis for their positive statements about QuidelOrtho's business, financials, and growth trajectory.

The Truth Emerges

66. The truth behind Defendants' fraud began to emerge on February 13, 2024, when QuidelOrtho released its financial results for its fourth fiscal quarter and year ended December 31, 2023 which fell far below its publicly issued projections. Among other things, the Company's Adjusted EPS was ***46 percent below*** the midpoint of Wall Street analysts' expectations, which was largely attributed to lower endemic COVID-19 revenues during the quarter from distributor

destocking. The Company also reported Adjusted EBITDA[2] ***28 percent below*** analysts' consensus of $271 million. The Company also slashed its 2024 financial forecasts, including a drastic cut to its COVID-19 revenue guidance. Specifically, QuidelOrtho lowered its endemic COVID-19 revenue forecast from the range of $200-$400 million to $200 million.

67. During the related earnings call on the same day, Defendants were asked about the Company's lowered guidance:

> **Analyst Alexander Nowak:** So you provided an endemic respiratory rate for 2023, and you were very confident in it throughout the year and sales still came in below that. So before COVID, the respiratory business for Quidel stand-alone was roughly $150 million of sales. Now your endemic rate for 2024 as it said today is $460 million to $730 million. Now if you get this endemic rate wrong for 2024, there's a lot of downside. I guess the question is why do you think this new number is right?
>
> **Defendant Bryant:** Thanks for the question, Alex. We think we have a pretty good understanding of market size, and we think the number of tests starting with flu, between $40 million and $60 million makes the most sense. We haven't seen something as low as $40 million in a while. And we wouldn't expect at this stage to see something more than $60 million. So I think we've pegged the market size correct. The question is what's your market share? Well, our market share actually has increased in the recent report that we saw this morning that increased slightly more than that. Well, the other factor is what's happening with your price. Well, our price basically is flat. And we've been able to take share in place Sofia analyzers with that same price. We've also seen a shift towards the combo assay, which is super healthy. So obviously, very difficult to predict this market, which is why we're widening the range.

68. During the same call, Defendant Bryant continued to mislead investors. Specifically, he failed to disclose problems that created a heightened risk that the Savanna RVP4

[2] EBITDA is earnings before interest, taxes, depreciation, and amortization. Adjusted EBITDA removes one-time, irregular, and non-recurring items that distort EBITDA.

Test would experience a delayed commercial launch in the United States. For example, Defendant Bryant stated that:

> ***The status of the submission of the 510(k) is on track*** per my previous comments. Recall that I had said that we expect to get clearance before the end of the first quarter. I think we're still on track for all that.
>
> […]
>
> Savanna has been a long time coming in the United States and our agenda at this point is clear, menu expansion and customer adoption. ***We're advancing both with FDA review of our RVP4 panel and others in the queue. Our U.S. sales team is meeting this week, and I can assure you a successful Savanna commercial launch is on their menu as well***. As noted earlier, we will invest in the higher-growth immunohematology side of our Transfusion Medicine business.
>
> […]
>
> Our guidance also assumes minimal contribution of between $30 million to $50 million in respiratory revenues from Savanna RVP4, and we expect that the revenue to be primarily in the fourth quarter of 2024, given the timing of approvals for the respiratory indication, which we expect in Q1. ***We continue to expect Savanna instrument placements of approximately 1,000 in 2024, which will pave the way for 2025 Savanna revenue growth.***

69. In reaction to these dismal results and weak guidance, multiple analysts immediately downgraded their ratings on QuidelOrtho stock and voiced their concerns. William Blair analyst Andrew Brackmann wrote that management needed to "rebuild some credibility" and Raymond James analyst Andrew Cooper took note of Defendants' "fairly deplorable communication and expectation setting both over the course of 2023 and even as recently as [January 2024]." Craig-Hallum analyst Alexander Nowak stated that "Q4 came in as one of the most surprising results we have seen in diagnostics in some time—and not in a pleasant way for shareholders." On this news, the price of QuidelOrtho common stock declined $21.50, or more than 32 percent, to close at $45.27 on February 14, 2024.

70. Then, on February 21, 2024, the Company's Board announced the dismissal of its President and CEO, Defendant Bryant along with his resignation as a Director on the Board, effective immediately.

71. Finally, on April 2, 2024, QuidelOrtho announced that it had withdrawn its FDA 510(k) submission for the Savanna RVP4 Test after recent data did not meet expectations. According to Citi analyst Patrick Donnelly, the Savanna RVP4 Test was "expected to be a key driver of Savanna uptake in the respiratory season." On this news, the price of QuidelOrtho stock dropped $4.85, or more than 10 percent, to close at $42.15 on April 2, 2024.

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

ADDITIONAL SCIENTER ALLEGATIONS

73. During the Class Period, as alleged herein, the Individual Defendants acted with scienter in that the Individual Defendants knew or were reckless as to whether the public documents and statements issued or disseminated in the name of the Company during the Class Period were materially false and misleading; knew or were reckless as to whether 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.

74. The Individual Defendants permitted QuidelOrtho to release these false and misleading statements and failed to file the necessary corrective disclosures, which artificially inflated the value of the Company's common stock.

75. As set forth herein, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding QuidelOrtho, their control over, receipt, and/or

modification of QuidelOrtho's allegedly materially misleading statements and omissions, and/or their positions with the Company that made them privy to confidential information concerning QuidelOrtho, participated in the fraudulent scheme alleged herein.

76. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud or deceit on purchasers of QuidelOrtho common stock by disseminating materially false and misleading statements and/or concealing material adverse facts. The scheme deceived the investing public regarding QuidelOrtho's business, operations, and management and the intrinsic value of QuidelOrtho common stock and caused Plaintiff and members of the Class to purchase QuidelOrtho common stock at artificially inflated prices.

LOSS CAUSATION/ECONOMIC LOSS

77. 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 QuidelOrtho's common stock, or maintained levels of artificial inflation in QuidelOrtho's common stock price, and operated as a fraud or deceit on Class Period purchasers of QuidelOrtho's common stock by materially misleading the investing public. Later, when QuidelOrtho and Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of QuidelOrtho's common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases of QuidelOrtho's common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

NO SAFE HARBOR

78. 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 were 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 QuidelOrtho who knew that the statement was false when made.

CLASS ACTION ALLEGATIONS

79. 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 QuidelOrtho's common stock during the Class Period and were damaged upon the revelation of the alleged corrective disclosure. 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.

80. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, QuidelOrtho's common stock was actively traded on the Nasdaq Global Select Market. 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 QuidelOrtho 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 February 22, 2024, there were approximately 66.85 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.

81. 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.

82. 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.

83. 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 QuidelOrtho;

(c) whether the Individual Defendants caused QuidelOrtho to issue false and misleading financial statements during the Class Period;

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

(e) whether the prices of QuidelOrtho'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.

84. 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.

Presumption of Reliance; Fraud-On-The-Market

85. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

(a) QuidelOrtho's common stock met the requirements for listing and was listed and actively traded on the Nasdaq Global Select Market during the Class Period, a highly efficient and automated market;

(b) QuidelOrtho 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) QuidelOrtho 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 QuidelOrtho was reflected in and incorporated into the Company's stock price during the Class Period.

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

87. 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.

COUNT I

Against All Defendants for Violations of
Section 10(b) and Rule 10b-5 Promulgated Thereunder

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

89. This Count asserted against Defendants 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.

90. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

91. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) employed devices, schemes and artifices to defraud;

(b) made untrue statements of material facts or 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; or

(c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of the Company's common stock during the Class Period.

92. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and 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 securities laws. These Defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

93. Individual Defendants, who are or were senior executives and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other Company's personnel to members of the investing public, including Plaintiff and the Class.

94. As a result of the foregoing, the market price of the Company's common stock was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of the Company's common stock during the Class Period in purchasing the Company's common stock at prices that were artificially inflated as a result of Defendants' false and misleading statements.

95. Had Plaintiff and the other members of the Class been aware that the market price of the Company's common stock had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased the Company's common stock at the artificially inflated prices that they did, or at all.

96. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

97. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchase of the Company's common stock during the Class Period.

COUNT II

Against the Individual Defendants
for Violations of Section 20(a) of the Exchange Act

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

99. 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 the Company's misstatement of revenue and profit and false financial statements.

100. As officers of a public business, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

101. Because of their positions of control and authority as senior executives and/or directors, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period concerning the Company's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company 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 the Company common stock.

102. By reason of the above conduct, the Individual Defendants 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.