

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

IN RE QUIDELORTHO CORPORATION
SECURITIES LITIGATION

No. 24-cv-02804-JAV

CLASS ACTION

JURY TRIAL DEMANDED

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

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Court-appointed Lead Plaintiff Central States, Southeast and Southwest Areas Health and Welfare Fund (“Central States”) and Teamsters Local 710 Pension Fund (“Local 710” and collectively the “Teamsters Funds” or “Lead Plaintiff”), by and through their undersigned counsel, brings this federal securities class action on behalf of itself and a class consisting of all persons and entities who or which purchased or otherwise acquired the publicly traded common stock of Quidel Corporation (“Quidel”) and/or its successor QuidelOrtho Corporation (“QuidelOrtho”) during the period from after market close on February 17, 2022 through April 1, 2024, inclusive (the “Class Period”), and were damaged thereby (the “Class”).¹ Lead Plaintiff asserts claims for violations of the Securities Exchange Act of 1934 (the “Exchange Act”) against QuidelOrtho, the Company’s former Chief Executive Officer (“CEO”), Douglas Bryant (“Bryant”); the Company’s Chief Financial Officer (“CFO”), Joseph Busky (“Busky”); the Company’s former CFO, Randall Steward (“Steward”); the Company’s former Chief Operating Officer (“COO”), Robert J. Bujarski (“Bujarski”); the Company’s former Executive Vice President, Chief Commercial Officer and Interim CEO, Michael Iskra (“Iskra”); and the Company’s Senior Vice President, Molecular Diagnostics and Point of Care, Tamara Ranalli (“Ranalli”) (collectively defined as the “Individual Defendants”).

Lead Plaintiff alleges the following based upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters. Lead Plaintiff’s information and belief

¹ As discussed more fully herein, on or about May 27, 2022, Quidel and Ortho Clinical Diagnostics Holdings PLC (“Ortho”) consummated a business combination whereby QuidelOrtho became the successor to Quidel pursuant to Rule 12g-3(a) under the Securities Exchange Act of 1934. QuidelOrtho is the named corporate Defendant for the claims alleged herein during the entire Class Period. Generally, as used herein, Quidel refers to Quidel Corporation prior to May 27, 2022 and QuidelOrtho refers to the successor entity on May 27, 2022 and thereafter as well as to the corporate Defendant for the entire Class Period. The “Company” refers to both Quidel and QuidelOrtho during those respective periods of time.

is based on the ongoing investigation of their undersigned counsel (“Lead Counsel”). This investigation includes review and analysis of, among other things: (i) public filings made by the Company with the SEC; (ii) transcripts of the Company’s conference calls with analysts and investors; (iii) the Company’s presentations, press releases, and other public statements issued by Defendants; (iv) research reports issued by securities and financial analysts; (v) news and media reports and other publicly available information concerning the Company and Defendants; (vi) economic analyses of the movement and pricing of the Company’s publicly traded securities; (vii) consultation with experts; and (viii) interviews of former employees of the Company (referred to herein as “FE-___”). Lead Counsel’s investigation into the factual allegations continues, and many of the relevant facts are known only by Defendants or are exclusively within their custody or control. Lead Plaintiff believes that additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. PRELIMINARY STATEMENT

1. This case arises from a series of material misrepresentations by the senior executives of QuidelOrtho about (a) “*the most important product in [the C]ompany’s history,*” the Savanna immunoassay multiplex testing analyzer and, specifically, the Savanna RVP4 test assay (“RVP4”), which promised to provide groundbreaking technology that would simultaneously test for four highly contagious respiratory infections in under thirty minutes; and (b) the Company’s “endemic” COVID-19 testing revenue guidance, which Defendants doubled in December 2022 while, in reality, the Company’s COVID-19 sales were “grossly declining.”

A. Summary of the Fraud

2. Quidel historically provided diagnostic testing solutions, including rapid immunoassay tests used in hospitals, laboratories and point of care locations, and which detected, among other things, respiratory infections. Quidel generated steady annual revenues of slightly

over \$500 million in 2018 and 2019. In February 2020, the Company's stock price traded between \$77 and \$81 per share.

3. In early 2020, COVID-19 emerged and became a global health pandemic. Laudably, Quidel responded to the COVID-19 outbreak, and by March 17, 2020, the Company began creating and manufacturing a series of diagnostic tests that detected COVID-19 infections for both clinical and at home use. Quidel sold these tests directly to customers and channel distributors, as well as to the U.S. government. The Company's COVID-19 testing successes created a surge of historic revenues, with COVID-19 pandemic test sales generating \$1.163 billion in 2020 and \$1.274 billion in 2021, totaling 70% and 75% of the Company's annual revenues, respectively. The Company's share price rose commensurately, reaching a high of \$283.45 per share on November 6, 2020.

4. By the middle of 2021, while COVID-19 test sales were still at a peak, Quidel began preparing for COVID-19 to reach its endemic stage, meaning that testing needs would reduce and become similar to the testing needs of other respiratory illnesses, such as influenza and RSV. The Company, led by Defendants Bryant and Steward, was eager to maintain the momentum and stock performance realized through the Company's COVID-19 successes.

5. In May 2021, Quidel began to explore a combination with Ortho, a merger that Raymond James analysts called "far from obvious." While the companies did not enjoy much product crossover, Quidel's soon-to-launch molecular diagnostic platform, named Savanna, was cited by both companies in the Merger proxy as an important "strategic consideration" in support of the Merger.

6. Quidel first unveiled its Savanna platform in 2011. Long marketed as Quidel's next flagship product, Savanna was touted as a molecular diagnostic testing solution that would provide

low cost “PCR” testing to allow physicians, pharmacies, and hospitals to accurately test for a multitude of infections and diseases in a fraction of the normal time needed for such tests. By mid-2021, the Company claimed it was finally ready to launch the Savanna device along with its first test, RVP4, a multiplex assay that would test for influenza A and B, COVID-19, and respiratory syncytial virus (RSV) from a single sample. On July 12, 2021, Quidel announced that it had secured a “CE Mark”—a self-certifying designation that allowed it to sell RVP4 in certain European countries.

7. After months of private discussions, the Quidel-Ortho Merger was publicly announced on December 23, 2021 with a scheduled closing by the end of May 2022. In the leadup to the May 2022 shareholder votes, the early success of Savanna’s European launch was a focus of analyst attention, with Defendants representing that Ortho’s global customer base would accelerate sales of Savanna and generate \$75 million of Merger revenue synergies in the coming years. On the first day of the Class Period on February 17, 2022, Defendant Bryant told investors that: *“Based on customer reviews in Europe, we believe Savanna will be a major growth driver, both in the U.S. and globally, for years to come.”* Reports of Savanna’s early successes continued unabated over the next two years, during which time QuidelOrtho shareholders were told that the RVP4 European launch was *“performing very nicely,” “continue[d] to go well with some early wins,”* was doing *“super well,”* and that those successes *“portend[] well for the rest of the globe.”* Defendants specifically lauded the positive response from Savanna RVP4’s European customers, highlighting the receipt of *“very positive customer feedback,” “really nice feedback,”* and *“great feedback,”* noting that *“frankly the folks there [in Europe] have been asking for more boxes than we are shipping.”*

8. Unknown to investors, Savanna was not ready for market in 2021, or by the end of the Class Period. Defendants rushed the European launch to push for the Merger, secure lucrative bonus payments, and finally deliver on a product that had been in development limbo for a decade. Several former employees involved in the development, marketing, and sales of Savanna have described how RVP4 could not generate reliable results and suffered from manufacturability design issues, resulting in the need to scrap more than half of the tests produced and creating design and performance flaws in a significant number of the remaining tests that went to market, rendering their results invalid. The test market—Europe—experienced all of these problems, and each complaint was recorded and reported up to the C-Suite. These major, possibly existential, issues were never resolved.

9. For example, FE-14, an Associate Director Engineer at Quidel who worked on Savanna’s development in 2019, was aware that the design flaws of the Savanna RVP4 test were highlighted to Senior Vice President, Research and Development, Werner Kroll as early as 2019. Rather than tackle those issues, the Savanna engineering team was disbanded, and Defendants Steward and Bujarski, together with Kroll, created a small “insular” team that pushed Savanna RVP4 through to market while turning a blind eye to its fundamental flaws.

10. Those unheeded warnings proved to be spot on and reflected in the European launch. Defendants’ rosy accounts of positive European customer feedback on RVP4 could not have been farther from the truth. The Savanna launch was limited, selling approximately 40 Savanna analyzers to a few customers in Austria, Germany, and Italy in the last quarter of 2021 and the first quarter of 2022, and expanding that base only slightly, selling approximately another 40–50 analyzers in 2023. Numerous former employees describe how European customer

complaints began right away and continued unabated, and even increased, throughout the Class Period.

11. FE-4 and FE-7 both worked directly on the marketing of RVP4 to the European market, drafted promotional materials, and participated in weekly and monthly meetings to discuss Savanna's sales and customer reception. Both former employees were updated on the multitude of issues that plagued Savanna RVP4 in the European market, and both described how there were consistent complaints about the Savanna devices breaking down and the RVP4 tests generating an alarming rate of "invalid" results, meaning that the tests simply failed to provide either a positive or negative response as to the presence of flu, COVID-19, or RSV, causing the test to be scrapped and rerun. According to FE-4, approximately 25% of the devices and another approximate 25% of the tests failed in the field and had to be replaced at cost to the Company, an experience that was "very alarming" and harmed the Company's reputation with its customers. FE-4 stated that Jürgen Becker, Scientific Marketing Manager, Europe, informed him that European Savanna RVP4 test customers were "irate." FE-7, the former Marketing Manager for Molecular Dx (EMEA), recounted how prevalent customer complaints were, noting how in one 2023 monthly PowerPoint report prepared for senior management, of the approximate 80 devices currently in the market, there had been 85 customer complaints about the devices, tests (or both)—more than actual devices. FE-7 stated quite plainly that in his 20-year career, he "*didn't remember any market launch that was so full of issues.*" Former Cost Accounting Manager, FE-6, described the European launch as "*flying a plane while building it.*"

12. Supposedly buoyed by the positive (and fabricated) European feedback, Defendants increased their push to bring RVP4 to market in the United States, despite the significant manufacturing issues and invalid test results. Defendants had a strong reason for

pushing forward. By the end of 2022, it was clear that the over \$1 billion of revenue generated by COVID-test sales in 2020 to 2022 was over as testing levels plummeted. While the worldwide decrease in testing was public knowledge, what was not known to investors was the fact that QuidelOrtho was losing its COVID-19 testing customers to competitors and needed to launch a new product to bridge that gap in revenue and prop up the Company's stock price. Moreover, the Company's leading testing platform currently in the market, known as Sofia, which was sold to test for COVID-19, as well as respiratory and other infections, was approaching "end of life," with its primary manufacturer ceasing production of key components. Moreover, in 2023, two other diagnostic instrument development projects—which had been held out together with Savanna as the Company's future growth drivers—had failed and were scrapped completely in 2023. With Savanna remaining as the only diagnostic instrument in development, its full U.S. launch was critical.

13. As soon as Savanna RVP4's limited European launch kicked off, and throughout the Class Period, Defendants promised investors that the full U.S. launch, and the resulting \$75 million of Merger revenue synergies and \$300 million of annual revenues, was around the corner.

14. However, unlike the CE Mark that allowed sales in Europe with what amounted essentially to a self-certification by QuidelOrtho that the product was ready for sale, sales in the U.S. had to be approved by the FDA, a government agency that sets out clear, and often exacting, standards for approval. Former employees described how the FDA communicated to the Company well in advance of its submission that the Company needed to demonstrate that the RVP4 test could *consistently* demonstrate a return of 95% sensitivity, or detectability, for the targeted viral infections.

15. Defendants—most prominently Defendant Bryant—projected high confidence in RVP4’s satisfaction of FDA requirements and the imminent approval and launch of RVP4 in the United States. After first projecting that the FDA submissions would be filed in late 2022 or early 2023, the Company, on August 8, 2023, announced that it had applied for clearance to sell the Savanna device and RVP4 test in the United States. Defendant Bryant stated: “*On behalf of our customers and shareholders, I’m thrilled that the US Savanna launch is progressing as the platform is robust, the total addressable market is huge and the outlook is very exciting.*” On September 12, 2023, Bryant represented that Savanna was ready for the U.S. market, “our largest opportunity,” because the Company had used the European launch to identify and correct errors. A few months later, on November 30, 2023, Bryant spoke as if the FDA approval was a done deal, stating: “*And so, as we’re about to enter our largest opportunity, our largest market, we will have resolved some of the things that would have needed to be resolved had we not launched somewhere else first.*”

16. However, as former employees have recounted, at no point did the Company’s internal testing or engineering, or real-time feedback from Europe, cause QuidelOrtho to correct the manufacturing and performance issues sufficient to meet the FDA’s consistent showing of 95% sensitivity. In fact, one former employee, FE-4 recounted how the person responsible for validating the RVP4 test results for its FDA submissions told him, at the time when FDA submissions were being filed, that Savanna RVP4 “*does not work*” and that it “*isn’t even a product.*” FE-2 corroborated hearing similar information from that same individual, who relayed that the validation team was not getting the needed sensitivity readings and not picking up enough results during validation prior to the test’s submission to the FDA. Another former employee, FE-1 who was a Senior Director, Regulatory Affairs during the Class Period, confirmed his understanding

that QuidelOrtho knew that it was not meeting the FDA's requirements when it submitted its 510(k) application for clearance to sell Savanna RVP4 in the United States, but went ahead anyway. FE-2 stated that issues with Savanna RVP4 were not fixed when it went on sale in Europe, were not fixed when it was sent to the FDA for approval, and were not fixed when he left the Company in the second half of 2023. FE-10, a Finance Director, recounted internal discussions about Savanna where employees joked that the product was a fraud—QuidelOrtho's "*Theranos*".

17. While Defendants were pushing their false Savanna RVP4 success story on investors, they engaged in a second fraudulent scheme targeted to raise investors valuation of the Company's COVID-19 test sales and, therefore, the Company's stock price. By the end of 2022, it was clear that the Company's COVID-19 testing revenues were being impacted by more than industry-wide declining testing trends, but that QuidelOrtho's COVID-19 testing products were rapidly losing market share, leading to "grossly declining" revenues, unhappy sales and account managers who missed their COVID-19 sales quotas "by a mile." As a result, QuidelOrtho COVID-19 test inventory levels piled up with major distributors who had no future need for these expiring products. Multiple former employees describe how concerning negative sales trends were communicated to Defendants Bryant and Busky beginning no later than the end of 2022 through various reports and meetings and conversations.

18. Initially, in the face of these negative trends, Defendants Bryant and Busky chose to present to investors their reasoned determination of the Company's "endemic" COVID-19 revenues for 2023, 2024, and thereafter. From August 2022 until almost the end of 2022, Bryant and Busky told investors that, based on the market and the Company's own sales, endemic COVID-19 revenues would be \$150 million to \$200 million per year, an 86% decrease from 2021 COVID-19 revenues.

19. This messaging changed dramatically after QuidelOrtho's December 13, 2022 Investor Day presentation and conference call. During the call, Defendants Bryant, Busky, Ranalli, Bujarski, and Iskra spoke to investors, focusing on the Company's strategy, key growth initiatives, integration, innovation, and long-term financial outlook, but also provided updates lowering the Company's long-term guidance. Investors reacted swiftly and negatively to the Company's lackluster update, and QuidelOrtho stock dropped **over 17%** by market close, its largest intraday drop since November 2020. In response, Defendant Busky went on a series of virtual calls with analysts to try to get the Company stock back on track. One way he accomplished this was to magically double the Company's annual endemic COVID-19 sales guidance, ***raising it in the space of days from \$150 to \$200 million, to \$200 to \$400 million.*** Defendants doubled endemic COVID revenues statements had their intended effect, and QuidelOrtho stock price began to rise back toward its pre-December price per share.

20. As described more fully below, not only was there no basis for Defendants' doubled revenue figures, but the information known to Defendants resulted in "grossly declining," not greater, revenues. Nonetheless, Defendants repeated this inflated endemic COVID-19 revenue number throughout 2023, while the Company's actual outlook for COVID-19 sales worsened. For example, FE-10 gave Defendant Busky a monthly in-person analysis during which Busky would ask follow-up questions about QuidelOrtho's significant inventory risk, and Busky received regular reports assessing the financial risk that excess inventory posed to the Company. Moreover, as described by multiple former employees, salespersons throughout the country missed their sales quotas "by a mile" because distributors and partners had turned away from QuidelOrtho's COVID-19 and respiratory testing devices.

21. In summary, by the end of 2023, unknown to investors, Savanna's European launch continued to falter under the weight of constant, unresolved customer complaints, the Company failed to produce consistent 95% sensitivity results sufficient to meet FDA approval requirements, over half of the RVP4 tests in production were defective and needed to be scrapped, the Company still had no automated production line for RVP4 cartridges after investing at least \$100 million in those efforts, and COVID-19 revenues continued to decline, losing out to competitors with better technology and a greater opportunity for Medicaid reimbursement. Yet, despite the daunting weight of this negative news, on January 8, 2024, Defendants participated in an analyst call and maintained the status quo, indicating essentially that no news was good news for the Company.

B. The Truth Begins To Emerge

22. Just a few weeks later, investors began to learn the truth and, as a result, suffered the consequences of Defendants' fraud.

23. On February 13, 2024, QuidelOrtho released financial results for its fourth fiscal quarter and year ended December 31, 2023 that 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 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 back to its initial 2022 guidance of \$200 million. Defendants Bryant and Busky continued to misrepresent RVP4 performance and imminent FDA approval.

24. On this news, QuidelOrtho's stock price plummeted, falling 32% in a single trading session on unusually high trading volume, and continued to decline over the following days. QuidelOrtho's Board of Directors reacted swiftly, firing Defendant Bryant the following day.

25. While the Company tried to spin its dismal results and slashed endemic COVID-19 revenue on market conditions that they got wrong, a UBS analyst report issued on March 5, 2024, cast serious doubt on that spin, noting that other competitors in the COVID-19 test market actually reported better than expected test sales in the fourth quarter of 2023. QuidelOrtho common stock dropped once more upon issuance of the report.

26. Then, on April 2, 2024, the falsity of Defendants' consistent refrain touting Savanna's success in Europe and readiness for the U.S. market, came crashing down. The Company issued a press release that promised good news—the 510(k) approval of a different test that had long been on the market under EUA—but ended with the heavily disappointing news that the Company had “withdrawn” its RVP4 submission, taking the Company back to square one in its now thirteen-year odyssey to launch Savanna. On this news, QuidelOrtho stock fell over 10%. Analysts noted that “the team needs to earn back credibility.”

27. The impact of Defendants' fraudulent representations continues to unravel. On May 7, 2024, the Company announced that after a several month search, the Board appointed Brian Blaser as its new CEO. The next day, the Company once again reduced QuidelOrtho's endemic COVID-19 revenues down to \$150 million. In addition, the Company reported that “Savanna revenue will be immaterial in 2024, with no expected US respiratory revenue contribution from Savanna in the 2024-2025 respiratory season.” To date, RVP4 has still not been submitted for FDA approval, and on November 7, 2024, Blaser further disclosed that the Company now anticipated Savanna RVP4 entering the U.S. market “in the later part of 2025” with most of the “ramp-up”

occurring in 2026 and 2027. Under Blaser's new direction, the Company fired many senior executives, including notably, Defendants Bujarski and Iskra on July 31, 2024.

28. Lead Plaintiff brings this action to hold Defendants accountable for the shareholder value they destroyed.

II. JURISDICTION AND VENUE

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

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

31. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(a)).

32. QuidelOrtho conducts substantial business in this District, and many of the acts and conduct that constitute the violations of law complained of herein, including the preparation and dissemination to the public of materially false and misleading information, occurred in this District. The Company's common stock trades on Nasdaq Global Select Market, a national stock exchange located in this District.

33. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

A. Lead Plaintiff

34. Lead Plaintiff Central States was founded in 1950 as a non-profit labor health fund. Central States is a healthcare fund that oversees more than \$13 billion in assets under management

for the benefit of over 500,000 participants and covered dependents, from 800 different employers, including participants from industries such as trucking, car haul, warehouse, construction, food processing, dairy, and grocery trucking, making it the largest labor healthcare fund in the country. As set forth in its certification (ECF No. 19-1), Central States purchased over 34,000 shares of QuidelOrtho common stock during the Class Period. Central States suffered damages as a result of the violations of the federal securities laws.

35. Lead Plaintiff Local 710 oversees approximately \$4 billion in investments for the benefit of participants and their beneficiaries. Local 710 is headquartered in Mokena, Illinois and represents more than 10,900 retired workers and 8,200 active workers across the Midwest, including freight, warehouse, trucking, and United Parcel Service workers. As set forth in its certification (ECF No. 19-1), Teamsters Funds purchased over 19,000 shares of QuidelOrtho common stock during the Class Period. Local 710 suffered damages as a result of the violations of the federal securities laws.

B. Defendants

36. QuidelOrtho is a Delaware corporation with its principal executive offices located in San Diego, California. The Company's common stock trades on the Nasdaq Global Select Market under the symbol "QDEL." On May 27, 2022, Quidel and Ortho consummated a business combination (the "Merger"), by way of (i) a scheme of arrangement undertaken by Ortho under Part 26 of the UK Companies Act 2006, pursuant to which each issued and outstanding share of Ortho was acquired by a nominee of the Company, such that Ortho became a wholly owned subsidiary of the Company; and (ii) a merger of Laguna Merger Sub, Inc. with and into Quidel, with Quidel surviving the merger as a wholly owned subsidiary of the Company. As a result of the Merger, QuidelOrtho became the successor issuer to Quidel pursuant to Rule 12g-3(a) under the

Exchange Act. While QuidelOrtho is headquartered in San Diego, the Company operates various offices across North America and globally, including in Europe, Asia, and Latin America.

37. Defendant Bryant served as the Company's Chief Executive Officer ("CEO") from March 2009 until it was publicly announced on February 21, 2024 that Bryant had been fired by the Board of Directors on February 14, 2024. Bryant served as Chairman of QuidelOrtho's Board of Directors from May 27, 2022 until December 12, 2022, and as a member of the Board from December 12, 2022, until his resignation from the Board on February 17, 2024, following his termination as CEO. During the relevant period of time, Bryant oversaw the Company's Executive Steering Committee for the Savanna project. Bryant signed the Company's materially misleading public filings, including quarterly and annual reports, all of which were filed with the SEC during the Class Period, and made other materially misleading statements to investors as set forth below.

38. Defendant Busky served as QuidelOrtho's Chief Financial Officer ("CFO") from May 27, 2022 to the present. Busky previously served as Ortho's CFO. Busky signed QuidelOrtho's materially misleading public filings, including quarterly and annual reports, all of which were filed with the SEC during the Class Period, and made other materially misleading statements to investors as set forth below.

39. Defendant Steward was the CFO of Quidel from October 21, 2011 until May 27, 2022, and thereafter served in the role of special advisor to QuidelOrtho relating to the Merger, the CFO transition, and other general matters between May 27, 2022 and March 31, 2024. During his tenure as CEO, Steward served as a member of Quidel's Executive Steering Committee for the Savanna project.

40. Defendant Bujarski served as the Chief Operating Officer of the Company from September 2020 until his termination on November 15, 2024, and served as Executive Vice

President of the Company from December 12, 2022 until his termination on November 15, 2024, and as Interim President of the Company from February 21, 2024 until May 6, 2024. During the relevant time, Bujarski served as a member of Quidel's Executive Steering Committee for the Savanna project. Bujarski made materially misleading statements to investors as set forth below.

41. Defendant Iskra served as Executive Vice President of Commercial Excellence and Strategy at Ortho from 2020 to 2022. After the Merger, Iskra served as QuidelOrtho's Chief Commercial Officer ("CCO") from May 27, 2022 until his termination on November 15, 2024, as Executive Vice President of the Company from December 11, 2022 until his termination on November 15, 2024, and as Interim CEO from February 21, 2024 until May 6, 2024. Iskra made materially misleading statements to investors as set forth below.

42. Defendant Ranalli joined Quidel Corporation in 2010 as an Associate Director for molecular program management and is currently the Senior Vice President, Molecular Diagnostics and Point of Care at QuidelOrtho. In her current role, Defendant Ranalli leads the management of all functions of the business unit in all regions and is accountable for growing revenue and market share worldwide. Ranalli was intimately involved with the development and European launch of the Savanna analyzer device and the Savanna RVP4 test, stating during a November 12, 2020 conference call that she "has been with the Savanna program since the inception of the project" and during a September 12, 2022 podcast appearance that Savanna "has really been an over 10 year labor of love for me." Ranalli made materially misleading statements to investors as set forth below.

43. Defendants Bryant, Busky, Steward, Bujarski, Iskra, and Ranalli are collectively referred to hereinafter as the "Individual Defendants." The Individual Defendants, because of their positions within the Company possessed the power and authority to control the contents of the

Company's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors. During their tenure, Individual Defendants Bryant, Busky, Steward, Bujarski, and Iskra were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations were materially false and/or misleading when made.

44. QuidelOrtho (and its predecessor entity Quidel) and the Individual Defendants are collectively referred to hereinafter as "Defendants."

C. Relevant Third Parties

45. Werner Kroll served as the Company's Senior Vice President, Research and Development and was heavily involved in the development of Savanna RVP4. Kroll reported to Defendant Bryant and was in constant communication with Defendant Busky. Kroll received reports and complaints regarding various issues with the Savanna RVP4 panel throughout the Class Period and was involved in the QuidelOrtho's decision to submit the application for FDA approval. During the relevant period of time, Kroll served as a member of Quidel's Executive Steering Committee for the Savanna project, along with Defendants Steward and Bujarski.

46. FE-1 worked at Quidel and then QuidelOrtho from approximately January 2020 through April 2024 in the Company's San Diego location. He served as Senior Director, Regulatory Affairs. In the earlier part of his employment, FE-1 reported to Ron Lollar, current Vice President, Clinical and Regulatory – Infectious Disease at QuidelOrtho. Later, FE-1 reported to Michelle Bodien, current Senior Director, Regulatory Affairs, at the Company.

47. FE-2 was formerly employed by Quidel and then QuidelOrtho from approximately February 2020 through September 2023. During that time, FE-2 served as Senior Director, Systems Engineering. In that role, FE-2 oversaw all the engineering for developing new instruments and sustaining the Company's existing instruments in the Company's San Diego location. His work included engineering for both instrumentation and hardware, and he worked on developing the engineering for the Savanna RVP4 test as well as the RVP4 cartridges used in that test. He reported to Werner Kroll at the start of the Class Period until the Merger closed, then to Pierre Emeric, former Global Head of Platform Research and Development, and then to Manoj Raghuraman, current Vice President, Hardware Engineering, at QuidelOrtho. Both Emeric and Raghuraman reported to Kroll, former Senior Vice President, Research & Development, at the Company.

48. FE-3 was formerly employed by Ortho prior to the Merger in Sales and Business Development and served in the same role during his tenure with QuidelOrtho, which lasted until April 2024. He was responsible for prospecting new business and growing existing accounts. He sold both Quidel and Ortho products after the Merger and reported to former Inside Sales and Associate Program Director FE-19, who in turn reported to former Vice President of Sales John Meckles.

49. FE-4 held various senior level marketing roles from mid-2020 until Fall 2023. During his tenure, he was responsible for marketing the Company's respiratory disease platforms, including QuickVue, Sofia, Solana, and Savanna RVP4. FE-4 led the launch of Savanna RVP4 in Europe and drafted a Savanna product overview and Savanna brochure, both of which were used to market Savanna in the Europe, Middle East, and Africa ("EMEA") region.

50. FE-5 worked at Quidel and then QuidelOrtho from May 2021 to December 2022 as a Territory Account Manager and from January 2023 to July 2023 as an Acute Account Manager. FE-5 was responsible for selling Quidel and, after the Merger, also Ortho products to hospital, doctor's offices, and reference lab accounts in the entire state of Michigan.

51. FE-6 was formerly employed as a Cost Accounting Manager at Quidel and then QuidelOrtho from 2010 until his departure in April 2024. From 2019 until March 2022, FE-6 reported to FE-10, and from March 2022 until April 2024, FE-6 reported to Melissa Holder, Plant Controller in San Diego, who reported to FE-10 until FE-10's departure in Fall 2023. During the Class Period, FE-6 worked with Operations on the cost accounting for the Savanna RVP4 test.

52. FE-7 was formerly employed at Quidel and then QuidelOrtho from March 2021 until May 2024. He worked as the Marketing Manager, Molecular Dx (EMEA) for the Company's infectious disease testing products for the territory of Europe, the Middle East, and Africa (EMEA). He was responsible for products that tested for respiratory viruses, including COVID, other coronaviruses, SARS, and the flu, including specifically Savanna RVP4, Sofia, Lyra, and Solana. FE-7 also worked on preparing marketing materials and the product brochure for Savanna RVP4's European sales.

53. FE-8 was employed by Quidel and then QuidelOrtho as a member of the Quality Assurance team from October 2020 until July 2024, where he worked out of the Company's San Diego, California office. During his tenure, he was responsible for coordinating Corrective and Preventive Actions (CAPA) and most recently reported to current director of Quality Operations, Samantha Ahern.

54. FE-9, who is based in Germany, was employed by Quidel and then QuidelOrtho from October 2017 through June 2024 as Vice President, Sales and Marketing, Europe. He was

responsible for sales and marketing efforts for the Company's products in Germany, Austria, Switzerland, the Benelux region, Italy, and the United Kingdom. He reported directly to and met at least once per quarter with the former Senior Vice President of International Commercial Operations, during which time they discussed Savanna's European business.

55. FE-10 was employed by Quidel and then QuidelOrtho from Fall 2020 until Fall 2023 as a Finance Director based in San Diego, California. During his tenure, FE-10 reported to vice presidents of finance, who in turn reported to Defendant Busky. FE-10 was one reporting level away from Busky from May 2022 through Fall 2023.

56. FE-11 joined Quidel in 2017 as a Territory Account Manager, and then served as a Manager, Field Sales Training East Coast from April 2022 until February 2023. After the Merger, FE-11 worked as a Channel Sales Manager at QuidelOrtho from February 2023 until July 2024. In that role, he managed two sales teams and worked with the Company's distributors in the Mid-Atlantic and Northeast regions.

57. FE-12 was formerly employed by QuidelOrtho as a Senior Scientist from January 2023 until June 2024. He worked exclusively on the Savanna platform and reported to Veronica Casas, who currently serves as Manager, Product Transfer, at the Company. Casas reported to Joern Mosner, currently Vice President, R&D at the Company. FE-12's team was responsible for creating manuals and specs for quality control, manufacturing, and raw materials for the Savanna RVP4 chemical assays, test cartridges, and software. His team also worked on transferring chemical assays from R&D (which developed the assays on a small scale) to larger, bulk, manufacturing scale.

58. FE-13 was formerly employed by Quidel and then QuidelOrtho as a Cost Accountant in San Diego from February 2022 until March 2023. His responsibilities included

analyzing work order variances from the Company's Triage and Savanna products and assisting in month-end close. He also worked on reconciling excess and obsolete materials costs at the main corporate warehouse, as well as analyzing scrap costs. Additionally, FE-13 worked on forecasting for the Triage and Savanna products and collaborated with members of the Finance team in those efforts.

59. FE-14 was an Engineer with Quidel, and then QuidelOrtho, from before the Class Period to the second half of 2023, with the title of Associate Director during the Class Period.

60. FE-15 was employed at Quidel and then QuidelOrtho from September 2015 until June 2023. FE-15 served as a Territory Manager from March 2019 to June 2023. As a Territory Manager, he was responsible for selling QuidelOrtho's respiratory products to acute (hospitals) and non-acute (doctor's offices and urgent care facilities) customers located in California and Nevada. He reported to current Regional Sales Director Lisa Yeager. He also attended weekly, quarterly, and monthly sales calls in which the Company's C-Suite participated.

61. FE-16 was an Account Manager who sold, among other things, QuidelOrtho tests for COVID, flu, and RSV to customers located in Northeast United States from late 2022 through September 2023.

62. FE-17 was formerly employed with Quidel Corporation as an Account Executive and later became responsible for growing QuidelOrtho's business through its sales to distributors of all of the Company's respiratory testing products, including Lyra, Sofia, and Solana, until his departure in early 2024.

63. FE-18 worked as a Senior Global Product Manager, Immunoassay in Vitro Diagnostic Tests during his employment with Quidel and then QuidelOrtho, a tenure which lasted from May 2021 until May 2024. Part of his responsibility involved reviewing the declining COVID

test sales data “every few weeks” in the Company’s finance/sales database. He also reported to current Director of Global Product Management Sean Redmond.

64. FE-19 worked as an Account Manager Inside Sales and Associate Program Director at QuidelOrtho from January 2023 until April 2024. During his tenure, he oversaw the Company’s Inside Sales Team and worked on its Inside Sales strategy. His team worked with national commercial accounts and reported to former Vice President of Sales John Meckles. FE-19 attended meetings with Meckles, along with Vice President, Customer Operations North America Charles Bellinghausen, and former Senior Vice President, North America Sales Sandra Savage.

65. FE-20 was formerly employed by Quidel and QuidelOrtho from January 2015 through May 2024 at the Company’s San Diego, California headquarters. In his last role as Senior Sales Performance and Compensation Analyst, a position which he held from September 2019 until May 2024, he was responsible for calculating sales incentive compensation for the Company’s 400 U.S.-based salespeople. In his role as Senior Sales Performance and Compensation Analyst, FE-20 reported to Associate Director Commercial FP&A Daniel Nash, who prior to the Merger reported to current Executive Vice President and Chief Operating Officer Defendant Bujarski. Following the Merger, Nash reported to Charles Bellinghausen, who in turn reported to current CFO Defendant Busky.

66. FE-21 was formerly employed with Ortho Clinical Diagnostics for several years until early 2022. After Ortho’s acquisition by Quidel, FE-21 served in a global director role from January 2022 to April 2024. In that role, FE-21 was responsible for creating and implementing sales training programs for the global sales team. In his final role at QuidelOrtho, FE-21 was two reporting levels below the C-suite.

IV. SUBSTANTIVE ALLEGATIONS OF FRAUD

A. Background on Quidel's Pre-COVID Business

67. Quidel was founded in San Diego, California, in 1979. Quidel introduced its first product, commercial dipstick pregnancy tests, in 1983. Quidel expanded substantially through acquisitions of other products, technologies, and companies to become a leader in the development, manufacturing, and marketing of rapid diagnostic testing solutions.

68. Prior to its Merger with Ortho, Quidel developed, manufactured, and marketed four product categories of diagnostic testing solutions globally: (1) rapid immunoassay (such as its Sofia platform, the Company's prevalent rapid immunoassay product used to detect the presence of certain bacteria or hormones that indicate various infectious respiratory and other illnesses or conditions); (2) cardiometabolic immunoassay (such as its Triage system, used to detect the presence of various markers for heart disease and the presence of various drugs using blood, plasma or urine samples); (3) molecular diagnostic solutions (such as its Lyra and Solana testing platforms, which are capable of testing for multiple diseases and pathogens in a single test); and (4) specialized diagnostic solutions (*i.e.*, specimen collection devices and biomarkers to detect viruses, autoimmune diseases, and effectiveness of osteoporosis therapies). Quidel sold its diagnostic testing solutions directly to end users and distributors for professional use in physician offices, hospitals, clinical laboratories, reference laboratories, urgent care clinics, universities, retail clinics, pharmacies, and wellness screening centers.

69. Quidel reported total revenues of \$534.9 million in 2019, with influenza testing revenues generating roughly 25% of that total. While influenza and other respiratory testing revenues were not a majority of the Company's sales, the higher margins on those tests contributed a disproportionately larger proportion of the Company's operating income. Historically, Quidel did not provide annual revenue guidance to the market, with a Piper Sandler analyst noting in a

February 12, 2020 analyst report that it was “custom” for Quidel to refrain from providing such information on an annual basis, and William Blair writing in a February 13, 2020 analyst report that, “[c]onsistent with historical practice, management did not provide specific guidance for the year.” As discussed further below, the Company reversed its historical aversion to providing guidance during the Class Period, following the Merger.

B. The COVID-19 Pandemic Drives Massive Revenue Growth at Quidel

70. In January 2020, the World Health Organization’s International Health Regulation Emergency Committee declared the COVID-19 outbreak a Public Health Emergency. Quidel became one of the first companies to develop PCR, rapid antigen, and “HDA” tests for COVID-19. On March 17, 2020, Quidel received “Emergency Use Authorization” (“EUA”) from the FDA for its Lyra SARS-CoV-2 Assay, which became a leading molecular test for COVID-19. On May 8, 2020, Quidel was first to market in the U.S. with a rapid antigen test that delivers results within 15 minutes with the Company’s Sofia SARS Antigen FIA. On December 21, 2020, Quidel received EUA from the FDA for its QuickVue SARS Antigen Test. On December 23, 2020, Quidel received EUA from the FDA for its Solana SARS Molecular Test for COVID-19. On March 1, 2021, Quidel received EUA from the FDA for its QuickVue At-Home COVID-19 Test.

71. By successfully pivoting its business to focus on the emergent needs brought on by the COVID-19 pandemic, Quidel’s revenues skyrocketed, selling billions of dollars of tests to U.S. government agencies, healthcare providers, and large retail pharmacy chains in 2020 and 2021.

72. While Quidel sold its COVID testing products to end users and distributors, it also worked closely with the U.S. Department of Health and Human Services (“HHS”) and the Department of Defense (“DoD”) to provide tests to Federally Qualified Health Centers, government agencies, and American households, which also provided large injections of revenue during 2020 and 2021.

73. For example, on September 23, 2020, Quidel entered into a \$62 million contract with the HHS for the National Institute of Health (“NIH”) that had a total award value of \$92.6 million in connection with the launch of the Rapid Acceleration of Diagnostics (“RADs”) initiative to increase testing capacity in the U.S. On February 10, 2021 and September 7, 2021, Quidel received supplemental orders worth \$5.5 million and \$18 million, respectively, in connection with efforts to scale-up rapid point of care (“POC”) antigen COVID-19 tests. On September 17, 2021, the DoD awarded Quidel a \$284.2 million contract for the sale of 25.6 million over-the-counter COVID-19 test kits—representing the largest government contract awarded for the sale of COVID test kits. On December 7, 2022 and September 20, 2023, the Company entered into \$97.5 million and \$28.6 million contracts with the HHS, respectively, for over the counter (“OTC”) COVID-19 tests that, as explained further *infra*, helped bolster waning sales and COVID-related revenue in 2023.

74. Quidel recorded \$1.163 billion dollars in COVID-related revenue in 2020, out of total reported revenue of \$1.661 billion (more than three times the Company’s total 2019 revenues). The Company’s explosive COVID-related revenue continued to increase throughout 2021 and 2022 to \$1.274 billion (out of \$1.698 billion in total revenue) and \$1.437 billion (out of \$3.266 billion in total revenue, which included Ortho product revenue), respectively. As such, COVID-related revenue provided an outsized contribution to the Company’s total revenues, accounting for 70% and 75% of the Company’s 2020 and 2021 pre-Merger total revenues, and 44% of the Company’s post-Merger total revenues in 2022. In those same years, influenza product sales constituted 8% (\$132.9 million), 4% (\$67.9 million), and 11% (\$359 million), respectively.

C. At the End of 2021, Quidel and Ortho Announce Their Merger, Touting \$100 Million In Revenue Synergies Driven by the Company’s Savanna Platform

75. On December 23, 2021, Quidel announced that it had signed a definitive agreement to acquire Ortho, a leader in the in-vitro diagnostic (IVD) business (the “Merger Announcement”). The Merger was approved by Quidel and Ortho stockholders on May 16, 2022, and on May 27, 2022, the Company announced that the Merger was completed, with shares of QuidelOrtho common stock trading on the Nasdaq Global Select Market at the open of business under the Quidel symbol “QDEL.”

76. Prior to the Merger, Ortho was one of the largest global IVD companies, with \$2 billion in annual revenue (compared to Quidel’s \$500 million in annual revenue pre-COVID-19), a significant global presence, and deeply rooted relationships with clinical laboratories. Ortho operated primarily in the clinical chemistry, immunoassay, and transfusion medicine spaces on a global basis (47% outside North America). Ortho maintained a strong commercial footprint in more than 130 countries and territories and with more than 2,300 employees.

77. Quidel’s COVID-19 windfall revenues made its acquisition of Ortho possible. As starkly noted by Kalorama Information (“Kalorama”), a leading publisher of market research in the healthcare area, on December 27, 2021 “[a] prediction that Quidel would buy Ortho a few years ago would have been greeted with incredulity, but COVID-19 has changed a lot of things.” Kalorama also noted that: “Quidel brings innovation and distribution in near-patient channels, Ortho Clinical brings in large clinical laboratories internationally, and a reputation for service.” FE-4 recalled how Ortho had wanted to get into the molecular business and that Goldman Sachs planned to help Ortho acquire Quidel. However, FE-4 explained that in 2021, Defendant Bryant told Ortho that Quidel could instead acquire Ortho because it received an influx of cash from COVID-19, and that the two companies could still realize the same business and revenue

synergies. According to the terms of the Merger, upon the completion of the Merger, Quidel stockholders would own approximately 62% of the combined company and Ortho shareholders would own approximately 38% of the combined company.

78. Quidel underscored that Ortho's broad global reach across 130-plus countries provided an opportunity to expand Quidel's existing product portfolio and provide exposure to new, emerging markets. Notably, Quidel stated that the acquisition would "increase financial flexibility with combined cost synergies of \$90 million by end of year three, and revenue synergies in excess of \$100 million by 2025." Over 75% of those \$100 million in revenue synergies were attributed to Quidel's Savanna platform, which had recently launched in Europe with its flagship RVP4 test, after over a decade of development and delayed launches.

79. By way of background, the Savanna platform was first announced to investors in 2011. Savanna was Quidel's new molecular diagnostic product that was marketed as a low-cost, fully integrated "sample-to-answer" system. According to the Company, Savanna would perform multiplex real-time Polymerase Chain Reaction ("PCR") tests by using the Savanna analyzer device and Savanna test assay cartridges.² Traditionally, PCR testing required heightened costs, specialized staffing and prolonged turnaround times. The innovation surrounding Savanna advertised that Savanna would provide rapid results on a number of infections in less than 30 minutes and allow for optimized point of care testing with no sample preparation required.

80. Savanna's assay functionality was intended to be scalable to a variety of infections. The first, and most important, Savanna assay cartridge introduced for use with the analyzer was

² An assay is a laboratory test or procedure used to analyze and measure the presence, quantity, or activity of a specific substance or biological component in a sample. For ease of reference, "assay" and "test" are used interchangeably herein and, with respect to Savanna, unless otherwise noted, refer to both the chemistry component and physical testing cartridge used in the Savanna device.

the Savanna Respiratory Viral Panel-4 (“RVP4”), which was marketed as having the capability to detect RNA sequences associated with influenza A and B, COVID-19, and respiratory syncytial virus (RSV) from a single nasal or nasopharyngeal sample. The Company advertised that the RVP4 cartridge was a self-contained, single-use assay that did not require any sample preparation prior to insertion into the Savanna analyzer.

81. As a molecular panel that could test for multiple respiratory illnesses at once, the Savanna RVP4 panel was expected to outperform the existing crowded test market, in which numerous competitors, and the Company itself, introduced antigen tests that could only test for one respiratory illness at a time. That market included Quidel’s Sofia analyzer, which required customers to purchase a separate Sofia test for each respiratory illness that the customer wished to test for. However, Quidel was not the only company pushing innovative testing products like Savanna RVP4, which created a race to launch the product and establish a “first to market” foothold within the market.

82. Before the Class Period and in the leadup to the Merger, Defendant Bryant hailed Savanna as *“the most important product introduction in our history.”* Bryant repeated this accolade shortly after the Merger was announced. While speaking at J.P. Morgan’s Annual Healthcare Conference on January 12, 2022, Bryant was asked why the Merger with Ortho was announced at year end. Bryant explained the timing as being related to the Savanna launch in Europe, stating that the Company was “launching probably *the most important product in [the Company’s history with Savanna]* and probably don’t have the commercial wherewithal to do it as well as they [Ortho] could.” Bryant also emphasized at the conference that: “We’re going after about *\$100 million in revenue synergies. And most of that to be upfront is due to the Savanna launch.*”

83. After being paraded as the Company’s “most important” new product for close to a decade, Quidel finally launched Savanna and its RVP4 test in late 2021, but only in certain European countries after obtaining a Conformité Européenne (“CE”) Mark on July 12, 2021. In 2021, a CE Mark reflected a manufacturer’s self-certifying declaration that its product complied with the EU’s requirements for sale. Having a CE Mark allowed Quidel to market and sell the Savanna system in certain European and other countries that accept the CE Mark. Under the then-current directive on in-vitro diagnostic medical devices (IVDD), Quidel was able to issue a self-certifying declaration of conformity in accordance with Annex III of IVDD without extensive clinical data or intervention from a notified body. This declaration self-certified that, among other things, the Company’s device met essential IVDD requirements regarding design, manufacturing, performance, labeling, and instructions for use.³ Securing a CE Mark was not a heavy lift, and involved none of the extensive clinical data, testing, or requirements necessary to secure FDA approval for sale in the United States.

84. Defendants launched Savanna in three European countries shortly after the July 2021 CE Mark was secured. In connection with the Merger and its promised synergies related to Savanna, Defendants represented by the end of 2021 that the European launch of Savanna RVP4 was already a success. For example, Defendant Bryant reported on December 23, 2021, in

³ The IVDD regulations governing CE marking have since been amended and superseded by the EU’s In Vitro Diagnostic Medical Device Regulation (IVDR), which increased the role of notifying bodies assessing medical devices and significantly increased the requirements for obtaining a CE mark, including detailed clinical evidence to support the safety, performance, and scientific validity of their devices. Certifications granted under the former and less stringent IVDD regulations, like those granting the Savanna RVP4 CE Mark, are valid for a limited period of time. Accordingly, the Company must lodge a formal application with an appropriate notified body for an IVDR Conformity Assessment by May 2026. This will initiate a review by a notified body in accordance with the newer IVDR regulations. If Savanna RVP4 is not approved under the new IVDD regulations, it will no longer be sold in Europe.

connection with the Merger announcement, that Savanna RVP4 in Europe was already a “*very successful launch*,” with “*super happy customers with a great product and a great offering*.”

85. Right away, analysts emphasized the importance of the Savanna launch to the Merger synergies and success. For example, analysts at William Blair wrote in an analyst report on January 7, 2022: “Savanna update was generally positive with the product having launched in the EU. Management noted a handful of initial customers and that performance appears to be good.” William Blair analysts also pointed out that Savanna was the key driver of the \$100 million in revenue synergies that were expected to result from the Merger, stating: “[W]e believe nearly 75% of revenue synergies are expected to come from Savanna.” On January 11, 2022, J.P. Morgan issued an Ortho report providing “takeaways” following a J.P. Morgan Healthcare Conference presentation by Defendants Bryant, Busky, and Ortho CEO Chris Smith, noting that: “Management highlighted that a key driver for the deal was the imminent launch of Savanna given the OCDX portfolio would not roll out a new product for three years (dry-dry).” The analyst continued, noting that: “Savanna would give the combined company a product with substantial potential that is ready for market now.”

86. Analysts largely came out in favor of the Merger, which was ultimately seen as a positive opportunity for both companies. For example, William Blair issued a report on December 23, 2021 explaining the “meaningful pros to consider[,]” including “revenue synergies (estimated to be about \$100 million by 2025, highlighted by benefits to the commercial launch of Quidel’s Savanna molecular platform)[.]”

87. On April 11, 2022, both Quidel and Ortho filed the Merger proxy statement with the SEC, which solicited their respective shareholders’ approval for the Merger (the “April 11, 2022 Proxy Statement”). Ultimately, Quidel and Ortho obtained approval from 57% and 82% of

their shareholders for the Merger, respectively. The April 11, 2022 Proxy Statement touted the cost and revenue synergies that the combined entity would generate, including approximately \$100 million in revenue synergies by fiscal year 2025, of which 75% was attributable to Savanna, as a result of the Company's expanded commercial team and opportunities identified for markets outside of the United States.

88. As demonstrated by Defendants' statements leading up to and after the Merger, Savanna was critical to the combined Company's future financial success. Moreover, because other potential revenue-driving new products were still in premature R&D stages, Savanna was intended to prop up the newly formed entity and maintain the Company's profits, as COVID testing demand began its decline to endemic levels. For this reason, analysts and investors were eager to learn more about the feedback Quidel received from the limited Savanna RVP4 launch in Europe on the basis that the reaction of customers to the Savanna RVP4 would provide objective insight into the panel's potential for FDA approval, as well as provide valuable information regarding its ability to secure market share and enjoy healthy profit margins.

89. In addition to Savanna, Defendants touted at the time of the Merger and early in the Class Period other potential growth—driving products that were still in their R&D stages—primarily Quidel's Project Leapfrog, a “next-generation” immunoassay analyzer, and Ortho's Project “Bam Bam” (a.k.a. Dry Dry), an immunoassay program using a new dry slide technology. Defendant Bryant spoke of these two projects on June 8, 2022, stating that the Company had: “Leapfrog, which is the next-generation immunoassay analyzer that dramatically improves both sensitivity and precision at the low end, which is particularly important with quantitative assays at Ortho, [and] an immunoassay program that they all call [Bam Bam] underway now, a big review

middle of July, where we're going to go through the details there and see where we're at." But neither of those products were close to launch, like the Company promised Savanna to be.

D. Throughout the Class Period, Defendants Report Positive RVP4 Performance and Feedback While Assuring Investors That RVP4 Was Ready for Its US Launch and Imminent FDA Approval

90. Throughout the Class Period, Defendants provided a consistent refrain of praise for Savanna RVP4's European launch, the positive performance of the RVP4 test in clinical trials, and the status of its FDA 510(k) application process, reiterating the Company's promise of generating over \$75 million in revenue synergies by 2025, as well as \$300 million in total annual revenues from Savanna sales.

91. For example, during the Company's fourth quarter 2021 earnings conference call on February 17, 2022, after the markets closed, Defendant Bryant told investors that "[t]he Savanna platform will be our next flagship product, and we are incredibly proud of the progress made to date." In a Form 8-K issued the same day, Defendant Bryant touted Savanna RVP4 and its anticipated U.S. launch as the Company's "key near-term opportunity[.]" On February 17, 2022 call, Bryant touted the progress that the Company had with Savanna as "*we prepare for its U.S. launch later this year*" and reported that they "*have received very positive customer feedback to date*" from European customers. Bryant also touted that the Company was going to generate \$300 million in revenue from Savanna within three years of the U.S. launch, stating that: "*Once launched in the U.S., we're targeting revenues of over \$300 million per year within 3 years. Much of that will be determined by our ability to manufacture instruments and fully automate cartridge manufacturing lines. But if we've demonstrated anything during this pandemic, is that we can scale rapidly, which bodes well for a flawless successful launch.*"

92. Analysts were encouraged by Defendants' uniformly positive statements concerning the European launch and the clear pathway to FDA approval. On February 18, 2022,

William Blair analysts “remain[ed] positive” on the Merger and reported that “management reiterated expectations for Savanna to reach revenues of over \$300 million per year within three years as part of its modeling in the S-4.” Craig-Hallum analysts wrote on February 18, 2022 that Quidel provided “[u]pdates on the core business centered around the highly anticipated Savanna launch.” In response to the February 17, 2022 news, Quidel’s stock price rose 10% on February 18, 2022, closing at \$97.84 per share from a February 17, 2022 close of \$88.44 per share, and continued to rise an additional 5.4% on the next trading day to close at \$103.09 per share.

93. Defendant Bryant continued to extol the positive feedback QuidelOrtho obtained from RVP4’s European launch during a March 9, 2022 Raymond James Annual Investors Conference, asserting confidently that Savanna is “*performing very nicely in Europe right now. We’re hearing really nice feedback. I think it’s the right design for the market at this time.*” Following the March 9, 2022 statements, which were delivered during trading hours, Quidel’s stock price increased by 3% after opening at \$99.13 per share on March 9, 2022, and closing at \$102.06 per share on the same day. Analysts were once again encouraged by Defendants’ positive statements and demonstrated their interest in customer feedback from the Savanna launch. For example, on April 8, 2022, a Craig-Hallum analyst report stated that: “We will be listening for commentary around Savannah [sic] launch and the Ortho Clinical Diagnostics (OCDX) acquisition which should further transform the base business. . . .”

94. During the Company’s Q1 2022 Earnings Call on May 4, 2022, shortly before the Ortho and Quidel shareholders voted to approve the Merger, Defendant Bryant discussed Savanna RVP4’s readiness for FDA approval and a full-scale U.S. launch, stating that: “*the only constraint with the launch, honestly, being our ability to get enough instruments into the market as quickly as possible as well as our ability to manufacture cartridges at very, very high volumes.*” Bryant

also assured investors that the Company’s “automated manufacturing line” would be up and running by Fall 2022 in order to “***ramp-up and outfit to over 1 million cartridges per month with \$300 million annual revenues and anticipated within 3 years of U.S. launch.***”

95. Analysts were reassured by Defendants’ statements, which confidently asserted that that the Company was ready to submit RVP4 for FDA approval and was poised to be able to ramp-up its manufacturing in time to both meet customer demand and achieve advantageous profit margins sufficient to achieve the aggressive target of \$300 million in annual revenues within three years of the U.S. launch.

96. For example, on May 5, 2022, Craig-Hallum issued a report that commented on Defendants’ statements, stating: “Savanna is set to launch later this year” and QuidelOrtho is “hard at work automating manufacturing for Savanna at scale.” Further, the report stated: “Management is applying its learnings in hyper-scaling from the COVID business and applying it to Savanna; once development is complete the manufacturing line should be able to produce 1M cartridges per month. QDEL also reiterated \$300M in annual sales from Savanna in three years. . . .”

97. A few months later, after the Merger closed, on September 13, 2022, Defendant Ranalli, the Senior Vice President, Molecular Diagnostics and Point of Care, participated in a *Repertoire* Podcast titled, “QuidelOrtho provides easier, faster test results with new molecular platform.” During this podcast, Defendant Ranalli confirmed that QuidelOrtho launched in Europe “around Christmas of last year” and touted that the Company had received “***great feedback from our initial customers.***”

98. Analysts once again championed Defendants’ statements regarding the positive feedback QuidelOrtho received from the Savanna European Launch. For example, Citi issued a report on September 28, 2022, titled “Takeaways From Meetings with Management,” which stated

that: “Management has noted early success in Europe, recently beating out key competitors on a 35-unit tender and having orders in place for their full manufacturing capacity for the foreseeable future. In Europe, the salesforce has targeted customers currently on competitor products for Savanna conversion, citing the cost and time savings associated with the mid-flex solution.”

99. A little over one month later, on November 2, 2022, Defendant Bryant continued to tout QuidelOrtho’s ability to ramp up production of Savanna instruments and RVP4 cartridges in advance of the anticipated U.S. launch, including through “*two automated high-volume lines are expected to be up and running by mid-2023, ahead of our US commercial launch.*” Analysts took note of Defendants’ statements and QuidelOrtho’s preparations for a U.S. launch. For example, Craig-Hallum issued a report on November 3, 2022 stating that: “Supply constraints for Savanna are largely fixed and the company is working to expand production capacity to prepare for the 2023 respiratory season.”

100. In 2023, Defendants adjusted investor expectations on the timing of the Savanna U.S. launch, shifting the launch out to later in 2023. For example, during the Raymond James Annual Institutional Investors Conference on March 7, 2023, Defendant Bryant told investors that: “*We expect EUA [for Savanna RVP4] either in April or worst case early May.*” Three months later, during the William Blair Growth Stock Conference on June 6, 2023, Defendant Busky stated: “*we do expect to get regulatory clearance in the US on the Savanna product and start placing those boxes as we move into the fourth quarter of this year. . . . But we have said that we expect three years post-launch that will be greater than \$250 million of revenue on that Savanna product.*”

101. On August 8, 2023, in its second quarter 2023 earnings release, QuidelOrtho announced that it had completed submissions to the FDA for both EUA and 510(k) clearance⁴ for Savanna and RVP4. Analysts followed for updates regularly. On December 18, 2023, Craig-Hallum's analyst wrote, "Savanna Is (Almost) Here: Approval for Savanna is nearing," explaining that "it does appear we are in the very late stages of FDA interaction. Several weeks ago, the company stated it should receive FDA approval of Savanna plus at least one test cartridge by the end of 2023." While the FDA did approve the Savanna device for sale at the end of December 2023, RVP4's FDA EUA and 510(k) submissions were still pending.

102. By the end of 2023, Defendants kept investors on their toes by pushing the FDA approval target out to Q1 2024. Specifically, during the Q4 2024 Earnings Call on February 13, 2024, Defendant Busky informed investors that QuidelOrtho anticipated FDA approval for Savanna RVP4 by the end of Q1 2024 and that the panel would contribute between \$30-\$50 million in respiratory revenue in 2024. Busky continued, stating that: *"Our guidance also assumes a 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."*

103. Despite moving the goalposts for FDA approval for Savanna RVP4, analysts continued to rely on Defendants' statements with the expectation that QuidelOrtho would soon be

⁴ Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. To be eligible for 510(k) clearance, a medical device must meet specific criteria, and a successful submission involves conducting comprehensive testing and validation studies, and compiling a thorough submission package that meets FDA requirements. As part of a 510(k) submission for IVDs, like Savanna, the FDA "regularly requests clinical samples with sufficient laboratory and/or clinical characterization to allow an assessment of the clinical validity of a new device. This is usually expressed in terms of clinical sensitivity and clinical specificity or agreement." See <https://www.fda.gov/medical-devices/ivd-regulatory-assistance/overview-ivd-regulation#7>.

able to recognize a substantial amount of revenue from its new flagship product. For example, a J.P. Morgan analyst report dated February 14, 2024, states that QuidelOrtho management “still expects approval [for Savanna RVP4] by the end of 1Q24” and “reiterated its prior LT product guide of >\$250M in annual revenue by year-3 post-launch[.]”

104. As late as March 5, 2024, Defendant Iskra informed investors that Savanna RVP4 is “our focus right now” and “*We’re pretty much coming out of the opportunities to be in place for that by the end of the year.*” During the same call, Defendants Iskra and Bujarski reaffirmed that QuidelOrtho anticipated receiving FDA clearance for Savanna RVP4 in 2024 and that the Company’s goal to achieve approximately \$250 million in Savanna-related revenue by 2026 was still intact. For example, Defendant Iskra stated that “*whether it’s \$250 million, \$275 million or \$245 million, it’s a big number, it’s a big opportunity, and we still believe in it.*” Similarly, Bujarski stated that “when you’re thinking about 2024, you’re thinking about our focus” in obtaining FDA approval for the RVP4 panel along with a CLIA Waiver, “more so than a revenue number[.]”

E. As the COVID-19 Pandemic Wanes, Defendants More Than Double the Company’s “Endemic” COVID-19 Revenue Numbers

105. While Defendants pushed their false narrative about Savanna’s success in Europe, ability to satisfy FDA’s clearance requirements, and readiness for a U.S. launch with automated production lines that could soon generate \$300 million in annual revenues, they also decided to boldly inflate endemic COVID revenues to pump up the Company’s stock price following a poorly received “Investor Day” conference that caused a 17% stock price crash.

106. By mid-2022, Defendants informed investors that QuidelOrtho expected COVID-19 to reach an “endemic” stage by 2023. In a pandemic, a disease, once localized in scope, starts to appear in other countries and continents, typically infecting a large number of people in a short

amount of time, often with significant economic and social ramifications due to its global impact. When that disease wanes, it can become endemic, where the disease persists at a consistent level within a region with fairly predictable rates of infection and spread, making it easier to prevent future outbreaks.⁵ As communicated by Defendants, an endemic disease state allowed the Company to more accurately assess the impact of COVID-related revenues on the Company's financial guidance relied on by investors.

107. As explained *supra*, in Section IV.B, the Company reported historic revenues as it was able to capitalize on the explosive demand for pandemic-stage COVID-19 testing products between 2020 and 2021. At its peak, over one million tests were administered daily in the United States. By the first quarter of 2022, QuidelOrtho began reporting "softening demand" for COVID-19 tests and told investors that the Company's "longer-term expectation is that COVID-19 tests and infections and related testing demand will continue to wane as COVID-19 becomes more seasonal, similar to flu demand."

108. In mid-2022, in connection with the endemic status of COVID-19, Defendants chose to put out guidance in which they told investors that QuidelOrtho anticipated between \$150-\$200 million annually in endemic COVID-related revenue moving forward. For example, during the Company's Q2 2022 Conference Call on August 4, 2022, Defendants Busky and Bryant were asked about "where we should be thinking about the numbers and where the different businesses can go." Defendant Busky responded that: "we believe that the COVID revenue, once it gets into an endemic stage, as we move into the next year, will be in that \$150 million to \$200 million range annually for the COVID revenue."

⁵ See, e.g., <https://www.merriam-webster.com/dictionary/endemic>.

109. This information was important to investors because it provided valuable insight as to how the Company's COVID testing products would contribute to total revenues. For example, William Blair issued a report on April 23, 2021, stating that: "the value COVID-19 brings to Quidel or any of the companies in this space should not be determined on one quarter or another, or even on 2021 revenue. Rather, the value coming from this opportunity is much more heavily skewed toward what the tail for testing looks like and the cash flows that it brings for many years to come."

110. Defendants repeated the August 2022 endemic figures over the following months. During a September 12, 2022 Morgan Stanley Global Healthcare Conference, Defendants were asked about "the growth algorithm underlying" the Company's "base business growth profile." Defendant Busky responded that: "if you think about the combined company business in an endemic state world, so *that's where again we've said COVID revenues in an endemic state will be \$150 million to \$200 million.*" Then, during QuidelOrtho's Q3 2022 Conference Call on November 2, 2022, Defendant Busky once again reaffirmed that QuidelOrtho's endemic COVID-related revenues were between \$150-\$200 million, with Defendant Bryant clarifying that that figure excluded any government contracts that had previously pumped up the Company's COVID-19 revenues.

111. These statements were not lost on analysts and investors, who worried about QuidelOrtho's ability to maintain profits as its high-margin COVID-19 revenues were set to shrink and then plateau. For example, Citi issued a report on September 19, 2022 that underscored investors' increased focus on the Company's margins as COVID-19 began its transition to an endemic state, stating that: "as COVID-related revenue comes out of the model there will be increased focus on base business margins and earnings."

112. At the end of 2022, however, Defendants made a dramatic upward shift in QuidelOrtho's endemic COVID-19 revenues, doubling the revenue figure out of whole cloth in response to a dramatic stock drop following the Company's December 13, 2022 Investor Day.

113. On December 13, 2022, during trading hours, the Company hosted its inaugural Investor Day following the May 2022 Merger. Presentations made by the executive team and business unit leaders, including Defendants Bryant, Busky, Ranalli, Bujarski, and Iskra, focused on the Company's strategy, key growth initiatives, integration, innovation, and long-term financial outlook. During the Investor Day presentation, Defendants provided updates to, among other things, the Company's long-term guidance, reporting, as reflected in a December 14, 2022 William Blair analyst report, that: "the updated topline growth algorithm for the upcoming 3 years [was] lowered to 6-9%, from 9-11%."

114. Investors reacted swiftly and negatively to the Company's lackluster updated guidance. QuidelOrtho stock dropped **over 17%** by market close, closing at \$82.08 per share, down from a close of \$97.50 per share on December 12, 2022. *Bloomberg* reported that QuidelOrtho shares fell the most intraday since November 2020.

115. Defendants embarked on a series of management calls and meetings with analysts to reverse the damage caused by the lowered guidance and growth targets. Eager to turn things around, Defendant Busky, after previously reaffirming endemic COVID-19 revenues of \$150 million to \$200 million for months, dramatically doubled those numbers in a series of reactionary calls with analysts following the failed Investor Day.

116. On December 20, 2022, William Blair issued a lengthy analyst report following several virtual meetings with Defendant Busky and QuidelOrtho's VP of Investor Relations, Bryan Brokmeier. William Blair wrote that: "[m]anagement provided some thoughts on endemic

COVID-19 testing levels, *noting that its prior estimate for between \$150 million and \$200 million of endemic COVID-19 testing revenue was likely conservative and that something between \$200 million and \$400 million is more realistic.*” This unexpected upward revision made just days after reaffirming prior guidance, doubled the Company’s endemic COVID-related revenue calculation (up 71% based on a comparison of midpoints for the ranges provided). On this news, QuidelOrtho’s stock rose nearly 5%, closing at \$85.65 per share on December 21, 2022.

117. Defendant Busky reiterated and even increased this new guidance on February 15, 2023, during QuidelOrtho’s Q4 2022 earnings conference call held shortly after the market closed. In response to an analyst question about “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 . . . what you just said about some of the seasonality in flu and respiratory in general,” Defendant Bryant responded that “\$300 million to \$500 million” was the range, and Busky stated that: “*We were saying 200 to 400 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.” Busky later reiterated that, unlike the \$200-\$400 million range for endemic COVID-related revenue, the \$300-\$500 million range was intended to include government orders, stating that “endemic level of annual revenue” is “up another \$100 million in 2023 guide because of those government orders. . . .” Analysts echoed this guidance in reports issued on February 15, 2023 and February 16, 2023. On this news and analyst coverage, QuidelOrtho’s stock rose 5.2%, closing at \$90.68 per share on heavy trading volume on February 16, 2023.

118. Defendants continued to tout the Company’s enlarged endemic COVID-19 revenue. During a March 7, 2023 Raymond James Annual Institutional Investors Conference, Defendant Bryant explained how the \$200-\$400 million range was based on a “top down”

approach “looking at historical data and the professional segment” and a “bottoms up approach” based on “marketers” that is “almost [] an account by account analysis.” Later, during the same conference, an analyst asked Bryant about the Company’s EBITDA expectations for 2024 and 2025 as COVID-related demand would begin shrink to endemic levels. In response, Bryant told investors that the Company’s outlook was improving, stating that: “*your comment about 2024 should be better than 2023 and 2025 better than 2024 I think is a reasonable expectation.*”

119. Analysts and investors championed Defendants’ statements. For example, on March 13, 2023, William Blair issued a report on QuidelOrtho that reiterated its Outperform rating, stating that “guidance was largely better than feared” and “we believe there remains enough room in expectations for the company to set itself up for an acceleration in growth and margins exiting the year and into 2024.”

120. Throughout the remainder of 2023, Defendants continued to advertise the Company’s expectation of \$200-\$400 million in endemic COVID-related revenues. For example, during QuidelOrtho’s Q1 2023 Conference Call on May 3, 2023, Defendant Bryant reaffirmed the Company’s endemic COVID-related revenue range and confirmed that the range was applicable to the “next few years,” stating that: “*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.*” Bryant added that QuidelOrtho was “*still very comfortable*” with this range “*moving forward[.]*”

121. Analysts and investors were encouraged by these results and Defendants’ reaffirmation that endemic COVID-related revenue would contribute up to \$400 million to respiratory revenue annually. For example, Craig-Hallum issued a report on May 4, 2023, stating that: “Management is leaving their COVID guidance unchanged, pointing to conservative

guidance at least in respiratory.” Similarly, J.P. Morgan issued a report on May 4, 2023, stating that: “Today the company reiterated its respiratory revenue guidance of \$610-875M including COVID revenue of \$300-\$500M. . . . On COVID, the company noted that after the outsized revenue in 1Q, QDEL elected to maintain the guide that ‘de-risks’ the backhalf of the year ramp in respiratory (company ended its government shipments in April, pulling forward some of that expected revenue to 1Q).”

122. During the Morgan Stanley Global Healthcare Conference on September 12, 2023, Defendant Bryant similarly stated that “*we should expect, therefore, moving forward, 2024 and beyond, to see \$200 million to \$400 million in COVID-specific – or COVID-only sales.*” In response, QuidelOrtho’s stock price increased by 3.5% after Defendants’ statements were made right before the close of trading hours on September 12, 2023. Specifically, QuidelOrtho’s stock price opened at \$74.08 per share on September 12, 2023, and closed at \$76.37 per share on September 13, 2023.

123. Analysts and investors continued to find Defendants’ statements regarding COVID-19-related revenue encouraging. For example, William Blair issued a report on October 12, 2023, that commented on management’s “intraquarter bullish tone,” stating that: “Upside here comes as little surprise given management’s intraquarter bullish tone on respiratory (COVID) testing demand from retail and point-of-care settings[.]” This report also made note of “Areas we are most focused on” that included “updated drivers of guidance[.]”

124. Towards the end of 2023, Defendants provided further insight into QuidelOrtho’s expectations for fiscal year 2024 COVID-related revenue. Specifically, during the Evercore ISI HealthCONx Conference Call on November 30, 2023, Defendant Bryant touted that the Company’s COVID-related revenue for 2024 “*will be higher than the midpoint*” of the endemic

range (*i.e.*, >\$300 million), stating that: ***“I would say, our \$200 million to \$400 million, we still think is the right number. I think, for 2024, we probably will be higher than the midpoint for COVID still.”***

125. Analysts and investors once again extolled Defendants’ statements regarding QuidelOrtho’s endemic COVID-related revenue expectations. For example, Craig-Hallum issued a report on December 18, 2023 that commented on the forementioned statements from management, stating that: “The team reiterated its guidance of \$200-400M respiratory revenue and anticipation of high gross margins (70%+) coming from these products. . . . For 2024, management thinks this endemic \$200-400M respiratory range is appropriate.”

126. About a month before QuidelOrtho reported Q4 and fiscal year 2023 earnings results, Defendant Bryant participated in the J.P. Morgan Healthcare Conference on January 8, 2024. During this conference, Bryant was asked why QuidelOrtho did not pre-announce earnings, such as “trends exiting the year from either revenue or margins. . . .” In response, Bryant stated that: ***“we historically have preannounced when we have something that’s materially different than you think. . . . So, we didn’t actually see a need to do that and we’ll have plenty to talk about at the earnings call here in a few weeks.”*** Later, during the conference, the same analyst asked Defendant Bryant whether the \$200-\$400 million endemic COVID-related revenue guide was still applicable to 2024. In response, Bryant once again reaffirmed this guidance.

127. Analysts and investors credited Defendants’ statements regarding endemic COVID-related revenue and the affirmation that there was “no need” to announce anything “materially different” with respect to previously provided guidance. For example, William Blair issued a report on January 13, 2024, stating that: “The lack of prerelease surprised investors. . . . We do not see this as negative. Mgmt. was clear: if nothing materially different from range, no

need to prerelease. ‘23 guidance (rev and profits) appear intact. . . . Respiratory Season . . . QDEL sees this as being a ‘normal’ respiratory season and taking sig. share.”

F. Unknown to Investors, Defendants’ Statements About Savanna RVP4’s Performance, Development and Readiness for the U.S. Market Were Knowingly False and Misleading

1. Defendants Faced Significant Pressure To Launch Savanna RVP4, While Ignoring “Fundamental Flaws” in the Product’s Design

128. The Savanna device and its flagship RVP4 test had been in development since 2011. After a decade of touting the growth potential from Savanna, Quidel’s senior management, including Defendants Bryant and Steward, were anxious to get Savanna and its first test panel—the RVP4—to market as soon as possible. As noted above, Savanna’s launch became even more crucial as merger talks between Quidel and Ortho commenced in Spring 2021 because the bulk of the Merger’s \$100 million revenue synergies were attributable to Savanna-generated revenue by 2025.

129. A key factor in Savanna’s success in the United States was the Company’s ability to be first to market with Savanna’s new molecular diagnostic technology. This was critical because installing Savanna instruments at customer sites and obtaining FDA approval for panels that test for high-volume respiratory illnesses, before competitors with similar products would allow the Company to establish a stronghold on market share for a multi-billion-dollar total addressable market (“TAM”). FE-1, QuidelOrtho’s Senior Director, Regulatory Affairs from January 2020 to April 2024, explained that Savanna promised to provide to the market a new technology that could generate test results in approximately 30 minutes but with the same high level of accuracy as PCR (Polymerase Chain Reaction) tests, which were much more accurate than existing instant-style test kits but could take a few days for results.

130. FE-1 explained that several competitors were developing products using similar technology as Savanna and, as a result, the Company was heavily motivated to be the first to market with this new test using new technology.

a. Savanna’s Executive Steering Committee, Led by Defendants Steward and Bujarski, and Overseen By Defendant Bryant, Ignored “Fundamental Flaws” in RVP4’s Design

131. The pressure to get the RVP4 to market, however, conflicted with clear warning signs that the test was not ready, and would never be ready, without fundamental corrections to its design and engineering—corrections that Defendants were not willing to invest in or address.

132. The development of Savanna and its RVP4 and other test cartridges faced early, existential setbacks. FE-14 was an Engineer with Quidel, and then QuidelOrtho, until the second half of 2023. FE-14 described how he had intimate knowledge of why Savanna RVP4 was not launched in the United States. According to FE-14, who had worked on the Savanna RVP4 project, there were “fundamental flaws” in the manufacturing of the Savanna RVP4 assay cassette, which prevented it from providing accurate results when he worked on the project before the start of the Class Period.

133. FE-14 stated that he was aware that the design flaws of the Savanna RVP4 test were highlighted to Senior Vice President, Research and Development Werner Kroll as early as 2019. Specifically, FE-14 explained how manufacturing challenges with regard to the Savanna RVP4 were identified early on in the process, and that the Company was not able to manufacture the Savanna RVP4 design requirements. FE-14 stated that the Company decided to “push through” the manufacturing challenges and “chose to ignore” them.

134. According to FE-14, this engineering team attempted to put Savanna RVP4 design reviews forward and work across the Company to come up with design solutions, which was a normal pathway forward at a medical device company. However, FE-14 stated that this team was

dismantled and attempts to put Savanna RVP4 design reviews forward ended at that time. FE-14 recalled that in 2020, Kroll, Defendant Steward, and Defendant Bujarski determined in a meeting to “dismantle” the large team working on the Savanna RVP4 and transfer the project to a small “insular” team, composed of current Director, Systems Engineering Matthew Morovich, current Director Engineering Bruce Jacono, and current Vice President Global Molecular R&D Johannes Kehle, that would handle RVP4 going forward. FE-14 described how the initial, larger Savanna RVP4 team wanted to hold design reviews and solve and address problems with the Savanna RVP4. However, FE-14 stated that the smaller insular Savanna RVP4 team did not provide any cross-functional information within the Company. FE-14 explained that Kroll pulled the project from the large team to “push it” to production.

135. FE-14 noted that Kroll’s goal, as well as the goal of Defendants Steward and Bujarski, was to get this project “over the goal line” and not to manufacture a “quality product.” FE-14 elaborated by describing how he learned from conversations with people in the engineering department who had knowledge of the RVP4 project that Quidel’s Executive Steering Committee for the Savanna project, which consisted of Kroll, Defendant Steward and Defendant Bujarski, all “championed” cutting corners on the RVP4 project throughout FE-14’s tenure through the second half of 2023. Specifically, FE-14 detailed that the Company skipped quality steps like reliability testing (which is supposed to ensure that the product was reliable and met specifications) because there were flaws with the Savanna RVP4 instrumentation, explaining that the RVP4 instrument and cartridge would break and fail and therefore the Company could not run a reliability test.

136. FE-14 opined that the Executive Steering Committee pushed the Savanna RVP4 project through even though they knew it was flawed because they were under pressure to release the product, and because they wanted to get paid their bonuses, noting his understanding that Kroll,

Defendant Steward, and Defendant Bujarski had large incentives in their employment contracts that were tied to Savanna RVP4 advances. According to FE-14, former CEO, Defendant Bryant, oversaw Quidel’s Executive Steering Committee for the Savanna project.

b. QuidelOrtho’s Primary Sofia Platform Faced End of Life Concerns, Increasing Pressure For A Savanna Launch

137. As Kroll, Defendant Steward, and Defendant Bujarski, overseen by Defendant Bryant, cut corners and pushed Savanna forward without addressing the serious manufacturability deficiencies in its design, other events besides the desire to get the product out first to market placed pressure on Defendants to launch RVP4. By the start of the Class Period, it was clear that not only was the revenue spike created by the COVID-19 pandemic not sustainable, but QuidelOrtho’s leading point of care Sofia platform faced critical “end of life” concerns while also losing market share to newer products that promised not only superior accuracy, but also were more attractive to distributors and end users because those tests were eligible for much more generous Medicare reimbursement, which provided much greater profit margins for point of care, pharmacy, and hospital customers.⁶

138. QuidelOrtho’s dominant point of care immunoassay—the Sofia 1 and Sofia 2 analyzers—faced end-of-life threats early on in the Class Period. Quidel launched Sofia after receiving FDA approval for the point of care analyzer in 2011. In 2017, the Company launched Sofia 2 after receiving FDA approval and a CLIA waiver⁷ for the Sofia influenza A+B and RSV

⁶ In the manufacturing context, the term “end of life” is generally understood to mean when the device will no longer be manufactured and supported. *See, e.g.*, <https://casusconsulting.com/eu-shelf-expiration-expected-lifetime-useful-service-life/#4-end-of-life->.

⁷ “CLIA” is the acronym for the Clinical Laboratory Improvement Amendments of 1988. This law requires any facility performing examinations of human specimens (*e.g.*, tissue, blood, urine, etc.) for diagnosis, prevention, or treatment purposes to be certified by the Secretary of the

Footnote continued on next page

immunoassays to be used on the Sofia 2 analyzer, which was marketed as providing improvements to the graphical user interface and optics system to provide an accurate, automated, and objective result in as few as three minutes. On May 8, 2020, Quidel received FDA approval for the Sofia 2 SARS Antigen assay. By the start of the Class Period, both Sofia 1 and Sofia 2 were being sold throughout the U.S. and in Europe, Latin America, and part of Asia in a more limited fashion. FE-1 described how both the Sofia 1 and Sofia 2 platforms were used for point of care testing, largely in physicians' offices, and that the Sofia 1 analyzer was more expensive than Sofia 2, but that its testing capabilities were more "robust," meaning that there were fewer complaints and problems with Sofia 1 because it was physically more durable than Sofia 2 and therefore had fewer issues. The Sofia analyzers tested not only for COVID, flu, RSV and strep, but also sold non-respiratory tests, including ones that detected Lyme Disease and early pregnancy detection.

139. Sales of Sofia analyzers and their related tests (including COVID-19 tests) contributed approximately \$1 billion of revenues in 2020, dominating the Company's total revenues of \$1.6 billion. However, according to the accounts of several former employees, by no later than mid-2023, the Sofia platform faced critical "end-of-life" concerns that posed a threat to its continued revenue contributions.

140. According to FE-1, in Summer 2023, the Company learned that Sofia 1 was becoming obsolete, reaching its production "end of life," and that QuidelOrtho would no longer be able to manufacture new Sofia 1 analyzers after another 12 to 15 months. Specifically, FE-1 explained that Sofia 1 assembly was subcontracted to a company based in Germany, known as an

Department of Health and Human Services. By the CLIA law, waived tests are those tests that are determined by CDC or FDA to be so simple that there is little risk of error, and CLIA-waived tests have a larger market as they can be used at point of care, non-laboratory medical providers and pharmacies.

“OEM” (Original Equipment Manufacturer) (the exact name of which he could not recall), that assembled key components like chips and boards for the Sofia 1. FE-1 described how the OEM informed QuidelOrtho that the components it assembled were coming up on their end-of-life, meaning that those components – chips and boards – would no longer be available, and that the OEM would stop assembling the components because it could no longer purchase the parts it needed. FE-1 described how, by sometime in 2024, Sofia 1 had already run out of necessary parts could no longer be sold.

141. FE-1 also noted that the Sofia 2 faced its own end-of-life risks that would materialize in 2025 or 2026, because certain chips and components used in Sofia 2 were also facing their manufacturing end, and QuidelOrtho could no longer purchase them from its supplier. FE-1 explained that the Sofia end-of-life scenarios “popped up” as Savanna was being developed, creating the pressure to develop products to replace Sofia. However, other than Savanna, FE-1 was not aware of any candidates within the R&D group, such that Savanna’s failure would be a “deal breaker.”

142. Multiple other former employees corroborate FE-1’s description of end-of-life concerns for Sofia 1 and 2, and the additional pressure that placed on the Company to launch Savanna.

143. For example, FE-4, a former senior level marketing employee until his departure in Fall 2023, stated QuidelOrtho’s contract with its Sofia battery supplier, a company named Planet Innovation, had expired, which caused QuidelOrtho to investigate the viability of sourcing components from the resale market for Sofia 2, which CW-4 described as “ridiculous” and “alarming” because Sofia 2 was a “crucial” component of the company’s business. FE-4 explained there were major supply chain concerns regarding manufacturing for the Sofia devices.

144. FE-4 worked on marketing materials for QuidelOrtho's QuickVue and Sofia products during his last year at the Company from late 2022 through October 2023, and confirmed FE-1's account of Sofia's near-term end-of-life risks. FE-4 recalled that there were "major concerns" about the Sofia platform's longevity. FE-4 confirmed that current Director, Global Product Management Sean Redmond, former Senior Vice President POCT Business Unit Bill Ferenczy and current Vice President, Strategy and Portfolio Management Rhys de Callier, each of whom were "close" to Defendant Bryant, were aware of the "major concerns" about Sofia. Further, FE-4 participated in end-of-life plan calls for Sofia 1, which he described as a "pure nightmare." By the time FE-4 left the Company in Fall 2023, QuidelOrtho had stopped manufacturing Sofia 1.

145. FE-2 indicated that it was "absolutely correct" that there were end-of-life concerns for both Sofia 1 and Sofia 2. He explained that Sofia 2 was supposed to replace Sofia 1, but the Company kept both, and both were facing end-of-life issues with their components. He noted that Sofia 1's issue was worse, because its electronics were very dated and out of compliance. FE-2 advised that Sofia 1 had stopped production before he left the Company in late 2023, which was only maintaining assays for the existing units.

146. FE-2 also confirmed that Sofia 2's production had slowed due to end-of-life concerns. FE-2 described Sofia 2 as having "forward looking" end-of-life issues. He explained that Sofia 2 was in jeopardy because it was facing the end-of-life for its components, noting that what was in the field was "OK" but explaining that the Company will not be able to make more Sofia 2 analyzers soon as the Company had purchased all the components for the Sofia 2. This means that there is a "drop dead" date in the future when the Company would no longer be able to make Sofia 2. According to FE-2, these end-of-life concerns for Sofia 1 and 2 added to the pressure regarding launching Savanna.

**c. The Sofia Platform Was Losing Market Share To Competitors,
Which Also Increased The Pressure To Launch Savanna**

147. The Sofia analyzers' sales potential also suffered because customers were choosing more modern technology over what the Sofia platform could offer. *See infra*, Section IV.G. For example, FE-3, a former QuidelOrtho salesman and business developer responsible for prospecting new business and growing existing accounts explained that, by the time of the Merger, he received feedback from some of his current and prospective QuidelOrtho customers that the Company's analyzers—including specifically the Sofia analyzers—"did not hold up" and therefore customers purchased tests from competitors because they had more state-of-the-art products. FE-3 added that the Sofia rapid test was Quidel's most popular COVID test but that some customers told him that it was "outdated." FE-3 noted that he would save customer feedback in Salesforce, a cloud-based platform that stores and tracks customer opportunities and sales data.

148. Further, there was less demand for the Sofia analyzer and other immunoassay tests because competitors' molecular tests had substantially higher reimbursement rates. Data from the U.S. Centers for Medicare & Medicaid Services ("CMS") and Medicare Administrative Contractor ("MAC") COVID-19 Test Pricing confirms that molecular tests received higher reimbursement rates compared to immunoassay tests, when testing for COVID, Influenza A&B, and RSV. For example, MAC COVID-19 Test Pricing from 2021 provides that the CMS reimbursement for an immunoassay combo test (*i.e.*, COVID + Influenza A&B) was between \$63.59-\$73.49 depending on the U.S. state or region, whereas the CMS reimbursement for a molecular test like Savanna RVP4 was \$142.63—*i.e.*, reimbursement for molecular tests was more than double the

reimbursement received for immunoassay tests.⁸ Updated reimbursement data for New York in 2024 further confirms that reimbursement rates for molecular tests were more than double the reimbursement provided for immunoassay tests.⁹

149. FE-5, a former Territory Account Manager from and then Acute Account Manager employed by Quidel and then QuidelOrtho from May 2021 through July 2023, responsible for sales in the state of Michigan, confirmed the large difference in Medicare and Medicaid reimbursement levels. FE-5 explained that QuidelOrtho's Sofia tests were antigen tests, whereas the tests sold by polymerase chain reaction (PCR) were molecular tests. FE-5 explained that Sofia lost out to the molecular PCR tests simply because the Medicare and Medicaid reimbursements for PCR tests were "drastically" higher than antigen tests. According to FE-5, Medicare and Medicaid reimbursement amounts are published annually with products listed as CPT codes by test and state. FE-5 detailed that a QuidelOrtho competitor sells a PCR test for Visby Medical for \$62.60 and that in Michigan, the Medicaid reimbursement for this PCR test is \$142.63 and the Medicare reimbursement for this PCR test is \$110.80. FE-5 recalled that the Sofia antigen tests, in comparison, sold for between \$23 and \$33 and were reimbursed in Michigan for between \$30 and \$60. Therefore, FE-5 noted that customers made a higher profit margin by selling PCR tests instead of the Sofia antigen tests.

⁸ The relevant Current Procedural Terminology ("CPT") codes are: 87428 for the immunoassay test (COVID + Flu A&B) and 87637 for the molecular test (COVID + Flu A&B + RSV).

⁹ Using the same CPT codes referenced *supra*, 2024 reimbursement data for NY shows that the reimbursement for a molecular test was \$147.38 and the reimbursement for an immunoassay test was \$72.63.

d. The Company's Two Other "Big Hitters"—Projects Bam Bam and Leapfrog—Were Scrapped, Further Increasing Pressure to Launch Savanna

150. During the Class Period, Defendants Bryant, Steward and Busky emphasized how critical Savanna's success was to the combined Company. After the Merger closed, Defendants continued to drive home that Savanna, along with two other development projects, were the key to QuidelOrtho's continued success. The two other projects were Ortho's Project "Bam Bam" (a.k.a. Dry Dry) and Quidel's Project Leapfrog. For example, during QuidelOrtho's second quarter earnings conference call on August 4, 2022, Defendant Bryant touted Savanna, Projects Leapfrog, and Bam Bam as "big hitters," stating:

And so, we've got a project internally that we've been calling BAM BAM, and that's progressing. That's probably a third, I think, of that R&D budget on that project alone.

Savanna, clearly, spending what's necessary to make the transfer from R&D into manufacturing at scale, there's a big lift and a big effort as well. But don't forget also we've got Project Leapfrog running in the background too, which is our next generation immunoassay platform. So there's three or four big hitters.

151. However, as discussed below, both Project Bam Bam and Project Leapfrog were ultimately scrapped in 2023, leaving Savanna as the sole near-term instrument development hope.

152. Former QuidelOrtho employees describe the impact of Project Bam Bam's failure on the newly combined Company. FE-2, the former Senior Director of Systems Engineering from February 2020 to September 2023, oversaw all the engineering for new instrument development and sustaining QuidelOrtho's devices and instruments out of the Company's San Diego headquarters. FE-2 described how Quidel bought Ortho because Ortho had a great marketing presence globally, which Quidel lacked. He added that Ortho sold huge, high-volume instruments, such as blood banks for hospitals, among other products, while Quidel sold much smaller instruments. According to FE-2, Ortho had one instrument (project name "Bam Bam") in

development at the time of the merger. FE-2 stated that Bam Bam was a “whole new technology,” presented a new direction and was the “first new thing in 20 years” for Ortho.

153. According to FE-2, Bam Bam was intended to change the optical model used to read assays. He elaborated that Ortho originated from the film company Kodak and had modified a film plant into an assay manufacturing plant. Bam Bam, FE-2 continued, was intended to create a new technology by using glass slides to read the assays.

154. FE-2 described how Quidel’s senior engineering team, led by Kroll, studied the Bam Bam project post-Merger and realized that the technology would not work, so QuidelOrtho shut the project down in 2023. As a result of Bam Bam’s demise, FE-2 recounted that a large number of legacy Ortho’s staff was working on Bam Bam, so when the project was shut down, a huge number of Ortho employees were laid off.

155. FE-2 explained the impact of Bam Bam’s termination on the pressure to push Savanna through to market. FE-2 explained that QuidelOrtho was focusing everything on Savanna after Bam Bam was cancelled; Savanna was “very, very important” to QuidelOrtho because it was all the Company had left from an instrument development perspective.

156. Defendant Bryant confirmed that Project Bam Bam had been shut down after an analyst asked for a status update for the project during the Evercore ISI HealthCONx Conference on November 30, 2023. In response, Defendant Bryant stated, “Are you referring to the program that used to be called dry-dry? Or internally, I think they called it bam-bam. So we’ve transitioned to a technology that we think is more appropriate and will be able to deliver faster.”

157. As for Project Leapfrog, the last time it was mentioned by the Company was a brief reference during a November 30, 2023 conference call. FE-2 confirmed that Project Leapfrog failed to deliver, and that project was also cancelled.

158. With Sofia facing serious end-of-life concerns, and the other key growth drivers either failing, like Project Bam Bam, or stalling and ultimately failing, like Project Leapfrog, Savanna, with its new, molecular diagnostics technology and speed, was a critical launch.

159. Savanna's critical importance to the combined Company's financial health and success was acknowledged and heavily anticipated by investors. On the same day the Merger was announced, William Blair released an analyst report evaluating the "meaningful pros" to be expected from the transaction. Among them were the \$100 million revenue synergies estimated by 2025, "highlighted by benefits to the commercial launch of Quidel's Savanna molecular platform." Similarly, Craig-Hallum released a report which described the ability to cross-sell Savanna as a "highly valuable opportunity" anticipated by the Merger. Finally, a few days after the Merger was announced, Raymond James released a report which noted the "particular opportunity for the Quidel products, especially the Savanna launch."

2. The European Launch of Savanna RVP4—Publicly Heralded as a Success—Was In Fact Overwhelmed With Customer Complaints and Product Failures That the Company Was Unable To Correct

160. On July 12, 2021, Quidel announced that it received a CE Mark for its Savanna® multiplex molecular analyzer and Savanna® RVP4 Assay (Respiratory Viral Panel-4). As noted in the Company press release, the CE Mark allowed Quidel to market and sell the Savanna system in certain European countries, as well as a small number of other countries that accept the CE Mark. In the press release, Defendant Bryant stated that: "Receipt of the CE Mark is an important step forward on our path to commercialize Savanna's powerful but simple-to-use molecular diagnostic technology." Bryant informed investors that the Company expected "to deploy our first batch of instruments to select international customers and the performance data generated will support our longer-term commercialization efforts as we build instrument inventory that we anticipate will be required for our planned broad-scale launch in the U.S."

161. Analysts and investors viewed this news as a positive sign. For example, Raymond James issued a report on July 12, 2021 that commented on Quidel's CE Mark announcement for the Savanna platform, stating that: "the first regulatory approval demonstrates technical hurdles being in the rearview for the much anticipated platform. While U.S. launch will likely be the gating factor to watch for more aggressive commercialization efforts, we view the CE Mark as a positive, albeit expected, sign."

162. While the CE Mark did allow Quidel to market the Savanna analyzer and RVP4 assay in Europe, the standards for bringing Savanna to market in Europe were far less stringent than the US. Indeed, as of July 2021, receipt of a CE Mark was "self-certifying," meaning that rather than meet any specific efficacy, safety or sensitivity standards, Quidel itself was the arbiter of whether Savanna and its RVP4 assay were ready to be sold.

163. FE-4 was a member of the team tasked with getting Savanna the July 2021 CE Mark, which allowed QuidelOrtho to market and sell the Savanna system in Europe. FE-4 explained that in 2021, the CE Mark process was significantly less stringent than achieving FDA 510(k) clearance because the CE marking procedure was self-certifying. FE-4 explained that the CE Mark process has since changed, and under new and more stringent In Vitro Diagnostic Regulation (IVDR) requirements, it is now more difficult for companies to receive the CE Mark than it was in 2021. FE-4 also explained that the new IVDR requirements are similar to FDA requirements, such that if Quidel could not get FDA approval for Savanna, IVDR approval in the EU was unlikely. FE-4 stated that after Savanna received the CE Mark, the Company believed that it would signal to the market that FDA clearance was "around the corner." FE-4 explained, however, that the clinical data for Savanna was "shoddy" which reflected that Savanna was not effective or ready for FDA clearance. FE-4 noted that QuidelOrtho did not have the required data

at the time of his departure (late 2023) to obtain the CE Mark for Savanna under the more stringent IVDR requirements.

164. FE-1 confirmed FE-4's account of how the CE Mark received by the Company in July 2021 was relatively easy to secure because the European regulations at the time allowed companies essentially to self-certify their products through the use of notified bodies, and it was therefore easier to obtain approval and launch new products in Europe than in the US. This is corroborated by a post issued by TÜV SÜD, a trusted global organization and notified body that certifies products and systems that demonstrate compliance with EU standards, which explains that "self-declared (i.e. with no notified body involvement)" devices under IVDD will now (after 2021) be subject to the more rigorous regulations under IVDR, including increased notified body involvement and more stringent requirements regarding technical documentation and clinical evidence.¹⁰

165. FE-6, a Cost Accounting Manager throughout the Class Period, advised that, at the end of 2021, QuidelOrtho was rushing to get the Savanna test to market in the EU. FE-6 described the process of bringing the Savanna to market as "flying a plane while building it." FE-4 further explained that there were concerns about the Savanna RVP4 test from the "beginning" of its European launch due to technical challenges, which FE-4 described as a "defining moment." Therefore, FE-4 recalled that "no one was confident" that it would work when QuidelOrtho launched the Savanna RVP4 test in Europe but that they did their best "to make it work."

166. FE-4 and FE-7 drafted the promotional marketing materials used for Savanna sales in Europe. FE-4 explained how QuidelOrtho published claims about the Savanna RVP4 test

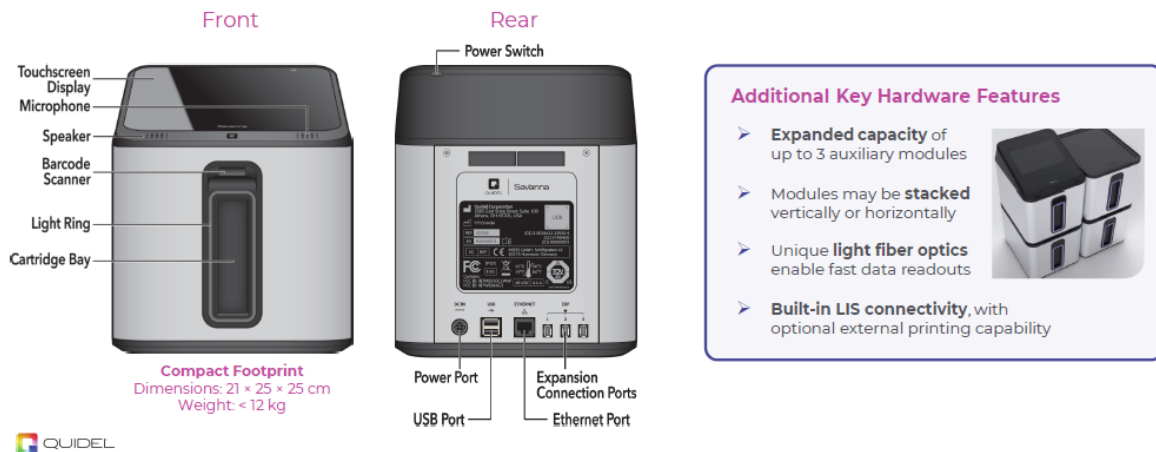
¹⁰ <https://www.tuvsud.com/en-us/industries/healthcare-and-medical-devices/medical-devices-and-ivd/medical-device-market-approval-and-certification/eu-in-vitro-diagnostic-medical-device-regulation>.

performance and capabilities in promotional materials that the Company did not actually test for. For example, in one promotional material titled “Welcome to Savanna®,” the Company indicated that among “Additional Key Hardware Features” was “Expanded capacity of up to 3 auxiliary models” that “may be stacked vertically or horizontally:”

The Savanna System Up Close

Savanna®

State-of-the-art instrumentation that **maximizes** operational efficiency



167. FE-4 stated that while this “expanded capacity” was something the Company hoped was possible in the future, there was no proof of concept regarding this “expanded capacity. FE-4 explained it simply did not exist at the time these materials were sent out or thereafter, but rather it was “just a wish or a dream.”

168. In that same “Welcome to Savanna®” promotional brochure, the Company noted that the RVP11 Respiratory Viral Panel that tested for 11 respiratory diseases was “Coming Soon” and that six other tests were “In Development:”

Other Multiplex Panels in Development

Savanna

Now Available

Respiratory Viral Panel-4 (RVP4)

- Influenza A
- Influenza B
- Respiratory Syncytial Virus
- SARS-CoV-2



QUIDEL

Coming Soon

Respiratory Viral Panel-11 (RVP11)

- Adenovirus
- Enterovirus
- Human Metapneumovirus
- Influenza A
- Influenza B
- Parainfluenza 1, 3
- Parainfluenza 2, 4
- Respiratory Syncytial Virus
- Rhinovirus
- Seasonal Coronavirus
- SARS-CoV-2

In Development

- Gastrointestinal Panel
- Gastrointestinal Parasite Panel
- Sexually Transmitted Infection Panel
- HSV / VZV / Syphilis Panel
- Vaginitis Panel
- Pharyngitis Panel



169. FE-4 stated that this was misleading because there was no evidence at the time that Savanna RVP11 was going to launch in the near future and that the Company knew this at the time the product overview was published. FE-4 noted that QuidelOrtho “barely” got four respiratory viral panels for the Savanna RVP4 and then asked rhetorically “how are they going to do 11 panels” for the Savanna RVP11. Moreover, the other tests listed as “in development” were “a pipe dream” and “nearly impossible.”

170. FE-4 recalled that QuidelOrtho sold only approximately 40 to 55 Savanna devices in Europe from the July 2021 launch through mid-2023, with around 30 devices sold to one purchaser in Italy, and the remaining handful in Austria and Germany. Those sales all occurred in late 2021 and the first quarter of 2022. FE-7 confirmed those numbers. FE-7 explained that the first customers for Savanna were a hospital in eastern Germany and a small hospital group in Austria, consisting of approximately five hospitals, and those sales occurred in approximately

December 2021. He added that in early to mid-2022, QuidelOrtho won a tender in Italy to supply 32 Savanna systems to 16 hospitals, for use in emergency rooms, labs, and maternity wards.

171. In their positions, FE-4 and FE-7 were kept updated on a weekly basis on all of the complaints and issues with Savanna RVP4 in the European market. FE-4 advised that out of all his United States-based co-workers, he had the “best pulse” on the Savanna RVP4 test’s performance in Europe because he worked directly with colleagues located in Italy and Germany and communicated with them weekly, specifically the current Scientific Marketing Manager Europe, Jürgen Becker.

172. FE-7 recalled that there were issues with Savanna from the beginning. FE-7 noted that in addition to multiple complaints about the Savanna device itself overheating, there were numerous problems with the RVP4 test cartridges, which were assembled in the United States on a manual assembly line, returning a high level of invalid test results.

173. FE-4 recalled that he personally became aware of technical challenges with the Savanna RVP4 test in Europe between June 2022 and November 2022, if not earlier. FE-4 described how approximately 25 percent of the Savanna RVP4 instruments sold in Europe had to be replaced, at cost, to QuidelOrtho because of “widespread failure” with the Savanna device and because the Savanna RVP4 test’s assay (which he described as a cartridge) was not working “from the very beginning.” FE-4 noted that there were times when the replacement tests also failed. FE-4 stated that Jürgen Becker, Scientific Marketing Manager, Europe, informed him that European Savanna RVP4 test customers were “irate.” FE-4 described the test’s one-in-four replacement rate in Europe as “depressing” for QuidelOrtho.

174. FE-4 recalled that approximately 25 percent of the RVP4’s test assays yielded an invalid result instead of a positive or negative result, which he described as “the worst result for a

clinician.” FE-7 corroborated this account. FE-7 described how the Savanna RVP4 assays produced a large number of “invalid” results. He explained that the test is supposed to return either a “positive” (indicating the presence of the virus) or “negative” (indicating the absence of the virus) result, at which point the doctor must assess the patient to determine treatment. An “invalid” result, he continued, meant that the test did not return either a positive or negative result, and that was a problem.

175. Additionally, according to FE-4, approximately 25 percent of the Savanna RVP4 tests’ instruments did not work in Europe. FE-4 explained that the test’s instrument overheated if it was on too long or if it ran assays for one to two hours, which caused its screen to freeze and not function. FE-4 noted that there were problems with the instrument’s spring ejection, which rendered the test useless because customers were unable to take the assay out of instrument after inserting it. FE-4 added that manufacturing of the test’s instrument was “not smooth.”

176. FE-7 advised that this problem forced the Company to replace the RVP4 test cartridges and Savanna instruments that returned invalid results for its customers, and that added costs. According to FE-7, the industry standard for generating invalid results is approximately 1–2%, but the invalid rate for Savanna was “definitely double digits,” between 10 and 30%. FE-7 noted that the costs of replacing the instruments and cartridges added up, as any test resulting in an invalid test result or instrument that overheated had to be replaced by QuidelOrtho free of charge. FE-7 explained that the 10% to 30% rate of replacement was a factor of ten higher than the industry standard rate.

177. European customer complaints stayed steady, and even increased, as the Class Period progressed. FE-8, a former member of the Quality Assurance team throughout the Class Period, recalled that QuidelOrtho received an “uptick” in complaints from European Savanna

RVP4 customers in approximately August 2023. FE-8 noted that these complaints were called in to technical support, who then escalated the complaints to product support. FE-8 recalled that the amount of Savanna RVP4 complaints QuidelOrtho received in August 2023 were “above trend.” FE-8 explained that QuidelOrtho previously received between 11 and 13 Savanna RVP4 complaints per month from European customers, but that the Company received more than 30 complaints in August 2023. FE-8 stated that QuidelOrtho subsequently tested the Savanna RVP4 parts that customers complained about and confirmed that there were indeed errors with the Savanna RVP4 test. FE-8 detailed that these customer complaints were all recorded in Salesforce.

178. FE-8 described that QuidelOrtho’s European customers complained that they were getting error codes from the Savanna RVP4 test. FE-8 explained that QuidelOrtho used a scorecard to grade customer complaints and that the Company assigned the following grades to complaints: “Green,” “Yellow,” and “Red.” According to FE-8, the August 2023 Savanna RVP4 complaints were graded “Red” and, following a field investigation that confirmed the RVP4 error codes, the issues raised were significant enough for QuidelOrtho to open a CAPA (Corrective and Preventative Action) investigation in Summer 2023. The CAPA investigation was formed to address these customer complaints, identify the root cause, and prevent it from happening again. FE-8 noted that current Vice President of Clinical, Regulatory & Quality Assurance Jenny Rial and current Director of Operations Chris Troxil were notified about this CAPA, and that Troxil reported to current Vice President, Operations Brad Smith. FE-8 added that the Research and Development team that developed the Savanna RVP4 test was also notified about this CAPA. FE-8 explained that information about this CAPA was shared internally in monthly or quarterly internal business unit reports to upper management. According to FE-8, QuidelOrtho was still investigating the root cause of these error codes at the time of his departure in July 2024.

179. FE-9, former Vice President, Sales and Marketing, Europe throughout the Class Period, confirmed that once QuidelOrtho began selling Savanna in Europe, customers reported problems included Savanna devices not working properly or giving valid results, with the RVP4 assays not working, or the controls not working. FE-9 further described how these problems were still being addressed when he left the Company in June 2024.

180. FE-7 indicated that the Company was working to fix the problems but commented that the RVP4 “test wasn’t stable enough to launch to market” in the United States as of the time he left in May 2024.

181. The steady, and even increasing, stream of customer complaints was communicated to senior management, including Individual Defendants. Indeed, as described below, QuidelOrtho senior management received reports of European customer complaints, which began as soon as the product launched in late 2021 and continued throughout the end of the Class Period.

182. FE-7 described how QuidelOrtho found itself “firefighting” in its efforts to respond to customer complaints. FE-7 noted that the Company was aware of the customer complaints and feared damage to its reputation due to the need constantly to fix problems or replace faulty RVP4 tests sold to customers. FE-7 noted that the Company had the capacity to supply the tests and to replace or repair malfunctioning units or cartridges, but the concern was for the Company’s reputation.

183. FE-7 explained that the Company had a formal complaint system for registering customer issues in the EU and that complaints logged in that system were sent to Defendant Tammi Ranalli, who reported directly to Bryant. FE-7 also explained that all complaints were sent formally to the Company’s office in Ireland, where Dara O’Connor, currently Sr Manager, Global Service - POC/MDx,5 prepared quarterly reports on the complaints and sent them to the

Company's headquarters in the United States. FE-7 stated complaints were also reported informally more often, possibly weekly, by email, and the marketing group, scientific marketing manager, and sales staff were in constant communication about Savanna's issues.

184. FE-7 explained that customers typically would complain to their sales reps regarding any issues; the sale reps would then submit the complaint paperwork to the head of Service in the EU, who then reported on complaint statistics for Europe. FE-7 explained there was no lack of visibility regarding Savanna's problems, and that every single issue with Savanna was reported to O'Connor. FE-9 confirmed that O'Connor was in "constant contact" with the U.S. headquarters, specifically Werner Kroll, regarding issues with Savanna. FE-9 recalled that Kroll relayed their discussions to Defendant Ranalli, and FE-9 believed that information was also relayed to Defendants Bryant and Bujarski.

185. Once Savanna launched in Europe in late 2021, FE-4 noted that current Director Global Product Management Jim Baldrice held calls at least monthly and that current Senior Vice President, Molecular Diagnostics Business Unit, Defendant Ranalli, attended these calls. FE-4 confirmed the accounts of others that Ranalli reported to Defendant Bryant. FE-4 stated that the focus of these calls was Savanna, and that both Baldrice and Defendant Ranalli knew that the Savanna device had "significant failures."

186. FE-4 detailed that during these calls held by Baldrice, Jürgen Becker disclosed to Ranalli that the Savanna RVP4 tests were failing in Europe and provided her with the negative customer feedback. FE-4 detailed that there were less than 10 people on these calls and that FE-7 and current Global Product Manager Amanda Zhang also attended these calls. FE-4 stated that 60% to 80% of European customer feedback on Savanna was negative.

187. FE-7 corroborated FE-4's accounts of the calls. According to FE-7, he participated in "many, many" meetings, occurring weekly, in which the problems with Savanna were frequently discussed. He explained that these were "Zoom-style" meetings with colleagues in the Company's San Diego and Athens, Ohio locations. FE-7 confirmed that these meetings were regularly attended by Tammy Ranalli, Jim Baldrice, and Amanda Zhang. FE-7 added that there were often representatives from R&D, Production Planning, and Logistics in attendance at these meetings.

188. As an example of the voluminous level of customer complaints, FE-7 recalled seeing one quarterly report in a PowerPoint presentation during a special call in 2023 with his then supervisor, Catherine Azzariti, currently the Head of EMEA Molecular Diagnostics Business Unit. In that single Power Point presentation, it was shown that there were 80 units and 85 complaints, which included problems with the instruments, the tests, or both. FE-7 explained that this presentation reflected that problems were not a one-time spike, but the product stayed at a high unsatisfactory level for months. FE-7 added that the problems with Savanna were so bad that every time a new instrument was sent to a customer, the Company sent them an additional, back-up instrument so that the customer would shift to the back-up instrument if problems arose. Although this saved QuidelOrtho's customers time and money, FE-7 stated, it increased the Company's inventory and production costs.

189. Former Cost Accounting Manager FE-6, who left the Company in April 2024, explained that it was his understanding as of April 2024 that the Company was going to halt production for Savanna RVP4 that month.

190. The European launch was not a success. Contrary to the Defendants constant refrain that they were receiving positive feedback from customers, and seeing increasing interest in

Savanna sales, they were faced with “irate” customers who lodged complaint after complaint, requiring replaced analyzers and tests. Perhaps summing it up the most concisely, FE-7 described how, in the 20 years he has been in this line of work, he “*didn’t remember any market launch that was so full of issues.*”

3. As Employees Compared Savanna to the Infamous Theranos Testing Device, Identified “Glaring Issues” and Bluntly Stated That “It Did Not Work,” Defendants Filed For FDA Clearance, Falsely Claiming Assured Success

191. As discussed above, Defendants already knew of the incredible number of customer complaints and failed Savanna devices and tests that permeated the limited European launch of RVP4. They affirmatively misrepresented the success of the European launch to investors, and continued to multiply their falsehoods by doggedly pushing Savanna through for FDA approval, all while knowing that the RVP4 did not satisfy the FDA’s sensitivity requirements and, as described further below, could not be effectively manufactured to scale in a way that could avoid the significant and well-above normal number of invalid and defective tests that came off of the Company’s slow manual production line and produce the tests at a price where the Company could ever see a profit on them. Throughout the Class Period, Defendants continued to tout Savanna RVP4’s readiness for FDA approval, while demonstrating their confidence by filing an EUA and 510(k) submission with the FDA for permission to launch in the U.S.

192. Unbeknownst to investors, Savanna RVP4 was not ready for FDA approval. In addition to the above first-hand accounts of the disastrous European launch, multiple other former employees explained how Savanna RVP4 production, testing and preparation for FDA submissions were riddled with “glaring issues” and the RVP4 test “never worked properly.”

193. For example, FE-2 stated that the engineering issues with the RVP4 test were not fixed when it went on sale in Europe in late 2021, were not fixed when it was sent to the FDA for

approval in the second quarter of 2023, and were not fixed when he left the Company in September 2023. Similarly, FE-10, Finance Director throughout the Class Period until Fall 2023, recalled that Savanna RVP4 had issues throughout his entire tenure.

194. FE-10 stated that he never thought Savanna would be in production and that every test ran for Savanna was “bad news.” FE-10 explained how, in early 2022, it became “a reality” for the Company that the manufacturing yields for RVP4 test were too low to receive FDA clearance. FE-10 added that longtime FP&A, Accounting and Operations Finance colleagues told him that QuidelOrtho had worked on the Savanna test for years and that their “consistent sentiment” was that they did not think the test “would ever work.”

195. Indeed, FE-10 detailed that prior to the Merger, employees at QuidelOrtho turned from optimistic about Savanna to perceiving that it was “not a real thing.” For example, FE-10 explained that during pre-Merger discussions about Ortho’s interest in a merger with Quidel because of Savanna, FE-10 and his colleagues remarked, “wait until they see that it doesn’t work.” FE-10 further explained that he heard in 2022 from a former Finance Manager and current Chief Operations Officer Phil McLellan that Savanna was failing tests, not doing what it was supposed to do and that QuidelOrtho was spending money on a product that was not going to work. FE-10 detailed that the former Finance Manager attended Savanna production meetings, as well as weekly meetings with Savanna manufacturing and met regularly with the then-Vice President of the Molecular Business unit, Defendant Ranalli.

196. FE-10 stated that he and his colleagues would joke that Savanna was a fraud and was QuidelOrtho’s version of Elizabeth Holmes and Theranos. Theranos, a company founded by Holmes, claimed to have developed devices to automate and miniaturize blood tests using microscopic blood volumes. The technology did not work as promised, but as reported in

Bloomberg, “Theranos and Holmes were going around giving interviews about how revolutionary their technology was, without ever mentioning that it didn’t work and they didn’t use it. This got them a lot of favorable press and a \$9 billion valuation, which went on for a while until the *Wall Street Journal*’s John Carreyrou reported in 2015 that the product didn’t work and that Theranos was lying about using it, after which Theranos fairly quickly collapsed.”

197. FE-11 confirmed FE-10’s accounts. According to FE-11, Quidel began training salespeople to pre-sell the Savanna RVP4 test in 2021 or 2022. However, FE-11 stated that it was “widely known” at that time that there were problems with the Savanna RVP4 tests and that Quidel was attempting to fix and resubmit the test to the FDA. FE-11 stated that the Savanna RVP4 test “never worked properly.”

198. FE-1, Senior Director, Regulatory Affairs during the Class Period, explained that the FDA submissions for Savanna RVP4 were under the purview of Michelle Bodien (also Senior Director, Regulatory Affairs) and Ron Lollar (Vice President, Clinical and Regulatory). FE-1 added that the regulatory work for the Savanna platform was based in Athens, Ohio, and that Lollar, who had the closest oversight of the product, reported to Kroll. FE-1 advised that Kroll, Lollar, and Bodien were the people at Quidel who made the decision to make the submission to the FDA in the second quarter of 2023, while it was likely that Defendant Bryant and other high level senior management were also involved given the importance of Savanna to the Company.

199. According to FE-1, the FDA laid out a test plan for the approval of Savanna, which required that the RVP4 needed to meet a certain functional level of approximately **95% or higher** for detectability and accuracy. In reality, however, FE-1 advised that Savanna could not meet that

level of accuracy either directly or through pooled samples.¹¹ FE-11 also explained that most tests have a sensitivity, or detectability, of 95% but that the Savanna RVP4 test “never came close” to the figure.

200. FE-1’s understanding was that the Company knew that it was not meeting the FDA’s requirements when it submitted its 510(k) application for clearance to sell Savanna RVP4 in the United States. FE-1 elaborated that some samples met the requirements, but some didn’t. According to FE-1, the FDA’s problem with Savanna was consistency: the test could not consistently meet the requisite targets set by the FDA.

201. FE-1 added that, at the time of filing its FDA submission, QuidelOrtho was under pressure from competitors that were developing competing products for Savanna, and QuidelOrtho was trying to be early to market with this technology. FE-1 also opined that the Company made the FDA submission in 2023 to boost the Company’s stock price.

202. FE-1 confirmed that that the Company—neither before nor during the FDA submission process—could get Savanna to work well enough to meet the FDA’s requirements for clearance. FE-1 added that that Savanna had many problems both with the product testing platform as well as with the RVP4 chemical assay test.

203. FE-1 advised that the Savanna test was rejected by the FDA because it was not able to meet the required detectability requirements consistently. He then explained how the Savanna test functioned to explain why it was not producing consistent results. According to FE-1, the test sample (meaning blood, saliva, or nasal swab which is being tested) is placed into a cassette, which is part of the test assay. Depending on the type of test, he added, the cassette is then heated, reacts

¹¹ FE-1 explained that pooled samples are samples from patients with known conditions but where there is no ability to trace the patients. Pooled samples are used only to test the products.

with chemicals, or both, to produce the test results. The problem with Savanna, he noted, was that the interactions between the assay and the platform or test device which read and analyzed the results was not producing consistent results.

204. FE-1 asserted that he had discussions with Bodien and Novis in late 2023, where it was discussed that QuidelOrtho management—specifically, according to FE-1’s understanding, Defendant Bryant, Defendant Bujarski, and Kroll—knew that Savanna RVP4 was not consistently meeting the FDA’s detectability requirements.

205. FE-1 elaborated that the Company would keep written documentation of the feedback and discussions with the FDA, including minutes of meetings with the FDA prior to submission, captured by someone in Regulatory Affairs. FE-1 confirmed that Lollar would have been involved in discussions and/or meetings with the FDA, and that he “wouldn’t be surprised” if Kroll was on the calls as well, as Kroll “had a way of getting into everything.” FE-1 also stated that he knew that Defendant Bryant was typically involved in discussions with the FDA regarding the Company’s COVID test related products, describing how Bryant had a practice of “open dialogue” with the FDA. In addition to the notes of FDA discussions kept at QuidelOrtho, FE-1 also explained that status updates in the form of notes and PowerPoint slides regarding the Savanna FDA application were reported regularly to the C-suite and the Board of Directors, at least monthly.

206. FE-4 also discussed the push for FDA clearance for U.S. sales. FE-4 noted that QuidelOrtho “pushed” for FDA clearance even though employees who worked directly or indirectly with the Savanna RVP4 test knew that the test had “glaring issues,” as detailed above. FE-4 recalled speaking in Summer 2023 with current Associate Director of Assay V&V, R&D

Shawna Prange (“Prange”), who commented to FE-4 that the Savanna *RVP4 test “does not work” and that it “isn’t even a product.”*

207. According to FE-4, Prange’s studies were critical for QuidelOrtho’s regulatory submissions. FE-4 noted that Prange reported to current Vice President, Clinical and Regulatory - Infectious Disease Ron Lollar (“Lollar”). FE-4 explained that Prange knew Savanna was not working and that the product could not achieve the required 95% confidence interval and “will never get it.” However, FE-4 recalled that Prange received “a lot of pressure” from a “top-down mandate” at the Company to approve Savanna “no matter the cost.”

208. FE-2 also learned from Prange, whose team was responsible for validating Savanna for FDA submission, that the normal validation process was to develop the chemistry, manufacture it, and put it in a cartridge. He continued that the validation team, led by Prange, then tests the chemistry to extremes for sensitivity under different conditions - such as 1 time, 5 times, and 10 times the normal conditions – to prove that the chemistry will work under varying conditions of viral loads and the test will detect the virus under a variety of conditions and extremes. His understanding was that the RVP4 test was not getting the needed sensitivity readings and not picking up enough results during validation prior to the test’s submission to the FDA.

209. Senior Scientist FE-12, who worked on Savanna throughout 2023 and the first half of 2024, confirmed Prange’s assessment, observing that the Company took so long to develop the test, but at the end, but it just did not work. FE-12 confirmed that there were problems with the Savanna tests regularly, namely that “across the board,” with different types of assays, there were high rates of invalid results and false positives. FE-12 confirmed that Savanna’s detectability issues continued throughout 2023 until the end of the Class Period.

210. FE-12 advised that, in addition to possible contamination issues, the Savanna test had problems on a molecular level. He explained that, for a PCR-type test to work, the test needs multiple components. He elaborated that one of the components is a “piece” of the virus’s genetic structure, either DNA or RNA. This genetic material, he continued, must be close to 100% to the virus tested to get a positive reaction. FE-12 indicated that, in the process of scaling up from pilot batches of assays of about 500 units to production scale, there were problems, and the test did not scale up properly; the rates of invalid or false positives were too high, even for use in-house.

211. FE-12 described the Company as taking “so many shortcuts,” which led to making mistakes, because it was rushing to get Savanna RVP4 to market. FE-12 explained that QuidelOrtho’s management kept “pushing aggressively” to generate data for all departments to release the assays as soon as possible as Savanna was supposed to be a “money maker” for the Company. FE-12 advised that he learned during weekly meetings with Cristina Ivy (“Ivy”), current Director of Research Development who managed the assay development team, of her efforts to push back against management on the production timeline. During these meetings, he continued, Ivy provided updates on the status of the research, the submission, and related background. According to FE-12, while Ivy provided that background, she also expressed criticism of the tight timeline imposed by management, and told the team that she had argued with management that it is better to go slow, test more rigorously, and get it right, then to rush, cut corners, and make mistakes, because doing so winds up costing more money to correct the mistakes.

212. FE-4 stated that as a scientist, he knew that Savanna would not get FDA clearance but that if it did, Savanna would eventually get recalled. FE-4 recalled that he met with a high-level senior executive who reported directly to Defendant Bryant in September 2023. FE-4 explained that he told this high-level senior executive in the meeting that he had his doubts about Savanna

and that Savanna would likely face the risk of a recall if it received FDA approval. FE-4 told a senior executive who reported directly to Bryant that “this thing doesn’t work...this ain’t ever gonna fly. And if it does...we’re gonna be facing the risk of a recall.” FE-2 echoed these sentiments. FE-2 explained that the Company’s plan was to fix issues as they went along, working in parallel with QuidelOrtho’s FDA application to prepare it for launch. This was a high-risk plan, according to FE-2, because the Company was manufacturing units that it would have to ultimately pull off the shelves.

213. FE-13, a Cost Accountant at QuidelOrtho in San Diego from February 2022 through March 2023 confirmed that that Savanna was not passing QuidelOrtho’s internal qualifications or testing in 2022 and early 2023. She added that the Company’s goal was to have Savanna “out the door,” meaning on the market, by the end of 2023, but the product was not passing QuidelOrtho’s internal tests. FE-13 explained that she learned of this goal and the product’s testing problems during daily “standups” for Triage and monthly leadership meetings. He advised that it was well known throughout the Company from the start of his employment that there were quality issues with Savanna.

214. Another Cost Account Manager echoed FE-13’s recollections about Savanna’s inability to pass internal testing. FE-6 indicated that he was aware that the Savanna product had huge problems with both the test instrument itself as well as its chemical assay. He described the problems as a “huge situation” and the unit cost had doubled for the instrument due to the quality control problems. FE-6 added that the problems with Savanna had “always” been there.

215. FE-6 explained that the yields for these consumable tests were approximately 30-40%; by “yield” he meant tests that could actually be used. He added that for a good ROI on production, the yields needed to be at least 70-80%, but Savanna was a “very low-yielding

product.” FE-6 confirmed that these problems, including the amount of scrap material generated and the poor yield rates, were recorded and reported every month to senior management. FE-6 elaborated that these problems were all documented in emails and in the Enterprise Resource Planning (“ERP”) system used by the company. FE-6 input all the information regarding cost accounting issues for Savanna into the JDE system; that information was summarized into reports, and those reports were then sent to management. He advised that these reports were then presented in month-end financial close meetings to upper management. He clarified that the people present in the month-end close meetings included Controller Missy Holder, the financial leader for the site at issue, and Global Operations Finance Senior Manager Richard Jenkins, who reported directly to Defendant Busky.

216. FE-13 corroborated other former employees’ accounts and confirmed that the issues with Savanna were communicated to the C-suite “all the time.” She noted that Savanna was supposed to be the Company’s next big “money-maker,” and “everyone” knew about its problems.

217. FE-2 explained in greater detail that everything done with developing the Savanna product, including every test of its performance, was documented. He noted that any change to the engineering or assay was required to be documented in a design review. He added that standard practice was for the engineers and scientists to report findings to their managers, who in turn presented the findings to senior management in Power Point presentations. Senior management included Kroll and Ranalli, who then reported information up to Defendants Bujarski and Bryant.

218. According to FE-2, the practice at QuidelOrtho was for the engineers and scientists to report findings to their managers, who in turn presented the findings to senior management in Power Point presentations. FE-2 explained that by senior management, he was specifically referring to Kroll and Defendant Bujarski, and that information was also forwarded on to

Defendants Bryant and Ranalli. He added that it was his understanding that this information was also reported to Defendant Iskra.

219. FE-2 further explained that all findings were reviewed by Kroll, who FE-2 met with weekly before and during the Class Period until his September 2023 departure. Kroll in turn decided how to move forward with projects. FE-2 stated that Kroll met with the Board and senior management quarterly to provide project updates on Savanna, and it was FE-2's understanding that senior management, including specifically Defendant Bryant, was made aware of Savanna's issues with its failure rate and assay problems at the time it was submitted to the FDA in mid-2023 and thereafter.

220. QuidelOrtho account managers explained how the years-long delayed Savanna launch hurt the Company's reputation and ability to sell Savanna to customers in the future. For example, FE-5, who worked at Quidel and then QuidelOrtho from May 2021 to December 2022 as a Territory Account Manager and then as an Acute Account Manager from January 2023 to July 2023 and who was responsible for selling Quidel and Ortho products in the entire state of Michigan, recalled that he was instructed to and did pre-sell "a ton" of Savanna RVP4 to customers in 2022. FE-5 noted that these pre-sales were used for manufacturing projections and assumptions about overall revenue pipeline assumptions. However, FE-5 explained that customers expected that the Savanna RVP4 test would come out in a "reasonable amount of time" and that they got sick of waiting. Therefore, FE-5 lost large accounts to competitors like Cepheid because customers moved on after the Savanna RVP4 test continued to experience delays. FE-5 recalled that he entered Savanna RVP4 test projected volumes based on pre-sales into Salesforce, which he referred to as a "closed loss" after the test was never approved in the United States. FE-5 noted

that QuidelOrtho wanted salespeople to generate interest for the Savanna RVP4 test but that the Company could “never actually back it up with an actual product.”

4. QuidelOrtho Spent Nearly \$100 Million To Create an Automated Manufacturing Line For Savanna, Which Never Materialized

221. In addition to extolling the false success of the Savanna European launch, and misrepresenting Savanna RVP4’s readiness for FDA approval, Defendants also touted the Company’s ability to readily manufacture thousands of Savanna devices and millions of RVP4 tests as soon as the promised FDA approval materialized.

222. The ability to automate the RVP4 production was essential to recognizing any profits on the new product. Indeed, Defendants promised an almost immediate realization of profits following the purportedly imminent FDA approval. Specifically, from the start of the Class Period, Defendants told investors that \$75 million of Merger revenue synergies would be realized by 2025 in connection with the Savanna launch, and that the Company would realize \$30-\$50 million in Savanna revenues by the end of 2024, and \$300 million per year within three years of launch. This could only be possible if the Company could not only overcome the myriad production failures described herein but could also build and operate an automated production line that would manufacture thousands of RVP4 at low cost (as opposed to the costly manual production line that also resulted in contaminated and defective tests, over 50% of which needed to be scrapped). Defendant confidently represented that “the only constraint” for the Savanna RVP4 launch in the U.S. would be the Company’s ability to manufacture instruments and cartridges “at very, very high volumes” and get them into the market as quickly as possible. Defendant Bryant specifically assured investors that the Company’s automated manufacturing line would be up and running in order to “*ramp-up and outfit to over 1 million cartridges per month[.]*” However, in reality,

QuidelOrtho was completely unprepared to launch a full-scale production of either the Savanna instrument or RVP4 test, even after pouring \$100 million into these efforts.

223. FE-4 stated that QuidelOrtho manually manufactured Savanna's assays for sale in Europe and for use in clinical trials. However, FE-4 explained that QuidelOrtho was forced to scrap between 50 and 80%, and sometimes 90%, of the Savanna assays it manufactured due to defects, which FE-4 described as "very alarming." FE-10, a Finance Director, confirmed FE-4's recollection, stating that the RVP4 production efforts only reached a manufacturing yield of approximately 50% by the time of FE-10's departure in Fall 2023, "way below" the Company's production threshold. FE-10 explained that a manufacturing yield is the percentage of non-defective items of all manufactured items, and the ideal yield rate for a product is 90%, meaning that only 10% of manufactured parts should be defective. FE-6 also confirmed that the production yields for the Savanna were 30 to 40% when they should have been 70 to 80%. He explained that this meant that only 3 or 4 out of every 10 tests from the production line were usable.

224. Not only did the Company scrap approximately half of its RVP4 manufacturing yield, but, according to FE-2, many RVP4 tests were scrapped during final inspection before Savanna RVP4 left the production facility in San Diego. FE-2 explained that after the tests were manufactured, and the initial number of clearly defective tests were scrapped, those tests were sent for final selection where "destructive" testing was done on a sample of the tests (meaning that those tests were run to test their adequacy, which clearly removed them from sales inventory). FE-2 described how many of the tests were scrapped during the final inspection of the product. FE-2 stated that QuidelOrtho detected high levels of "invalid" test results, meaning that the manufacturing for the test had a poor yield, which meant that there was a high failure rate because a high percentage of the tests were not working. FE-2 explained that a standard industry failure

rate should be around 5%. With RVP4, however, the Company would “scrap out” quite a bit—up to 50% of the entire production line—and recalled that there were times when the Company had to shut the entire production line down because everything was failing.

225. FE-2 described that the number of invalid tests was bad for the Company. FE-2 confirmed that, for example, in a production batch of 1000 units, 500 may need to be scrapped immediately; of the remaining 500 units, 50 may be selected for random quality testing, and of that testing sample, an additional 10% to 50% would fail. Of the remaining 450 units, he continued, an additional 10% to 50% would likely fail in the field, elaborating that, based on statistical sampling (which is an industry standard practice), the Company knows that a certain percent of the product released to the field will fail.

226. FE-7 recalled hearing about problems with the manufacturing of the RVP4 tests in San Diego as well. He recalled that there were many manufacturing and production problems, leading to a lot of scrap materials, before the tests were even sent to customers. He added that many tests failed quality control and could not be sold, which raised costs. He explained that there were problems with the manufacturing production process as well as contaminated tests. He noted that the production was largely manual at the time, which increased costs and the potential for human error and contamination. He recalled the Company “constantly” talked about building a large, expensive, automated production line for the test, but had trouble getting the automated line set up.

227. The Company incurred material costs in connection with the efforts to properly and efficiently manufacture Savanna, all of which were ultimately unsuccessful as of the end of the Class Period.

228. For example, FE-6, a former Cost Accounting Manager who was responsible for analyzing costs of Savanna production based on the existing manual production lines for Savanna during the Class Period, confirmed that the Company “poured millions” into building a fully automated production line for Savanna, but that production line was still not operational as of April 2024. He added that it was never confirmed to him where the fully automated production line was going to be situated; several places had been mentioned, but it was still “up in the air” and testing was still ongoing as of April 2024. FE-6’s understanding was that the Company had spent “upwards of \$80 to \$100 million” on the incomplete automated production line.

229. FE-6 indicated that he raised “red flags” about rising costs multiple times. For example, FE-6 indicated that concerns regarding costs were raised during monthly close meetings. He elaborated that he reported on the manufacturing variances (which he explained were excessive costs from production issues) at these meetings and that those concerns were raised “up the chain” of reporting to management. FE-6 recalled that the monthly close meetings were attended by: Melissa (“Missy”) Holder, Plant Controller; and Richard Jenkins, Vice President, Finance Global Operations. Further, each month, FE-6 told Defendant Busky that the Company would charge costs to R&D because Savanna still needed adjustments and research to address its failures.

G. In Reality, While Defendants Suddenly Doubled QuidelOrtho’s Endemic COVID-19 Revenue Guidance at the End of 2022, QuidelOrtho’s COVID-19 Test Sales Were in a Steep and Continuing Decline

230. Throughout the Class Period, as described above, Defendants misrepresented the success of Savanna RVP4’s European launch, its readiness for the U.S. market and its ability to satisfy the FDA’s specified benchmarks for clearance, and its capability to be manufactured at a scale and cost sufficient to achieve the promised revenues if it were ever to receive FDA clearance. By the end of 2022, Defendants engaged in a new scheme to defraud investors when they doubled the Company’s endemic COVID-19 testing guidance without any basis for doing so. In fact, all

objective evidence known to Defendants revealed that the Company stood to see *less* COVID-19 revenues and not more due to lost market share, outdated platforms, and a concerning buildup of unsaleable inventory.

1. QuidelOrtho's COVID-19 Test Sales Declined Dramatically by the End of 2022 As the Company's Customers Purchased Newer and More Accurate Tests from Competitors

231. While Defendants reported a decline in COVID sales in 2022, as noted above, Defendants told investors that, by early 2022, COVID-19 was reaching the endemic stage, and began issuing guidance based on the Company's assessment of COVID-19 endemic revenues, absent any unforeseen large government contracts. During all of 2022, Defendants Busky and Bryant reported that endemic COVID-19 revenues would be in the range of \$150 million to \$200 million. Then, in an abrupt revision just days following a disastrous December 13, 2022 Investor Day and a resulting 17% drop in QuidelOrtho's stock price, Defendants reported that the Company's COVID-19 endemic revenues were actually going to be between \$200 million and \$400 million, double the revenues projected less than a week earlier.

232. This changed guidance was a fiction, and Defendants knew it. Indeed, this projection of \$200 to \$400 million in COVID-19 endemic revenue was in direct conflict with the Company's actual COVID-19 test sales and revenue trends, all of which were directly reported to senior management, including the Individual Defendants.

233. FE-11, a former Channel Sales Manager throughout the Class Period, stated that there was a "huge decline" in COVID test sales beginning in August 2021. Specifically, QuidelOrtho sold more COVID tests to its distributors than those distributors could resell to their end-users. FE-11 stated that distributors pushed back on prices and contract terms with QuidelOrtho. According to FE-11, COVID-19 test customers "trickled off" and QuidelOrtho began seeing "steady declines." FE-11 detailed that during this time, for example, Cardinal Health

stopped ordering COVID tests from QuidelOrtho because it had ordered a bulk of at-home COVID tests kits which were never moved from distribution warehouses. FE-11 added that at the same time, McKesson Corporation and Henry Schein also stopped ordering COVID tests from QuidelOrtho.

234. QuidelOrtho's declining sales were not simply attributed to reductions in COVID-19 infections. For example, FE-11 recalled that QuidelOrtho lost COVID test customers to competitors, including Abbott Laboratories. FE-11 detailed that customers preferred Abbott's molecular tests and that Abbott offered customers a larger reimbursement than QuidelOrtho.

235. FE-3 corroborated FE-11's account. FE-3 was a former Sales and Business Development employee first at Ortho and then at QuidelOrtho from the Merger until April 2024, where he sold the Company's products, including Sofia and Solana analyzers and tests, to hospitals. FE-3 reported to FE-19, who reported to VP of Sales John Meckles.

236. According to FE-3, QuidelOrtho's revenue was "grossly declining" by Q1 2023, stating that QuidelOrtho missed its COVID and respiratory sales quotas in Q1, Q2, Q3 and Q4 2023 due to the Quidel portfolio of products. FE-3 explained that QuidelOrtho's primarily sales product during the COVID-19 pandemic was the Sofia analyzers and tests and that QuidelOrtho's COVID test sales "went cold" after the pandemic lessened. FE-3 detailed that, as described above, Sofia tested for SARS-COVID, Flu, RSV and other respiratory illnesses, but not all in one test as was planned for with the Savanna and other competitor tests on the market. FE-3 noted that customers had to purchase a separate Sofia test for each respiratory illness and could not use the same Sofia test to test for COVID, flu, or other respiratory illnesses. The feedback FE-3 received from some QuidelOrtho customers was that the Company's analyzers "did not hold up" and therefore customers purchased tests from competitors because they had more state-of-the-art

products. FE-3 added that the Sofia rapid test was Quidel's most popular COVID test but that some customers told him that it was "outdated."

237. FE-3 explained that he called accounts in 2023 with declining business to "stop the bleeding" and loss in revenue. FE-3 recalled that these accounts told him in 2023 that they stopped ordering respiratory tests from QuidelOrtho and switched to competitors because the competitors offered more "state-of-the-art" respiratory tests with newer technology, more modern analyzers, faster results, and more capabilities. FE-3 also received feedback from accounts that some Sofia tests were inaccurate and occasionally provided false positives while competitors' respiratory tests were more accurate.

238. FE-3 noted that he logged feedback from these conversations with his accounts in CRM Salesforce and shared the feedback in weekly meetings with FE-19 and his team. According to FE-3, FE-19 thereafter attended business manager meetings where sales were discussed with senior management.

239. Several other former employees with direct responsibility for selling Sofia and other COVID-19 tests have similar accounts of dramatically lowered sales by and throughout 2023, as QuidelOrtho's sales dropped, not solely because COVID-19 entered the endemic phase, but because QuidelOrtho lost business and market share to competitors with superior products.

240. For example, FE-15, a former Quidel and then QuidelOrtho employee with the Company from September 2015 to June 2023, was a Territory Manager responsible for selling QuidelOrtho's respiratory products to acute (hospitals) and non-acute (doctor's offices and urgent care facilities) customers located in California and Nevada during the Class Period until his June 2023 departure. According to FE-15, COVID test sales at QuidelOrtho began declining in late 2022. FE-15 recalled that COVID tests sales at the Company continued to decline in 2023 and

were not “anywhere near” the levels they were in 2021 and 2022. FE-15 explained that the market became saturated and flooded with alternative and cheaper COVID tests during this time and that acute and non-acute customers stopped purchasing COVID tests from QuidelOrtho and instead purchased newer, cheaper, and faster tests from competitors. FE-15 detailed how customers told him that they stopped buying QuidelOrtho’s Sofia COVID tests and began using molecular and cheaper rapid visual COVID tests instead.

241. FE-15 noted that QuidelOrtho’s respiratory season was from late fall through early spring. FE-15 recalled that he saw “significant” change in the behavior of customers between late Fall 2022 and early Spring 2023. FE-15 detailed that during this time, 30 to 40% of his total customers stopped purchasing COVID tests from QuidelOrtho. FE-15 stated that he obtained this information from sales reports. FE-15 explained that after pulling these sales reports, he subsequently called customers to find out why they stopped purchasing COVID tests from QuidelOrtho. According to FE-15, the feedback he received from his customers was that while they were not testing for COVID as frequently as they were earlier in the pandemic, they were also purchasing newer tests from competitors.

242. FE-15 explained that the Company’s distributors often convinced QuidelOrtho’s non-acute clients to purchase respiratory products, including COVID tests, from competitors instead of from QuidelOrtho. FE-15 noted that distributors convinced the Company’s non-acute clients to switch from QuidelOrtho’s products because the distributors made more money from selling competitors’ products. FE-15 explained that he was friends with the distributors and that they told him directly that they convinced his clients to purchase from competitors because they made more money from those sales.

243. According to FE-15, he participated in weekly, quarterly and monthly sales calls during his tenure. FE-15 noted that QuidelOrtho's C-suite participated in the Company's monthly sales calls. FE-15 recalled that it was discussed in late 2022 and early 2023 on the weekly and monthly sales calls that the Company's respiratory sales were slowing down.

244. FE-16, an Account Manager who sold, among other things, QuidelOrtho tests for COVID, flu and RSV to customers located in Northeast United States from late 2022 through September 2023, described how COVID tests sales in hospitals were "completely gone" in 2023 and that Quidel's acute business "disappeared overnight." According to FE-16, QuidelOrtho was very aware that the need for COVID testing in hospitals was declining in 2023.

245. FE-16 specified that two large conglomerates of hospitals in the Northeast that he sold products to had previously purchased COVID tests from Quidel and that he visited facilities from each conglomerate in 2023. According to FE-16, he saw that they stored Quidel's Solana devices in a closet when he visited because they had no use for them. FE-16 noted that Quidel provided the conglomerates and other acute customers free COVID demo kits and heavily discounted COVID tests to its customers because there was an "urgency" to sell them in Q4 2022, Q1 2023 and throughout his tenure. FE-16 recalled that he also visited a rural, community hospital in the Northeast in 2023 and that this hospital moved onto Cepheid's COVID tests and was not using QuidelOrtho's COVID testing solutions.

246. FE-16 noted that customers throughout the United States were not buying COVID tests and other acute products from QuidelOrtho in 2023. FE-16 detailed that he spoke to colleagues located throughout the U.S. and that they all talked about how no one was buying QuidelOrtho's acute products. FE-16 noted that he and his colleagues laughed and asked each other what they were doing with all the Quidel products that they were unable to sell.

247. Another Account Executive responsible for selling all of Quidel's respiratory products, including the Lyra, Sofia and Solana, to distributors, hospitals, reference labs, and private practices, FE-17, similarly recalled that in 2022 and 2023, "no one" was buying COVID tests such that QuidelOrtho's distributors purchased "significantly" fewer COVID tests in 2022 and 2023. FE-17 also stated that Defendant Bryant was involved in forecasting projections during FE-17's tenure at QuidelOrtho. FE-17 noted that he and his colleagues discussed their belief that Bryant was fired in February 2024 because he made, at legacy Ortho leaders' direction, unattainable 2023 COVID sales projections.

248. FE-18 was employed with Quidel and then QuidelOrtho throughout the Class Period as a Senior Global Product Manager, Immunoassay in Vitro Diagnostic Tests. FE-18 advised that she assisted QuidelOrtho with its product launches, go-to-market strategies and retail marketing campaigns. FE-18 worked with over the counter (OTC) products from 2021 to 2023 and with point of care (POC)/respiratory products from 2023 to 2024, and reported to four different managers during his tenure, most recently to current Director of Global Product Management, Sean Redmond.

249. FE-18 recalled that sales for all COVID products, including COVID tests, began declining "across the board" sometime in 2023 compared to 2021 and 2022. According to FE-18, CVS and Walgreens accounted for 75 to 80 percent of QuidelOrtho's retail OTC COVID-19 business. FE-18 suggested that QuidelOrtho lost a lot of COVID test customers, mostly small pharmacies, to Chinese competitors after the FDA approved additional and cheaper COVID tests, some of which were "dirt cheap."

250. Sales of COVID-19 tests in Europe also significantly declined by 2023. FE-9, a former Vice President of Sales and Marketing in Europe from 2017 through the end of the Class

Period, commented that as the COVID pandemic eased, the market for the COVID tests (including Savanna in Europe) declined. He noted that hospitals were still testing their patients in 2022 and 2023, but that approximately 50 Chinese companies entered the European market, selling significantly cheaper test kits. This competitive pressure caused QuidelOrtho to not be able to sell as much product, noting that things “went down” pretty quickly. FE-9 explained that the Chinese-made products were “flow” tests, which he described as cheap, simple tests that provided results in fifteen minutes, and that these tests were mainly used by hospitals to save money. He noted that hospitals would use the cheap, quick test first, and then follow up with PCR or Savanna type tests to confirm a positive result.

2. QuidelOrtho Employees Uniformly Missed Unattainable COVID-19 Sales Goals in 2023, Which Was Discussed With Senior Management, Including Defendants

251. The impact of the Company’s dramatically lower endemic COVID-19 sales was felt directly by QuidelOrtho’s sales teams, who had no chance of making “unattainable” sales quotas set for them at the beginning of 2023. Because compensation was directly tied to whether the sales teams could meet the sales quotas set for them by management, the inflated sales quotas were identified at the start of 2023 and brought to the attention of senior management, including the Individual Defendants.

252. FE-3 explained how, QuidelOrtho’s revenue was “grossly declining” beginning in Q1 2023, and his hospital customers informed him that they stopped ordering Sofia tests in favor of other competitors’ products because the single Sofia tests were “outdated” and not as accurate as competitors’ products. *See supra*, ¶¶236-37. These lost sales directly impacted the QuidelOrtho sales teams because their compensation was directly tied to whether they could meet the sales quotas set for them by management.

253. FE-3 explained how QuidelOrtho customers would typically buy the tests that could be used on the Quidel analyzers and other devices on a regular, weekly or monthly basis. When customers reduced or cancelled these standing orders, they informed the Company's customer service department who then notified the shipping team to adjust the standing orders. FE-3 detailed that sales representatives were not immediately notified when an account reduced or cancelled their standing orders, but later realized that it occurred after they saw a decline in their sales numbers, which negatively affected their commission.

254. FE-3 explained that these declining sales directly impacted whether sales personnel would receive any commission at year end because the Company did not provide commissions if the salesperson's percent to forecast was under 93 percent. FE-3 recalled that in 2023, the average percent to forecast for the Company's salespeople that sold QuidelOrtho's COVID tests and respiratory products was between 65 and 68 percent, far short of the 93 percent needed to earn commissions. FE-3 explained that the Company missed its sales quotas for QuidelOrtho COVID-19 and other respiratory products in every quarter of 2023.

255. FE-21 explained that QuidelOrtho was manufacturing fewer COVID tests as a result of COVID test sales declining. FE-21 explained that people were not testing as often as they were earlier in the pandemic, and it was clear by Q2 2023 that COVID test sales were declining across the board. According to FE-21, QuidelOrtho's 2023 COVID test sales targets were inflated, and colleagues asked each other "how are we going to make our numbers?" in 2023.

256. FE-16 similarly recalled that he received sales quotas during his tenure that were "astronomically high" due to the need for COVID testing in hospitals declining. FE-16 detailed that COVID tests accounted for more than half of his sales quotas and, according to FE-16, he did not reach his 2023 sales quotas because the need for COVID tests disappeared in 2023.

257. According to FE-3, QuidelOrtho maintained quota attainment data and other metrics in Microsoft Power BI, which was accessible to QuidelOrtho salespeople and all Company employees, including the C-Suite. FE-3 explained that salespeople could sort sales reports in Microsoft Power BI to identify the source(s) of revenue decline, including specific products. FE-3 stated that he used the sales data maintained in Microsoft Power BI to analyze the territory that he was responsible for, but that upper management utilized Microsoft Power BI to analyze data and “see the bigger picture,” *i.e.*, all of the Company’s territories. FE-3 stated that using the Microsoft Power BI, you could easily see the huge decline in the Quidel side of the business; it was seen “easily and obviously.” FE-3 added that one of the metrics tracked in Power BI was “percent to forecast,” which QuidelOrtho’s hierarchy anticipated would be 100%, but throughout 2023, percent to forecast for COVID tests and respiratory products Company-wide was only in the mid-60 percent range.

258. FE-19, FE-3’s direct supervisor, confirmed his accounts of steeply declining COVID-19 revenue and missed sales quotas beginning in 2023. FE-19 recalled that COVID test sales “dropped off” in 2023 and that “a lot” of hospitals stopped ordering COVID tests from QuidelOrtho during this time. FE-19 further recalled that most sales representatives at QuidelOrtho missed their respiratory sales quotas in 2023. According to FE-19, some regional sales representatives missed their respiratory sales quotas in 2023 “by a mile.” FE-19 stated that he tracked respiratory sales quotas quarterly in Microsoft Power BI and did not see any quotas that were met by the time he departed in April 2024.

259. FE-19 recalled that during his tenure with QuidelOrtho, he “always” attended meetings with former Senior Vice President, North America Sales Sandra Savage, former Vice President of Sales John Meckles and/or current Vice President, Customer Operations North

America Charles Bellinghausen. FE-19 detailed that during these meetings in 2023, sales leaders asked Savage, Meckles and/or Bellinghausen how the Company was going to “take care” of its salespeople “through this?” FE-19 clarified that by “through this,” the sales leaders meant “not being able to hit our numbers.”

260. FE-20 was a Senior Sales Performance and Compensation Analyst who reported to Associate Director Commercial Financial Planning & Analysis (FP&A) Daniel Nash. Nash reported to Defendant Bujarski until the Merger and then reported to Charles Bellinghausen, VP of Customer Operations North America, who in turn reported directly to CFO Defendant Busky. FE-20’s team worked with the Company’s Commercial Finance team that tracked the sales of commercial products, including QuickVue, Sofia and molecular products, to customers. FE-20 and his team helped establish sales quotas and calculated sales compensation for salespeople located in the United States.

261. FE-20 stated that sales compensation goals originated from QuidelOrtho’s Commercial Finance team, including former Vice President, Head of Global Commercial Finance Robert Dunn, who provided 2023 compensation targets to current Vice President, Customer Operations North America Charles Bellinghausen and Daniel Nash, to whom FE-20 reported. FE-20 noted that Dunn reported to current CFO Defendant Busky, which, FE-20 explained, suggests that 2023 sales quotas came from Busky.

262. According to FE-20, salespeople were “angry and frustrated” after receiving their 2023 sales quotas because their respiratory sales quotas were unattainable.

263. FE-20 explained how it became clear by the second quarter of 2023, “if not earlier,” that U.S.-based salespeople were not going to hit their 2023 annual respiratory sales quotas, which he described as “unattainable.” Therefore, FE-20 stated that there was “a lot of reworking” done

to mitigate that. FE-20 explained that by Q2 or Q3 2023, QuidelOrtho began reducing its 2023 respiratory sales quotas so that its salespeople would receive some compensation.

264. These missed sales quotas and lower customer demand for COVID-19 products were communicated directly to the highest levels of senior management, including Defendant Busky. FE-20 detailed that Charles Bellinghausen directed Daniel Nash to crunch sales performance data throughout 2023 so that they could show the Finance team, and specifically Elana Benayon and Robert Dunn, how far off QuidelOrtho was from hitting its 2023 annual respiratory sales quotas. According to FE-20, Bellinghausen consistently communicated and met with Ortho leadership, including Dunn and Defendant Busky, throughout 2023. FE-20 stated Bellinghausen reported to Busky and other leaders that the Company was not going to hit its 2023 respiratory sales quotas during meetings at the end of each quarter in 2023. FE-20 detailed that during the last few weeks of each quarter in 2023, Bellinghausen met with Savage, Henson, Brengel and current Head of People and Culture Rita Masini to discuss quarterly compensation payouts, among other things. FE-20 noted that Defendant Busky attended a few of these meetings in 2023 as well.

265. FE-20 explained that Nash conducted sales analysis throughout 2023 and summarized his analysis in detailed and lengthy PowerPoint presentations and reports (10 to 20 pages long), which he provided to Bellinghausen to present in these meetings, including meetings that Defendant Busky attended.

266. FE-20 recalled that these reports and presentations contained sales data that reflected that quarterly compensation payouts were lower than projected and highlighted the stark difference between sales quotas and sales compensation payouts. FE-20 noted that the goal of these presentations and reports was to convince Ortho leadership to increase compensation payouts to

salespeople so that they would be motivated to stay at the Company and not leave to join competitors. FE-20 added that he helped calculate new business quotas for salespeople and provided this data to Nash.

267. FE-20 recalled that by Q4 2023, QuidelOrtho had reduced its 2023 respiratory sales quotas by \$50 to \$90 million for roughly 150 of the 400 salespeople mainly because the Company's COVID and flu assays were not selling as well as projected due to a lack of customer demand. FE-20 noted that former Senior Vice President, North America Sales Sandra Savage specifically advocated for QuidelOrtho to reduce its 2023 respiratory sales quotas.

268. FE-20 recalled that out of the 400-U.S. based salespeople at QuidelOrtho, only "a handful" of them ultimately hit their annual respiratory sales quota in 2023. FE-20 noted that QuidelOrtho audited the payouts of the few employees that did reach their 2023 respiratory sales quotas to make sure their numbers were accurate before providing them with compensation.

3. Declining Sales and Increased Competition Lead to "Enormous" Inventory Issues, Which Were Reported Up to Senior Management Including Defendants

269. QuidelOrtho's declining COVID-19 sales performance was also evident from the significant volume of unused COVID-19 inventory.

270. Regarding inventory issues, FE-10 discussed how the Company's Sofia and QuickVue COVID-19 test inventory grew to concerning numbers in 2022 and 2023. According to FE-10, QuidelOrtho had excess Sofia and QuickVue inventory during his tenure, which he noted was his biggest concern. FE-10 detailed that inventory of QuickVue and Sofia tests started building up at QuidelOrtho and got "out of control" in February 2021 but that the U.S. government "bailed out" the Company in August 2021 by ordering a lot of COVID tests. FE-10 added that inventory continued building throughout FE-10's tenure, which ended in Fall 2023. FE-10 specified that the Company built up "a lot" of inventory of Sofia ABC tests (combination of flu A+B and COVID),

Sofia flu tests, Sofia COVID tests, QuickVue flu tests and QuickVue COVID tests. FE-10 explained that there were “always excess inventory problems” in Q2 2022 and that the Company had a “consistent pattern” of manufacturing too many products every year during Q1 and sales “fell off a cliff” in Q2 after flu season, causing QuidelOrtho’s COVID-19 test inventory to grow to concerning numbers.

271. FE-10 recalled that when demand for Sofia and QuickVue COVID tests and QuickVue SARS-COVID tests declined, the Company had to scrap these products and write them off as an expense on the Company’s balance sheet. FE-10 detailed that the Company mostly scrapped inventory of Sofia ABC tests, Sofia flu tests, Sofia COVID tests, QuickVue flu tests and QuickVue COVID tests. FE-10 stated that QuidelOrtho was a “poorly managed operation” because the Company manufactured products that did not sell, which caused inventory to build up (especially in the summer) and led to layoffs. FE-10 referred to this as a “cycle of chaos.”

272. FE-10 recalled that he participated in quarterly Excess and Obsolete (E&O) meetings during his tenure at QuidelOrtho where the Company’s significant levels of COVID-test inventory was regularly discussed.

273. According to FE-10, former Vice President, Finance Kristin Caltrider initially oversaw these meetings but that current Vice President, Finance Global Operations Richard Jenkins oversaw these meetings after Caltrider departed the Company in March 2022. FE-10 added that plant controllers led these meetings and that finance and operations employees, including supply chain, material planning, and purchasing employees also attended these meetings.

274. FE-10 explained that the E&O meeting participants discussed products that were aging and about to expire. FE-10 stated that the number of tests that were set to expire increased

each quarter during his tenure and the E&O meeting participants commented to each other during every meeting “wow, this is the most E&O I remember us having.”

275. FE-10 explained that while the Company was not concerned about excess inventory prior to the May 2022 Merger, following the Merger, individuals from Ortho were concerned about excess inventory and asked FE-10 and his finance colleagues to “dig into the weeds” and run risk analyses. FE-10 detailed that during peak levels of inventory, QuidelOrtho was selling less than 1 million tests per week but maintained “tens of millions” of respiratory tests in inventory, including 30 million QuickVue tests.

276. FE-10 maintained and updated a report called the McKellar Report, which included sales data for raw materials and finished goods, how much product was selling each week, and how much of each product the Company had in inventory. FE-10 stated that the McKellar Report reflected that “nothing is selling” and that inventory levels were going “up, up, up” beginning in early 2021 and consistently increased throughout FE-10’s tenure. FE-10 stated that Jenkins provided E&O numbers to CFO Defendant Busky.

277. FE-10 described how Defendant Busky asked him for solutions to inventory problems the Company was facing, partially because Busky wanted guidance on “how to spin” this inventory issue on quarterly earnings calls. FE-10 noted that he and other finance colleagues smirked while listening to some earnings calls because Busky painted a “rosy picture” and put a “positive spin on the situation.”

278. FE-10 explained that he recorded his analysis about how much product was expiring in the coming months in a spreadsheet, which he would send to Jenkins. Jenkins would then relay this analysis to Defendant Busky. FE-10 added that Busky would discuss the analysis and data directly with FE-10.

279. When presented with Defendant Busky's December 2022 public statement where Busky stated during an analyst conference call that: "we don't have so much of a demand problem right now. We have a supply problem. We got to get more products," FE-10 remarked that QuidelOrtho did not have a supply chain problem at the time this statement was made and therefore FE-10 stated that he is "not sure what he's talking about." FE-10 added that QuidelOrtho could always build up supply for Sofia and QuickVue tests and that ramping up was never a problem for the Company. FE-10 noted that ramping down was a problem for QuidelOrtho because all vendors charged "exorbitant fees" to ramp down.

280. FE-10 stated that at the end of each quarter during the last six months or year of his tenure, which ended in Fall 2023, current CFO Defendant Busky asked FE-10 to run numbers and provide analysis before Busky conducted earnings calls with investors. FE-10 detailed that Busky specifically asked him how much exposure QuidelOrtho had in terms of inventory, how much inventory did the Company have if it did not sell anything and how much product did the Company have to scrap. FE-10 noted that Busky asked him these questions in case someone on the earnings call asked Busky about these issues. FE-10 recalled that the analysis that he presented Busky did not paint a "rosy picture" or a "good future" because QuidelOrtho was "carrying way more" Sofia and QuickVue inventory than it should have been.

H. Investors Learn the Truth

1. February 13, 2024: QuidelOrtho Announces Q4 2023 Results and Slashes Endemic COVID-19 Revenue Guidance, While Continuing To Mislead Investors About Savanna RVP4

281. On January 8, 2024, Defendants Bryant and Busky presented at the J.P. Morgan 42nd Annual Healthcare Conference, a heavily anticipated industry event attended by many of QuidelOrtho's competitors and analysts. The Company notably did not preannounce its fourth quarter or 2023 financial results. On January 13, 2024, William Blair published an analyst report

containing “key takeaways” from the presentation and calls with company management. William Blair analysts commented that QuidelOrtho’s decision not to pre-release its fourth quarter and full year 2023 financial results “surprised investors,” but that this was not a cause for alarm because: “Mgmt. was clear: *if nothing materially different from range, no need to prerelease.*” As a result, William Blair reported that “*23 guidance (rev and profits) appears intact.*” William Blair also noted that QuidelOrtho made comments that investors should “expect to be in the guidance range for influenza and other respiratory rev, *with COVID higher*” and that “*Q1 [2024] looks like a normal respiratory season.*”

282. Given these assurances, QuidelOrtho’s stock nosedived when, just weeks later, after the market closed on February 13, 2024, the Company reported fourth quarter and year-end 2023 financial results that fell far below previous guidance and analyst consensus estimates. In a press release, QuidelOrtho reported a 14% decline in fourth quarter 2023 revenues, and attributed that decline to poor performance in the Company’s sales of COVID-19 and influenza testing. The Company’s fourth quarter revenues of \$742.6 million were nearly 7% below the Wall Street estimate of \$796.9 million. Driving this stark decline was the Company’s drop in fourth quarter respiratory revenue, which came in at \$174.6 million, 22% lower than analyst consensus of \$223 million. As a direct result of the drop in respiratory revenue, the Company’s fourth quarter Adjusted EPS was *46 percent below* the midpoint of analysts’ consensus, and its fourth quarter Adjusted EBITDA¹² was *28 percent below* analysts’ consensus of \$271 million.

283. On a conference call following the press release, Defendant Bryant conceded that he “will not sugarcoat the fact that our fourth quarter numbers fell short of our expectations”

¹² EBITDA is earnings before interest, taxes, depreciation, and amortization. Adjusted EBITDA removes one-time, irregular, and non-recurring items that distort EBITDA.

because the Company had “overestimated the size of the endemic COVID-19 and flu season.” Bryant stated that while the rate of COVID-19 “prevalence” in North America was steady in the fourth quarter, the Company “lacked the inflection point in demand,” which he attributed to “distributor destocking on COVID-19 products,” and further relayed that the distributor destocking of QuidelOrtho’s COVID-19 products “will continue into Q1 of 2024.” In reality, though, QuidelOrtho’s distributor destocking was not new. As FEs-3, 9-21 explain, demand for QuidelOrtho’s COVID-19-related sales declined beginning in 2022 and throughout 2023, and its distributors purchased “significantly” fewer tests and decreased recurring orders due to lessened demand and increased competition.

284. Defendant Busky caught the market further off guard by slashing the Company’s endemic COVID-related revenue guidance for 2024, which had been affirmed just weeks earlier. Where the Company’s prior “endemic” annual respiratory revenue guidance was \$610 million to \$775 million, with COVID-19 revenues contributing \$200 to \$400 million of that total, Busky announced that QuidelOrtho was significantly reducing its 2024 endemic respiratory revenue guidance to \$460 million to \$730 million, now capping QuidelOrtho’s COVID-19 2024 revenue contribution at roughly \$200 million. Because of this massive reduction to fiscal year 2024 guidance for endemic COVID-19 revenue, Busky explained that the Company had lowered its forecasted 2024 Adjusted EBITDA and Adjusted EPS, stating: “[o]ur adjusted EBITDA and EBITDA margin, as well as adjusted EPS are obviously significantly impacted by bringing down the estimate for endemic COVID-19 revenue and widening the range for flu, which impacts the bottom line disproportionately given the high margins on these products.”

285. Defendants attempted to soften the blow of the slashed respiratory and COVID-19 revenue guidance by reinforcing—in the Company’s press release, investor presentation and on

the earnings call—that Savanna RVP4 would contribute \$30 million to \$50 million of respiratory revenues in 2024, and that Savanna would contribute \$250 million in revenue over the next three years. Defendant Busky confirmed on the earnings call that the Company’s revised 2024 respiratory guidance included a “contribution of between \$30 million to \$50 million in respiratory revenues from Savanna RVP4.” Defendant Bryant later affirmed that: “I don’t really see that the \$250 million [of Savanna revenues three years post-launch] will be something that will need to change.”

286. Financial analysts on the call peppered Defendants Busky and Bryant with pointed questions about QuidelOrtho’s disappointing earnings and guidance, and why these results diverged so significantly from longstanding assurances that were most recently confirmed in January. For example, an analyst from RBC questioned why the Company “didn’t preannounce, which typically you have in early January,” asking specifically whether there was “anything that’s come up in the last month that kind of surprised you that you didn’t know about in January?” Bryant responded in the negative, admitting that Defendants affirmatively decided not to preannounce bad news, despite being fully aware of it, stating: “*The total revenue we knew . . . [t]he miss was about 6% or 7% of what we had projected.*” Bryant attempted to defend this decision by stating that while he knew of the revenue miss, he “wouldn’t have [had] all the answers to all the questions that we would have during the one-on-ones at the conference,” conceding “*I could have told you, obviously, that any gain or loss relative to the forecast with respiratory has a bigger impact.*”

287. An analyst from William Blair, who had recently reported that management had signaled no negative surprises in January, asked about the Company’s “change in philosophy to setting [the] annual range” for guidance “versus . . . your process in the past.” Defendant Bryant

attributed the decision to cut guidance based on the fact that industry-wide COVID sales in the fourth quarter had “dropped pretty dramatically[,]” leading to the Company’s “dramatic change in philosophy.” Another analyst pressed the Individual Defendants on their confidence level in the 2024 guidance since Defendants had previously “provided an endemic respiratory rate for 2023 and you were very confident in that throughout the year and sales still came in below that.” In response, Defendant Bryant explained that the Company now had a “pretty good understanding of market size[,]” claiming (falsely), however, that the Company’s market share somehow “actually has increased” despite the fall in revenue.

288. Analysts sought clarity on Defendants’ confidence in Savanna’s \$40 to \$50 million contribution to 2024 revenues. A William Blair analyst asked whether there was “any part of the [2024 guidance] that you’d call out as a little bit higher risk or things need to sort of go your way in order to achieve those?” Defendant Busky responded in the negative, explaining that aside from the “big ticket item in the respiratory section”—the reduced COVID-19 revenues—“*I don’t see a lot of risk*” in 2024 revenue guidance, noting that flu, RSV and strep were anticipated to be consistent with 2023 results, and “now you’ve got the additional respiratory revenue for Savanna that I talked about in the range of \$30 million to \$50 million, which we expect will mostly come in Q4.”

289. In response to an analyst’s question regarding guidance for 2025 and Savanna, Defendant Busky affirmed that Savanna RVP4 would be in the market in 2024, “[a]nd then *Savanna becomes more accretive with continued growth in 2025.*” Another analyst bluntly asked Defendants Bryant and Busky whether they had “all the trial activity” they needed for Savanna RVP4 approval, to which Bryant confirmed the 510(k) submission was “on track” for FDA approval, as well as the important CLIA Waiver, for Savanna, stating that: “The CLIA Waiver is

expected by year end. *The status of the submission of the 510(k) is on track from 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.*" Bryant also specifically confirmed, in response to an analyst question, that Savanna was forecasted to contribute \$250 million in revenues three years post-launch, which had commenced in December 2023, stating: "we achieved what we set out to do in 2024 . . . so I don't really see that that \$250 million will be something that will need to change the forecast. . . ."

290. Despite Defendants' positive (and false and misleading) statements concerning Savanna RVP4 2024 revenue, that news could not overcome analysts' surprise at QuidelOrtho's dismal results and weak guidance, especially when compared to Defendants' previous statements, including Defendant Bryant's statement from a month earlier at the J.P. Morgan Healthcare Conference, where he reaffirmed that endemic COVID revenue guidance of \$200 million to \$400 million was "**very much on track for 2024**" (see ¶344(v), *infra*). Within the next few days, six analysts cut QuidelOrtho price targets by an average of 40%, and three analysts downgraded their investment recommendations.

291. Analysts at Craig-Hallum downgraded QuidelOrtho shares, noting that "[r]espiratory is still the only thing that matters for this stock" and 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.**" The analyst attributed "[m]uch of the surprise" to the stark contrast between the Individual Defendants' January 2024 statements, "where the picture for Q4 was painted as good: '[we would] have preannounced when we have something that's materially different than you think,'" and the reality where "Q4 sales and EPS missed, while at the same time, 2024 was painted as an investment year with earnings effectively half of what the Street had modeled." Commenting

further on 2024 guidance, Craig-Hallum stated that “[a] major complication is we were told the 2023 respiratory range of \$610-775M was the endemic rate; we are now told this estimate was wrong, and the new \$460-730M target for 2024 is correct,” concluding that *“[w]e cannot see the stock working near-term.”*

292. Similarly, Raymond James issued an analyst report that downgraded QuidelOrtho shares after “a major 28% EBITDA miss in 4Q *only worsened by fairly deplorable communication and expectation setting both over the course of 2023 and even as recently as last month.*” This report discussed the Company’s revised 2024 financial guidance for endemic COVID-19 revenue from \$200-\$400 million down to \$200 million, stating that: “[t]hese metrics all make sense from the new base, but not necessarily from the prior outlook, and we understand and share investor frustration on that front.” William Blair analysts also expressed frustration with the “disconnect” between the expectations set by QuidelOrtho management and the Company’s fourth quarter and fiscal year 2023 results. William Blair acknowledged that QuidelOrtho shares were *“in the penalty box”* and downgraded its rating to “Market Perform,” pointing to, among other things, the need for management to “show progress on its execution” and *“rebuild some credibility[.]”*

293. On February 14, 2024, the first trading day after Defendants’ after-market revelations, QuidelOrtho’s stock price immediately declined, *falling 32% in a single trading session on unusually high trading volume.* By the close of trading on February 14, 2024, QuidelOrtho stock dropped \$21.50 per share, down from a February 13, 2024 closing price of \$66.77 per share to a February 14, 2024 closing price of \$45.27 per share. This marked the lowest stock price for Quidel in over five years, and the price continued to slide. The following day, QuidelOrtho’s stock price dropped *an additional 3% on unusually heavy trading volume*, falling

by \$1.29 per share. The Company's stock *dropped another 5% on February 16, 2024*, following the release of a Form 8-K correcting its recent "2024 Guidance to widen the range for adjusted diluted EPS to align with 2024 Guidance for adjusted EBITDA," closing at \$41.76 per share on unusually high trading volume.

294. Defendants' February 13, 2024 positive statements regarding Savanna RVP4 and its purported near-term approval and considerable 2024 revenue contribution were viewed by some analysts as a bright spot in otherwise disappointing news for the Company's critical respiratory sales division. A J.P. Morgan analyst report repeated QuidelOrtho management's statements that the Company "still expects approval [for Savanna RVP4] by the end of 1Q24" and "reiterated its prior guide of >\$250M in annual revenue by year-3 post-launch" after "100% of its 1,000 expected placements for the year have indicated their strong desire to run the respiratory panel. . . ." A William Blair analyst report nearly repeated verbatim Defendant Bryant's statements on Savanna—that "[t]he CLIA Waiver is expected by year end" and that "[t]he status of the submission of the 510(k) is on track," before discussing Savanna's contribution to respiratory revenue, stating: "FDA regulatory approval for the respiratory panel (RVP4) remains on track for the end of the first quarter. It also expects to be CLIA-waived by year-end." Other analysts noted how much was riding on a successful Savanna RVP4 2024 launch. For example, an RBC Capital analyst report stated that "[a] delay in the launch of pipeline products, including the Savanna diagnostic platform, would likely lead to pressure on the stock" and "[a]ny pushback in the approval or launch of Savanna is likely to be viewed negatively by investors, causing a drop in shares."

295. On February 29, 2024, QuidelOrtho filed the Company's annual report for fiscal year 2023 on Form 10-K with the SEC (the "2023 Form 10-K"), which contained the same

disappointing results for fiscal year 2023, as previously disclosed on February 13 and 16, 2024. In addition, QuidelOrtho's 2023 Form 10-K disclosed that the Company's fiscal year 2023 Point of Care revenue decreased YoY by **54%**, "driven by decreases of \$846.0 million in sales of QuickVue SARS Antigen assays and \$219.1 million in sales of Sofia SARS Antigen assays." The 2023 Form 10-K also disclosed that QuidelOrtho's fiscal year 2023 Molecular Diagnostics revenue decreased YoY by **67%**, "primarily driven by lower demand for the Lyra SARS Antigen assay due to the end of the public health emergency in the U.S."

296. Analysts continued to react negatively to QuidelOrtho's dismal 2023 financial results and 2024 financial guidance. On March 4, 2024, before the market opened, one reputable analyst called into question Defendants' February 13, 2024 representations that the Company's poor 2023 results were attributable to market-wide decreases in COVID-19 testing. UBS issued a March 4, 2024 analyst report (the "March 4, 2024 UBS Report") downgrading QuidelOrtho stock to Sell. In this report, UBS used its own proprietary database, and reported that: "***QDEL is seeing sharper declines in COVID revenues vs. PCR peers as DHR and HOLX.***"¹³ This UBS analyst report further elaborated on the divergence between QuidelOrtho and other diagnostic companies, which indicated that the Company was experiencing a loss of market share for COVID-19 sales to competitors' products that offer more in terms of testing and insurance reimbursement. The report stated:

We note that QDEL's COVID testing revenues in 2023 and 2024 are declining greater than other COVID testing peers. While management stated QDEL is taking share, we believe this may be only against other over-the-counter tests which

¹³ Based on UBS's proprietary database, the March 4, 2024 UBS Report states that QuidelOrtho's total COVID-related revenue for fiscal year 2023 were \$407 million. Using this data, QuidelOrtho made \$260 million in COVID-related revenue for fiscal year 2023, excluding the \$147 million in COVID-related revenue from one off government orders. This \$260 million was **\$40 million** short of the midpoint (\$300 million), and **\$140 million** short of the top end, of QuidelOrtho's endemic COVID-related revenue range of \$200-\$400 million.

drive the majority of QDEL's COVID revenues. Further, *we note that PCR peers such as DHR and HOLX beat consensus for 4Q23 COVID revenues. We believe given the current flu and RSV seasons there could be a shift to assays that offer 4-in-1 testing, which are also often reimbursed by insurance.*

297. The competitor companies identified by UBS as seeing better than expected Q4 2023 COVID-19 test sales confirmed the analysts' observations. Indeed, Danaher (NYSE ticker "DHR"), a global science and technology company that operates a large diagnostics business segment, and Hologic ("NASDAQ ticker "HOLX"), a medical technology company, hosted earnings calls on February 1, 2024 and February 2, 2024, respectively, to report their quarterly results. Hologic reported that the company experienced "higher than expected COVID revenues." Similarly, while Danaher reported a decline in COVID-19 revenues, that decline was less than the Company had expected.

298. The UBS Report which revealed QuidelOrtho was experiencing sharper declines in COVID-related revenues compared to peers was cited by several news outlets. For example, *Fintel*, *SeekingAlpha*, and *TipRanks* all reported articles released March 4, 2024 that UBS downgraded QuidelOrtho to sell, and @360DxNews tweeted an article regarding the same, noting: "The investment bank cited risks in the firm's guidance for respiratory test sales and in the launch of the Savanna point-of-care MDx system."

299. In the wake of the March 4, 2024 UBS Report, QuidelOrtho's stock dropped nearly 3%, falling from a close of \$45.53 on March 1, 2024 to a close of \$44.33 per share on March 4, 2024. The stock fell an additional \$1.39 on March 5, 2024, closing at \$42.94.

2. Defendant Bryant Is Fired Immediately Following the February 13 Disclosures

300. On February 21, 2024, shortly after the market opened, the Company revealed that the Board of Directors had "determined to terminate Douglas C. Bryant" from his role as CEO on February 14, 2024, and that Bryant thereafter resigned from the QuidelOrtho Board on February

17, 2024. The Company formed a temporary Office of the CEO as the search began for a new CEO. The Office of the CEO consisted of Company Chief Commercial Officer Defendant Iskra, Chief Operating Officer Defendant Bujarski and CFO Defendant Busky, with Mr. Iskra named as the interim CEO and Mr. Bujarski the interim president. The Company reaffirmed guidance delivered on February 13, 2024, but announced that it was postponing the much-anticipated Investor Day that had been scheduled for March 20, 2024.

301. Bryant's termination was directly related to the Company's surprising February 13, 2024 financial results, with a Citi analyst report noting that: "[g]iven the recent disappointing results and execution issues, we expect investors will receive this change positively." William Blair issued an analyst report following the news, writing that Bryant's tenure "had its challenges, with sometimes overly optimistic messaging and delays on efforts such as new product launches (Savanna) or synergy capture (Ortho acquisition). And following last week's 2024 guidance debacle and the ensuing calls from many investors advocating for a change in management, we understand why the board made this move." Similarly, on February 22, 2024, *Fierce Biotech* reported on the firing, stating that: "In the wake of a full-year earnings sheet that showed an 8% year-over-year drop in revenues and a major slump in operating income that sent its net earnings into the red, QuidelOrtho is making some changes at the top."

302. FE-3 recalled that prior to his departure, former QuidelOrtho CEO Defendant Bryant recorded a video that was emailed to all Company employees in connection with his firing. FE-3 detailed that in the video, Bryant took the blame or "rap" for the "unrealistic sales targets" that were set for QuidelOrtho in 2023.

3. April 2, 2024: QuidelOrtho Withdraws Its Savanna RVP4 FDA Application

303. On April 2, 2024, at the market open, QuidelOrtho issued a press release that disclosed the Company's decision to withdraw the FDA 510(k) submission for Savanna RVP4 (the "April 2, 2024 Press Release"). According to the Company, the decision to withdraw the submission was made "*upon reviewing the performance of the Savanna RVP4+ assay against the clinical market's expectations.*" The Company stated that while "[d]ata generated over a 9-month period for the four viruses targeted by the assay initially showed great promise, which led to the FDA submission in July 2023," but that "*the final dataset, submitted in February 2024, did not meet our expectations.*" While the April 2, 2024 Press Release revealed that Savanna's data did not meet Company expectations, as described in detail above, the Company had known internally since the start of the Class Period that: (a) reports from the European launch demonstrated that the Savanna RVP4 was not ready for a market launch, with tests regularly failing to work even in that limited launch; (b) "no one" thought the FDA would approve the Savanna RVP4 test in 2023; (c) problems with Savanna RVP4 were "widely known;" (d) QuidelOrtho applied for FDA approval in 2023 despite persisting and unresolved problems with Savanna RVP4; and (e) QuidelOrtho did not have the required data to obtain FDA approval, never achieving the consistent 95% sensitivity clearly required by the FDA for approval. *See* Section IV.F.

304. Although news regarding Savanna RVP4's 510(k) submission was artfully embedded in a press release that also reported positive news regarding QuidelOrtho's receipt of FDA 510(k) clearance for its QuickVue COVID-19 Test, analysts and investors were shocked by this disclosure, which completely contradicted Defendants' statements, including Defendant Bryant's statement from just two months earlier that the 510(k) submission for Savanna RVP4 was "*still on track*" for approval before the end of the first quarter of 2024. Even more stark was the

juxtaposition of this disclosure next to the lengthy discussion of Savanna RVP4 by Defendants Iskra and Bujarski less than a month earlier during a March 5, 2024 conference. There, in response to an analyst question about “any updates to share today in terms of RVP4 and kind of how you think about the timeline for getting that to market and really kind of being able to go pedal to the metal in that portfolio?,” Defendant Iskra confirmed that the Company was “***absolutely clear***” that its “***first priority is execute on Savanna***,” that the “focus around Savanna is building out the menu and delivering that,” and confirming that, as to Savanna revenues, “whether it’s \$250 million, \$275 million or \$245 million, it’s a big number, it’s a big opportunity, and we still believe in it.”

305. Analysts reported on this surprising negative disclosure. William Blair analyst report issued on April 2, 2024 commented on the fact that QuidelOrtho “management did not provide much detail around what specifically went wrong” and stated that: “***[t]he news on Savanna does not help improve sentiment on shares, and we are not all that surprised to see the stock trading down high-single-digits in this morning’s session.***” Noting that Savanna RVP4 “is a required assay to help drive a meaningful number of platform placements,” William Blair made clear that withdrawal of the FDA application came at a “critical time that is potentially lost for the company” as similar products offered by QuidelOrtho’s competitors like bioMerieux and its similar Spotfire platform obtaining 510(k) clearance and CLIA-waiver approval in March. Similarly, a Raymond James analyst report issued on the same day commented on the decline in QuidelOrtho’s share price, stating that this “***news likely represent[s] the proverbial last straw for some holders.***”

306. Following this news, QuidelOrtho’s share price sank by **10%** on unusually high trading volume, falling \$4.97 per share from a \$47.12 per share opening price on April 2, 2024 to a \$42.15 per share closing price on April 2, 2024.

I. After the Class Period Ends, Savanna Faces Additional Setbacks and Delays, Endemic COVID Revenues Decline Further, and More C-Suite Executives Are Fired

1. QuidelOrtho Appoints a New CEO While Firing More High Level Executives

307. On May 2, 2024, QuidelOrtho announced the appointment of Brian J. Blaser as President and CEO, effective May 6, 2024. Analysts approved of Blaser's appointment, hoping that his leadership would be more transparent than his predecessor. For example, a Raymond James analyst report issued on May 2, 2024 commented on the new CEO appointment, stating that: "[o]ur initial reactions are positive, with the strong fit and rapid hire helping set the stage for QuidelOrtho to push to the future with clear leadership, and we hope, clear communication and realistic expectation setting, both of which created challenges for investors in the past."

308. Shortly after Blaser's appointment as CEO, on May 8, 2024, QuidelOrtho announced mass layoffs, including a 5%-6% reduction in the Company's overall headcount that would result in about \$100 million in cost savings.

309. More C-suite firings followed. On July 31, 2024, newly appointed CEO Blaser announced the termination of Defendants Iskra and Bujarski, effective November 15, 2024. Both Iskra, as Chief Commercial Officer and interim CEO, and Bujarski, as Chief Operating Officer, were directly involved with QuidelOrtho's flailing Savanna efforts and the Company's operations, including COVID-19 sales and revenues, throughout the Class Period. On October 9, 2024, Senior Vice President of R&D, Werner Kroll, was replaced by Jonathan Siegrist, who would become the Company's new Executive Vice President of Research & Development and Chief Technology Officer. Kroll had overseen the development of Savanna and, as discussed above, Kroll was consistently made aware of Savanna's design, functionality, and manufacturing issues and reported those issues to the Board at every Board meeting.

2. Savanna RVP4 Suffers From Continued Delays and Bad News

310. On May 8, 2024, when the Company reported its financial results for the first quarter of 2024, Defendant Busky disclosed that QuidelOrtho expects “Savanna revenue will be immaterial in 2024, with no expected US respiratory revenue contribution from Savanna in the 2024-2025 respiratory season.” This stood in stark contrast to Busky’s statements only three months earlier that Savanna RVP4 would be market-ready in 2024, “[a]nd then Savanna becomes more accretive with continued growth in 2025.”

311. Analysts took note of this critical pivot in messaging about Savanna. An RBC Capital analyst report issued on May 9, 2024 stated that: “[e]ncouraging analysts to take \$75m of COVID and all ‘24 Savanna revenue out of their models was a good idea, in our view; and we think was one of the more prudent decisions made by management since Savanna was first submitted to the FDA (>10 years ago).” A Raymond James analyst report issued on May 13, 2024 reacted similarly, but emphasized that: “investors still have their doubts as the team needs to earn back credibility.”

312. Additional delays to Savanna’s launch continued throughout 2024. During the Company’s Q2 2024 Earnings call the following quarter, Blaser admitted that that: “[a]fter multiple delays and disappointments, Savanna is admittedly late to the party.” Analysts still viewed QuidelOrtho as “un-investible” given the Company’s “massive miss” for Q4 2023 earnings and the Company’s decision to pull guidance. For example, a Craig-Hallum analyst report issued on July 25, 2024 explained that QuidelOrtho “is now clearly late to the party and has yet to prove that Savanna can be a viable platform in the U.S.[,]” which is “an impediment to investor confidence” given that Savanna is a “key component” of the Company’s growth moving forward.

313. A clinical study report published on July 11, 2024 by the Institute of Medical Microbiology confirmed the accounts of many former employees whose accounts are alleged

herein. In this study, titled *Diagnostic accuracy of Savanna RVP4 (QuidelOrtho) for the detection of Influenza A virus, RSV, and SARS-COV-2*, the Institute of Medical Microbiology compared the diagnostic accuracy of Savanna RVP4 to its competitor Cepheid's similar product, Xpert Express, based on samples taken from patients in Germany in 2023-2024. The study confirmed what had long been evident to the Company, the Individual Defendants and numerous former employees and their colleagues throughout the Class Period: RVP4 could not consistently detect infection with the requisite 95% sensitivity.

314. The study specifically tested for three of the four infections targeted by RVP4 (COVID-19, Flu A and RSV, but not Flu B), and concluded that RVP4's sensitivity overall was between 85% and 95%, with ranges of (a) 72%-93% (average of 85%) for SARS-COV-2; (b) 75%-98% (average of 91%) for Flu A; and (c) 77%-100% (average of 95%) for RSV. These ranges and averages were in line with what the Company already knew, as explained by numerous former employees. The study also confirmed the significant number of invalid and defective tests produced—9.9% as compared to 0.7% of its competitor—and noted how that figure made the RVP4 test a poor candidate for acute and point of care testing where the need for immediate and accurate results was paramount. Specifically, the study found that the “proportion of erroneous and invalid RVP4 tests (**9.9%**, or 29 of the 292 swabs tested) was higher compared to Xpert tests (0.7%, or 2 out of 292 swabs tested),” which would “would limit the use of RVP4 as a point of care test, particularly in emergency units, when test runs are not continuously monitored by the staff to re-start the test in case of errors.” The reported number of erroneous and invalid results reflected in this study corroborate accounts of former employees that confirm Savanna RVP4 suffered from issues “across the board,” including an abnormally and even excessively high rate of invalid results. Further, Savanna RVP4's unsuitability for point of care placement corroborates

the accounts of multiple former employees that Savanna was not ready for EU launch and once launched, was fraught with customer complaints due to errors with the test.

315. Ultimately, by the Company’s Q3 2024 Earnings Call on November 7, 2024, Blaser disclosed that the Company now anticipated Savanna RVP4 entering the U.S. market “in the later part of 2025” with most of the “ramp-up” occurring in 2026 and 2027. To date, the Company has not announced that it has resubmitted the Savanna RVP4 assay—or any other new Savanna assay—to the FDA for approval.

3. QuidelOrtho’s COVID-19 and Respiratory Revenues Continue To Decline After the Class Period End

316. In the quarters immediately following the Class Period, QuidelOrtho’s COVID-19-related and other respiratory revenues continued to decrease. Specifically, the Company reported the following financial metrics, with significant year-over-year declines in total and respiratory revenue attributable to decreased COVID revenue:

Financial Metric	Q1 2024 (in millions)	YoY Delta	Q2 2024 (in millions)	YoY Delta	Q3 2024 (in millions)	YoY Delta
Total Revenue	\$711	(16%)	\$637	(4%) ¹⁴	\$727.1	(2.3%)
Respiratory Revenue	\$137	(48%) ¹⁵	\$58	(35%)	\$165.1	(10.8%)
Adjusted EBITDA	\$132	(46%)	\$90	(20%)	171	1.1%
Adjusted EBITDA Margin	19%	(34%)	14%	(17%)	23.5%	3.5%

317. In fact, during the Company’s Q1 2024 Earnings Call, Busky disclosed that QuidelOrtho was lowering the Company’s guidance for endemic COVID-19 revenue to **\$150**

¹⁴ The Q2 2024 Press Release states that the “decrease in total revenue was primarily due to lower COVID-19 revenue in the second quarter of 2024 compared to the prior year period.”

¹⁵ QuidelOrtho’s Q1 2024 Press Release states that the 48% decrease was “primarily due to lower COVID-19 revenue in the first quarter of 2024 compared to the prior year period.”

million for the full year 2024, down from a prior expectation of \$200 million. The Company also announced it was temporarily suspending guidance.

318. Two quarters later, when the Company reported its Q3 2024 results, QuidelOrtho reinstated the Company's previously suspended financial guidance—but below prior estimates—acknowledging the Company's prior guidance was overstated:

Financial Metric	FY 2024 Guidance (Prior)	FY 2024 Guidance (Reinstated)	Delta (midpoint)
Total revenues (reported)	\$2.76 - \$3.07 billion	\$2.75 - \$2.80 billion	(5%)
Adjusted EBITDA	\$565 - \$720 million	\$530 - \$550 million	(16%)
Adjusted EBITDA margin	21% - 24%	19.3% - 19.6%	(13.5%)
Adjusted diluted EPS	\$2.40 - \$3.07 million	\$1.69 - \$1.91	(34%)

319. By January 6, 2025, QuidelOrtho's stock had crashed 40%, or \$30.18, in 2024. According to *News Bites Finance's* Global Round Up – Bullish and Bearish Signals, Quidel's stock has underperformed 94% of NASDAQ-listed stocks in the same period of time. This is, fundamentally, a relative price change of -65.3% as compared to the NASDAQ-100 Index, which rose 24.9% over the same period.

V. DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS

320. Defendants Bryant, Busky, Bujarski, Iskra, and Ranalli made materially false and misleading statements and omissions concerning: (i) the progress, success, and feedback regarding QuidelOrtho's European launch of Savanna RVP4; (ii) Savanna RVP4's readiness for a U.S. launch and FDA approval; (iii) the Company's ability to manufacture Savanna RVP4 at the necessary scale to achieve over \$75 million in revenue synergies and \$300 million in overall revenue; and (iv) QuidelOrtho's endemic COVID-19 revenue. The following identifies each of Defendants' materially false and misleading statements and the reasons for each statement's

falsity. Lead Plaintiff alleges generally that the statements that are ***bolded and italicized*** are materially false and misleading.

A. Defendants Misrepresented the European Launch of Savanna RVP4 Throughout the Class Period

321. The Company launched Savanna RVP4 in Europe in late 2021, while the Merger with Ortho was being negotiated and then announced publicly on December 23, 2021. A few weeks prior to the start of the Class Period, Defendant Bryant made clear to investors that Savanna is “the most important product in [the C]ompany’s history.” Throughout the Class Period, which begins on February 17, 2022 after the markets closed, Defendants made a series of consistently false and misleading statements regarding the progress, success, and feedback given regarding Savanna RVP4’s performance in Europe, affirmatively assuring investors that Savanna RVP4 was performing well and receiving positive feedback from its European launch customers. Specifically, Defendants made the following false and misleading statements throughout the Class Period:

(a) On February 17, 2022, in the Company’s earnings release for the fourth quarter and fiscal year 2021 (“Q4 2021 Earnings Release”), Defendant Bryant stated: “***Based on customer reviews in Europe, we believe Savanna will be a major growth driver, both in the U.S. and globally, for years to come.***”

(b) Also on February 17, 2022, during an earnings call to discuss these results (“Q4 2021 Earnings Call”), Defendant Bryant stated: “We’re in market in a limited launch with our Respiratory Viral Panel 4 respiratory panel and ***have received very positive customer feedback to date***, including requests for additional instruments.”

(c) On March 9, 2022, during the Raymond James Annual Institutional Investors Conference, Defendant Bryant stated: “That’s Savanna, ***that’s beautiful, performing***

very nicely in Europe right now. We're hearing really nice feedback. I think it's the right design for the market at this time."

(d) During the same conference, an analyst asked about Savanna and whether any of its panels were "more applicable" to different locations. In response, Defendant Bryant stated: "We launched in Europe, it was the safest, easiest. We have a direct sales force there. And so we've placed units with a small number of customers. Each one of those [European customers] -- well, one in particular, dramatically increased the number of units they wanted after they had experience with it. So that was encouraging. *We're receiving some really nice feedback.* But that's just RVP4 at the moment."

(e) On June 8, 2022, at the Willaim Blair Annual Growth Stock Conference, Defendant Bryant stated: "*we just launched Savanna in Europe in a couple of different countries [sic] have done super well. We took pretty significant share from [indiscernible] recently in Italy. And I think right now the demand creation is not the issue.*"

(f) On August 4, 2022, during an earnings call to discuss the Company's second quarter 2022 results ("Q2 2022 Earnings Call"), Defendant Bryant stated: "*Our limited European launch of Savanna with RVP4 continues to go well with some early wins. As manufacturing capacity ramps, we plan a full European launch in Q4, followed by 2023 menu expansions.*"

(g) On September 12, 2022, during the Morgan Stanley Global Healthcare Conference, Defendant Bryant stated: "*And we've been pretty pleased with what we've done in Europe with the Savanna launch early on and I would say it portends well for the rest of the globe.*"

(h) On September 13, 2022, during an episode of *Repertoire* Podcast entitled “QuidelOrtho provides easier, faster test results with new molecular platform,” Defendant Ranalli stated: “We actually obtained CE marking and we’ve done a launch in Europe around Christmas time last year. So we’ve been available in the market and *we have been [sic] great feedback from our initial customers.*”

(i) On November 2, 2022, during an earnings call to discuss the Company’s third quarter 2022 results (“Q3 2022 Earnings Call”), Defendant Bryant stated: “*we are shifting boxes that we had intended to ship early in the United States to Europe where, frankly, the folks there have been asking for more boxes than we are shipping. So it’s just that straightforward.*”

(j) Also on the Q3 2022 Earnings Call, Defendant Bryant stated: “*we are seeing demand in Europe and are increasingly confident that Savanna placements and revenue will accelerate throughout 2023.*”

(k) On December 13, 2022, in the investor presentation that accompanied QuidelOrtho’s 2022 Investor Day, QuidelOrtho, in a slide dedicated to Savanna, stated: “Our Differentiator Personalized, *Prompt & Precise*,” also writing “Less than 25 minutes from sample to result *without sacrificing quality & performance.*”

(l) On December 13, 2022, during a conference call held in connection with QuidelOrtho’s 2022 Investor Day, Defendant Ranalli stated: “On the second part of the slide, you’ll see our three-year Savanna installed base target of 6,000 boxes and our three-year Savanna run rate target, which is greater than \$250 million in revenue. This is a slight adjustment to what you may have seen previously. *The number of installed base target is a little bit lower. However, the pull-through in those installed bases is a little bit higher, right. And this is based on the data*

that we're seeing with our current launch in Europe. So, fewer boxes placed, but those boxes are running at a higher rate than our original estimation."

(m) On January 9, 2023, during the 41st Annual J.P. Morgan Healthcare Conference, Defendant Bryant stated: "*We've demonstrated in Europe and elsewhere that there is demand. We see pretty strong demand expressed by US customers as well for this product, and we have a wait list. So, I think this is going to go well . . . If I'm wrong, you won't see me here next year. I'll be hiding.*"

(n) On February 15, 2023, during an earnings call to discuss the Company's fourth quarter and fiscal year results for 2022 ("Q4 2022 Earnings Call"), Defendant Busky stated: "*Savanna sales in Europe are expected to drive strong growth within our Molecular Diagnostics business, which, along with the expected ramp in the US volumes after receipt of regulatory clearance, are expected to drive meaningful revenue in the back half of the year.*"

(o) Also during the Q4 2022 Earnings Call, an analyst asked Defendant Bryant a question regarding the "cross-selling excitement" that he referred to earlier. In response, Bryant stated: "*And I think it would be fair to say that we've been reasonably successful in a limited launch in Europe with Savanna too.*"

(p) On May 3, 2023, during an earnings call to discuss the Company's financial results for the first quarter 2023 ("Q1 2023 Earnings Call"), Defendant Busky stated: "*Savanna sales in Europe are expected to ramp as we move through the year, which along with expected U.S. volumes after anticipated receipt of regulatory clearance are expected to drive meaningful revenue in the back half of the year.*"

(q) On August 8, 2023, during an earnings call to discuss the Company's second quarter 2023 results ("Q3 2023 Earnings Call"), Defendant Bryant described how, while

the molecular diagnostics business had declined because of declining Lyra assay sales, “***Notably, this was partially offset by Savanna, which continued to perform well in the EU***, with a modest improvement in sales year-over-year. ***Given the product’s ease-of-use and industry-leading speed, we are seeing a lot of customer interest and have expanded our reach to more customers across Europe.***”

(r) On November 30, 2023, during the Evercore ISI HealthCONx Conference, Defendant Bryant was asked about “longer term, what is the Savanna thesis, what should we expect from Savanna?” to which Bryant responded: “Well, we like the idea of the small syndromic panel and when you think about you’ve got competitors that have very large panels and you have competitors that have just one or two assays. And I think that the smaller syndromic panel of 4 to 5 analytes, I think the largest panel we have has 11, but those needs that exist out there we think can be addressed with something that’s faster and simpler, easier to run and frankly just more modern will be supercompetitive. And that’s what our marketing data says. ***And we do have customers in Europe***, we do have IUO customers in the US ***and the feedback at this point has been encouraging.***”

(s) On January 8, 2024, during the J.P. Morgan Healthcare Conference, Defendant Bryant stated: “***I think we can talk more during Q&A, if you like, about the attributes of Savanna. But we already have evidence both in Europe and ex-US and now in the United States that we’re going to be extremely competitive.***”

322. Each and every statement identified in ¶321(a) – (s) was materially false or, at a minimum, misleading when made. Defendants’ consistent statements throughout the Class Period that they, for example, “received ***very positive customer feedback to date***” in Europe, that Savanna RVP4 was “***performing very nicely in Europe right now***,” that the Company was “***hearing really***

nice feedback” and *“have done super well”* with the European Savanna launch, that the *“limited European launch of Savanna with RVP4 continues to go well with some early wins”* and *“portends well for the rest of the globe,”* that the Company had received *“great feedback from our initial customers”* in Europe, that based on “demand in Europe,” the Company was *“increasingly confident that Savanna placements and revenue will accelerate throughout 2023,”* that Savanna was *“prompt & precise” “without sacrificing quality & performance,”* that “we’ve been reasonably *successful in a limited launch in Europe with Savanna,*” that Savanna *“continued to perform well in the EU”* where *“we are seeing a lot of customer interest,”* and that European *“feedback at this point has been encouraging”* not only lacked any reliable foundation, but were directly contradicted by the actual, consistently poor performance of RVP4 in Europe, as directly reflected in the number of defective and invalid RVP4 tests, defective Savanna instruments and related string of escalating customer complaints, the sum total of which caused FE-7, QuidelOrtho’s Marketing Manager, Molecular Dx (EMEA), to state that he “didn’t remember any market launch that was so full of issues” in his twenty-year career.

323. Put simply, the European launch of Savanna RVP4 was an abject failure, which was confirmed by former employees and described in detail above (*see* Section IV.F). FE-4 noted that there were concerns about Savanna from the “beginning” of its European launch due to technical challenges, such that “no one was confident” that it would work when QuidelOrtho launched the Savanna RVP4 test in Europe. Moreover, regarding Savanna’s development, FE-12 stated the Company took “so many shortcuts,” which led to making mistakes, because it was rushing to get Savanna RVP4 to market, such that the process of bringing Savanna to market was, according to FE-6, akin to “flying a plane while building it.” FE-4, who had the “best pulse” on Savanna RVP4’s performance in Europe, knew of Savanna’s technical challenges by June 2022,

if not earlier, and confirmed QuidelOrtho's European customers were "irate" over the test's one-in-four replacement rate due to technical issues and invalid results.

324. Further, according to FE-10, by mid-2022, employees at QuidelOrtho turned from optimistic about Savanna to perceiving that it was "not a real thing" and joked that Savanna was a fraud and was QuidelOrtho's version of fraudulent diagnostic device Theranos. While Savanna was praised as a reason for the Merger, FE-10 and his colleagues remarked, "wait until they see that it doesn't work." FE-2 confirmed that issues with Savanna RVP4 and engineering issues were not fixed by the time it went on sale in Europe and by April 2024, RVP4 still "wasn't stable enough to launch to market" in the United States.

325. These pervasive problems with Savanna were well-documented and reported to the Individual Defendants. Specifically, FE-4 explained that the Company held at least monthly calls, on which Defendant Ranalli (who reported to Defendant Bryant) was present, to discuss Savanna's negative feedback and customer complaints. FE-7 similarly recalled "many, many" weekly meetings in which problems with Savanna were frequently discussed. Specifically, FE-7 recalled an instance where, during a presentation with the Head of EMEA Molecular Diagnostics in 2023, a quarterly report reflected that out of 80 units, there were 85 complaints, including problems with the instruments, the tests, or both. FE-7 explained the problems with Savanna were so bad that that every time a new instrument was sent to a customer, the Company sent them an additional, back-up instrument so that the customer would shift to the back-up instrument if problems arose, increasing QuidelOrtho's inventory and production costs.

326. Further, according to FE-8, mounting complaints from European Savanna RVP4 customers were so significant that the Company opened a field investigation and subsequent CAPA investigation to identify the root cause of the issues which had still not been resolved as of

July 2024, and was reported internally in monthly or quarterly business unit reports. FE-13 confirmed that issues with Savanna were communicated to the C-suite “all the time,” because Savanna was supposed to be the Company’s next big “money-maker,” and “everyone” knew about its problems. FE-12 confirmed that QuidelOrtho’s management kept “pushing aggressively” to generate data to release the assays as soon as possible as Savanna was supposed to be a “money maker” for the Company.

B. Defendants Misrepresented Savanna’s Readiness for a U.S. Launch and FDA Approval Throughout the Class Period

327. Throughout the Class Period, Defendants made a series of objectively false and misleading statements regarding the progress of the development of Savanna RVP4 for FDA approval, RVP4’s satisfaction of FDA threshold requirements, and readiness for a U.S. launch. Specifically, Defendants made the following false and misleading statements throughout the Class Period:

(a) On February 17, 2022, in the Company’s Q4 2021 Earnings Release, Defendant Bryant stated: “*Our key near-term opportunity is the anticipated U.S. launch of our revolutionary Savanna multiplex molecular platform*, which allows for testing of up to 12 pathogens from a single sample in less than 25 minutes.”

(b) Also on the Q4 2021 Earnings Call, Defendant Bryant stated: “And *as long as we’re on the subject of future cash flow strength, I’d also like to address progress we’ve made with our revolutionary Savanna platform and what lies in store for us as we prepare for its U.S. launch later this year. The Savanna platform will be our next flagship product, and we are incredibly proud of the progress made to date.*”

(c) On March 9, 2022, during the Raymond James Annual Institutional Investors Conference, Defendant Bryant was asked about RVP4 and other panels represented to

be in development (“RVP11, HSV/VZV, GI, pharyngitis”), and specifically, his thoughts “about the rollout in international versus U.S. and maybe closer to the point-of-care versus more in the hospital setting.” In response, he stated: “We see demand right now in Europe. We think we will see demand in South Africa pretty quickly. *And then here, it’s just about – it’s a matter of timing in terms of FDA clearance.*”

(d) On November 2, 2022, during the Q3 2022 Earnings Call, Defendant Bryant stated: “*We continue to focus on overcoming manufacturing and supply chain challenges as we ramp up production of both instruments and cartridges. Additionally, we completed development activities for all Savanna panels planned for launch in 2023.*”

(e) Also on the Q3 2022 Earnings Call, when asked for an update regarding Savanna timelines, Defendant Bryant stated: *There’s nothing really that’s changed in terms of when the panels will be launched. The only addition is that we’re pulling up some of our thoughts with respect to 510(k) submission So again, there’s nothing really different in terms of the timelines that we’ve communicated before.*”

(f) Defendant Bryant was asked directly on the Q3 2022 Earnings Call to confirm that with respect to “the \$300 million guide out there for a three-year period. No change to that if US gets pushed out, it’s just kind of coming from different places. Is that right? And then I guess with that \$300 million, that guide you do have out there, I know it’s not going to be linear, right, so how do we think about that as we work our way through 2023, assuming, let’s say, US gets pushed out a little bit?” Bryant responded that: “*we’re not making any change to the \$300 million plus target that we had over the three-year period. We’re just shifting where we’re sending the product based on the availability. So we’re not going to need to allocate so much as we might have before between the two major continents.*”

(g) On February 15, 2023, during the Q4 2022 Earnings Call, an analyst asked Defendant Bryant for an update on the Savanna timeline. In response, Defendant Bryant stated: *“We’re still expecting RVP for EUA in April and the 510(k) will be just shortly after that. So, we’re very much on track for the launch. As I said, the instrument build issues have been largely resolved. We think we are already at the capacity to have a meaningful launch.* And we’re at the point where we’re most – *most of the effort right now is around cartridge ramp up. . . . we expect to have the ability to make millions of cartridges very shortly.”*

(h) On March 7, 2023, Defendant Bryant responded to questions about the Savanna FDA approval process during the Raymond James Institutional Investors Conference, where the analyst asked, “is there anything incremental since you last spoke about the conversations with FDA, your expectations on EUA versus 510(k) or anything in that front?” In response, Bryant stated: *“We expect EUA either in April or worst case early May. . . . But for the moment, we’re still sticking to this idea that we should be able to generate \$30 million to \$40 million in Savanna revenue, which obviously includes what we’re doing in Europe now too.”*

(i) On May 3, 2023, during the Q1 2023 Earnings Call, an analyst asked Defendants for an update on the Savanna U.S. launch. In response, Defendant Bryant stated: “First point is that we’re in process of submitting the EUA for RVP and simultaneously, we’re working on the submission of the 510(k) package. *So from a timing perspective, I think we’re in reasonably good shape to be ahead of the upcoming respiratory season. In addition, I think our confidence comes from having solved supply chain issues and now more reliably making and stocking instruments. So that’s not going to be a challenge for us. And we now have the second line nearly validated on the cartridge manufacturing,* which puts us in really good shape in terms of the volumes that we require in 2023 and 2024. So we’re pretty confident.”

(j) Also on the Q1 2023 Earnings Call, Defendant Bryant stated: “*We’re anticipating an expanded global launch ahead of the next respiratory season . . . So, Savanna is coming, the platform is robust and the total addressable market is huge. The outlook is exciting.*”

(k) On the same Q1 2023 Earnings Call, in response to an analyst question regarding whether Savanna could still “get EUA” given that “COVID is no longer considered an emergency by the White House” or “is it going to be a 510(k) that’s ultimately the approval path in US, just what is that timeline?,” Defendant Bryant stated: “*Savanna meets the criteria that the FDA are looking for* I have no reason to believe that the products that we have submitted will not be.”

(l) On June 6, 2023, at the William Blair Growth Stock Conference, Defendant Bryant stated: “*And then finally, the one that we talk about, in fact, have talked about in every single meeting today is the launch of Savanna, which we’re very close to in the United States. We did launch in Europe in a limited fashion. Learned a lot there. We’re in a position where we’re building inventories of instruments and cartridges in order to support Europe. This year, the US beginning in the fourth quarter, and then also supplying of cartridges for all of our clinical trial sites for a number of syndromic panels. So those are the three near-term drivers.*”

(m) On the same call, in response to an analyst question regarding “How important is Savanna” to achieving “6% to 9%” growth, Defendant Busky stated:

And then finally, Molecular, *coming back to Savanna, we do expect to get regulatory clearance in the US on the Savanna product and start placing those boxes as we move into the fourth quarter of this year.* We haven’t really talked too much about the slope of that revenue ramp in 2024 and 2025. But we have said that *we expect three years post-launch that will be greater than \$250 million of revenue on that Savanna product.*

(n) On the Q3 2023 Earnings Call, an analyst asked, “how the initial launch of Savanna in Europe went” and whether the Company was seeing “share gains take place and how that has changed the initial US game plan once we get the approval?” In response, Defendant Bryant stated: “Well, I think it’s a bit of foreshadowing of what we might expect. The competitors that we thought based on European feedback might be vulnerable were indeed those same 2 competitors *and we’ve done there quite well. The issues that are reported in Europe we see as being applicable here in the United States, too. So particularly with respect to the respiratory launch, I think we’re in really good shape here in the US*”

(o) On September 12, 2023, during the Morgan Stanley Global Healthcare conference, an analyst asked Defendants “what is the path to a broader presence in Europe for Savanna look like?” In response, Defendant Bryant stated: “Well, first, realize, we did a limited launch. . . . *And so, as we’re about to enter our largest opportunity, our largest market, we will have resolved some of the things that would have needed to be resolved had we not launched somewhere else first.*”

(p) On November 30, 2023, during the Evercore ISI HealthCONX Conference, an analyst asked Defendant Bryant “what’s happened with Savanna? It looks like there was some timing pushout.” In response, Bryant stated: “*Let’s be completely open. We submitted to the FDA in July and we completed the clinical trial during the summer. There was a lot of to-and-fro and we’ve been in communication constantly with the FDA.* The one issue which we’ve agreed was that we needed to run some samples during respiratory season. And *the FDA’s concern wasn’t the performance of the product. It was they want to see how the instrument and cartridge performs with respiratory season samples...*”

(q) On January 8, 2024, during the J.P. Morgan Healthcare Conference, Defendant Bryant was asked: “Can you give us a sense of when we should expect the RVP4 panel, should that be approved during the respiratory season here? And just kind of yet any update on what you’ve heard from the Agency or anything?” to which he responded: ***“Well, we’re in good shape. And I would commit to being in market before the end of the quarter.”***

(r) On February 13, 2024, during an earnings call to discuss the Company’s fourth quarter and fiscal year results for 2023 (“Q4 2023 Earnings Call”), Defendant Bryant was asked: “And then on Savanna, I just want to understand, I guess like the gating factors to getting RVP4 approved, is there any – do you feel like you have all the trial activity you need done at this point? That’s number one. And number two, when do you expect to be CLIA Waiver for Savanna? Does that come in conjunction with RVP4 or do you think that’s later in the year?” In response, Bryant stated: ***“The status of the submission of the 510(k) is on track from 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.”*** On that same call, Bryant stated: ***“We are advancing both with FDA review of our RVP4 panel and others in the queue. Our US sales team is meeting this week, and I can assure you a successful Savanna commercial launch is on their menu as well.”***

(s) Defendant Busky further stated on the Q4 2023 Earnings Call that: ***“We continue to expect Savanna instrument placements of approximately 1,000 in 2024, which will pave the way for 2025 Savanna revenue growth.”***

(t) On March 5, 2024, during a Raymond James Institutional Investors Conference, Defendant Iskra was asked: “And maybe we’ll just go to Savanna now. Any updates to share today in terms of RVP4 and kind of how you think about the timeline for getting that to

market and really kind of being able to go pedal to the metal in that portfolio?” In response, Iskra stated:

So, the focus around Savanna is building out the menu and delivering that. RVP4+ for us, our focus right now is primarily in the back end of the year. That's the flu season and the respiratory season. We're pretty much coming out of the opportunities to be in place for that by the end of the year. Somebody asked me if I was comfortable with where we are on that, and I'll tell them same thing. I'm totally like, I won't be comfortable until I see it, right? So, let's just be honest about it. We are dealing with some things we don't fully control. But for the things we do control, I would tell you it's getting a lot of attention, right? All three of us [Iskra, Busky and Bujarski] and others are heavily focused on it and doing all we can do to get not just RVP4 out, but the other menu items. And that's what we need.

(u) On the same call, an analyst asked Defendant Iskra about the “arrows in the quiver” at QuidelOrtho, based on previous opportunities touted for Point of Care and Molecular, and “where are we in terms of kind of really driving that traction today?” In response, Iskra stated: *“we still firmly believe that the market opportunity in Molecular where we are today provides a great opportunity,”* and *“Savanna is made for this market, which we're well across ease of use, on performance, and on cost. . . . I'll make it absolutely clear: our first priority is execute on Savanna, get a foothold there, and then expand.”*

(v) During the same call, another analyst asked Defendants Iskra, Bujarski and Busky about the “\$250 million run rate goal” for Savanna, quizzing them about whether that “is still the goal” and “is it still kind of what we should be thinking about and expecting?” In response, Defendant Iskra stated *“\$250 million is the goal, and it's out there”* and “net-net, we are driving to that number, but we're watching a lot of things that will factor into it. But nonetheless, *whether it's \$250 million, \$275 million or \$245 million, it's a big number, it's a big opportunity, and we still believe in it.*”

(w) The same analyst followed up and asked, “as you think about the bridge to get there, and you mentioned the menu, what's your vision of what that menu looks like at that

point? Is it, hey, we've gotten RVP4, RVP11, syphilis added. Is it five assays? Is it 7, 10? Like what does it take to get there?" Defendant Bujarski responded: "I think *the ones that the field, I would say, is most interested, RVP4 with CLIA Waiver, right? Without the CLIA Waiver, you just don't get to the breadth – you don't get to the breadth of the placement. So, that's going to be a key catalyst* as well as STI. And those are the first two. Now, that might not get you to the \$250 million, but when you start to say, when do we start to get traction, what gets the field very excited, *those are the ones right out of the gate. So, when you're thinking about 2024, you're thinking about our focus, more so than a revenue number for 2024, any of that. You got to have the menu to really make this platform a success, and those are the ones that we're focused on straight away.*"

328. Defendants' statements in ¶327(a) – (w), including their statements about the Company's ability to satisfy the FDA's requirements for RVP4 approval (¶327(g), (h), (k), (m), (p), (r)); about how the Company is "now more reliably making and stocking instruments" (¶327(i); *see also* (¶327(d), (l)); and about how Savanna's "technical issues are not obviously insurmountable" and the Company will have "resolved some of the things that would have needed to be resolved had we not launched elsewhere first" (¶327(o)), were materially false and misleading when made. *See generally, supra*, Section IV.F.

329. For example, as explained further above in Section IV.F.2-3, undisclosed to investors was the fact that the Company's production of RVP4 resulted in an unacceptable number of invalid test results, which would prevent both FDA approval and any successful launch in the United States. As FE-4 explained, approximately 25 percent of the RVP4's test assays yielded an invalid result, which is "the worst result for a clinician," according to FE-4. FE-7 confirmed that

Savanna’s invalid rate was “definitely double digits,” between 10-30%, much higher than the 1-2% industry standard.

330. Former employees also demonstrate why representations identified in ¶327(c), (e), (f), (g), (h), (k), (m), (p), (r)), such as Defendant Bryant’s statement that he had “*no reason to believe that the products that we have submitted will not be [FDA approved]*,” were false and misleading. As described above, the FDA set out a clear requirement that, in order to secure approval to sell in the United States, the RVP4 would have to demonstrate a consistent result of 95% sensitivity for detecting infection, and the Company simply never met that standard, either before or after its RVP4 FDA submission. *See supra*, Section IV.F.2-3. For example, according to FE-1, the FDA laid out a test plan for the approval of Savanna, which required RVP4 to meet a certain functional level of approximately 95% or higher for detectability and accuracy. Defendant Bryant, FE-1 explained, had a practice of “open dialogue” with the FDA, and FE-1 confirmed the FDA’s problem with Savanna was its consistency, and the test’s inability to consistently meet the requisite targets. FE-1 confirmed that the Company knew it was not meeting the FDA’s requirements when it submitted its 510(k) application for clearance to sell Savanna RVP4 in the U.S.

331. Other former employees consistently confirm that the RVP4 never satisfied the FDA’s requirements. For example, FE-11 explained that most tests have a sensitivity of 95% but that the Savanna RVP4 test “never came close” to that figure. FE-4 confirmed that QuidelOrtho “pushed” for FDA clearance even though employees who worked directly or indirectly with the Savanna RVP4 test knew that the test had “glaring issues.” Both FE-4 and FE-2 described how Prange, the Associate Director of Assay V&V, R&D, whose studies were critical to QuidelOrtho’s regulatory submissions, stated that the RVP4 did not satisfy FDA requirements and directly

commented to FE-4 that the Savanna RVP4 test “does not work” and that it “isn’t even a product.” FE-4 recalled that Prange received “a lot of pressure” from a “top-down mandate” at the Company to approve Savanna “no matter the cost.”

332. FE-2 further explained that Kroll met with the Board and senior management quarterly to provide project updates on Savanna, and senior management, including specifically Defendant Bryant, was made aware of Savanna’s issues with its failure rate and assay problems at the time it was submitted to the FDA in mid-2023 and thereafter. RVP4’s inability to meet the FDA’s requirement for consistent 95% sensitivity rates was corroborated by a study published after the close of the Class Period demonstrating that European samples from 2023-2024 failed to meet 95% sensitivity in a consistent manner, or at all, depending on the infection being tested for. *See* ¶¶313-14.

333. Further, Defendants’ statements in ¶327(f) and (h) were also false as they mislead investors about the Company’s ability to rely on European Savanna RVP4 sales to make up for the loss of anticipated revenues from the delayed U.S. launch. When Defendant Bryant explained on November 2, 2022 that if the U.S. launch gets “pushed out a little bit,” the Company was “*not making any change to the \$300 million plus target that we had over the three-year period*” because “[w]e’re just shifting where we’re sending the product based on the availability . . . between the two continents,” and on March 7, 2023 that “*we should be able to generate \$30 million to \$40 million in Savanna revenue, which obviously includes what we’re doing in Europe now too*,” he indicated that sales in Europe were sufficiently material to offset the hundreds of millions of dollars of projected revenue. *See* ¶327(f), (h); *see also* ¶327(j), (l). However, as was later disclosed on June 5, 2024, the Company generated only \$2.56 million from Savanna RVP4 sales in Europe in 2023, which equated to 0.08% of total Company 2023 revenue, or \$640,000 per

quarter. That nominal figure was “a modest improvement over” 2022 European Savanna sales, as Defendant Bryant commented on August 8, 2023 that Savanna “continued to perform well in the EU with a modest improvement in sales year-over-year.”

334. Moreover, Defendants’ statements that the Company was “very much on track for the launch” and that they were “anticipating an expanded global launch ahead of the next respiratory season” and similar statements made above in ¶327(a), (b), (j), (n), (p), (q), (s) were false and misleading for the reasons stated above and herein because, in truth, Savanna RVP4 suffered from a myriad of issues that kept it from FDA approval. *See generally*, Section IV.F. For example, FE-2 stated that issues with Savanna RVP4 were not fixed when it went on sale in Europe, were not fixed when it was sent to the FDA for approval and were not fixed by September 2023.

335. Defendants’ statements regarding the specific timing of FDA approval for Savanna identified in ¶327(p) – (r) were false and misleading for the additional reason that, in August 2023, Bryant stated that the Company would not comment on the status or timing of the FDA submission, noting that “once we make submissions to the FDA and they are under active review, we don’t comment any further” and that with respect to discussions with the FDA, there was “not one [part of the process] which we can discuss while the products are under active review.” Yet, as months went by without approval, desperate to paint a positive picture for investors, Defendants began to make false and unsubstantiated statements about the very things they said were improper just months earlier, namely that after submission to the FDA in July, “*the FDA’s concern wasn’t the performance of the product,*” that Defendant Bryant “*commit[ted] to being in market before the end of [Q1 2024],*” and that the “*status of the submission of the 510(k) is on track . . . we expect to get clearance before the end of the first quarter.*”

336. Defendants Bryant, Iskra and Bujarski’s 2024 statements about Savanna RVP4 and its path for 2024 approval and revenue generation (§327(t) – (w)) were glaringly false and misleading. Even by the Company’s own admission on April 2, 2024, in February 2024, the Company knew unequivocally that “the final dataset, submitted in February 2024, did not meet our expectations” and the FDA did or was about to reject the application if the Company did not withdraw it. Of course, as alleged fully herein, it was not just a “final dataset” from February that did not meet the FDA’s threshold for clearance. As numerous former employees explained, at no point before or during the Class Period was the Company able to consistently achieve a 95% sensitivity, or detectability, percentage—the objective threshold that the FDA clearly established for the test. *See generally* Section IV.F.3.

337. Moreover, Defendants also made the following false and misleading statements regarding the development of and timing for additional panels for Savanna beyond RVP4:

(a) On September 13, 2022, during an episode of *Repertoire* Podcast entitled “QuidelOrtho provides easier, faster test results with new molecular platform,” Defendant Ranalli discussed six additional Savanna tests “that are actually currently in development,” which is contradicted by several former employees:

In addition to RVP4, which we are going through the EUA process with that panel, we will have a larger respiratory panel, which is the full RVP11. And that includes a whole host of the most common different respiratory viruses. Again, those things like adenovirus and parainfluenza and human metapneumovirus. ***But outside the respiratory world, which we obviously do love, we’re going into some GI panels.*** So we’ll have a parasite panel and a combo bacterial viral panel. And so a lot of these are foodborne pathogens or viruses or parasites that you would get endemic in different areas. ***And then we’ll have a sexually transmitted infection panel. And so that will include mycoplasma genitalium, trichomonas, chlamydia, and gonorrhea. So the four most common STIs all in the same panel. We’ll have a broader pharyngitis panel.*** Most of you guys are probably aware that in addition to Group A strep, you know, we were the first company to come out with a strep C and G. ***And we’re also adding a couple of different bacterial pharyngitis causes onto a comprehensive pharyngitis panel. We have a HSV-VZV panel, which***

we're adding syphilis to as well. So that's kind of an all-encompassing lesion panel. And then finally, a vaginitis panel. And those are the ones that are actually currently in development. That's not, you know, we're actually adding more and more new products that I can't talk about yet. But *those are the next six that are coming out that we're super excited about.*

(b) On February 15, 2023, during the Q4 2022 Earnings Call, Defendant Bryant stated: *"Beyond [HSV and RVP4], we expect to begin clinical trials for RVP11, STI, two GI panels, bacterial, viral and a parasite panel, pharyngitis and vaginitis. We have purposely focused our initial menu on these areas to take advantage of Savanna's unique features, faster turnaround time, test flexibility, and lower total cost of ownership."*

(c) On the Q1 2023 Earnings Call, Defendant Bryant stated: *"Our initial menu includes our RVP4 Respiratory Viral Panel, followed by an HSV/VCZ lesion panel, RVP11, a panel for sexually transmitted infections including chlamydia, gonorrhea, mycoplasma genitalia and trichomonas vaginalis, plus two gastrointestinal panel, one bacterial and/or viral and the second parasitic, a pharyngitis panel, and a vaginitis panel."*

(d) Also on the Q1 2023 Earnings Call, an analyst asked Defendants to "go back to Savanna commentary" and "talk about the steps for menu development" and how they should be "thinking about additional assays rolling off over the next handful of years?" In response, Defendant Bryant stated: *"We are well on our way on assay development and almost everything that we had teed up for what I would call wave one.* And I would say our clin and rec teams are already teed up with respect to the clinical trials. *So the assays that I mentioned in the script are very much on track.* Is there further work to do here and there? Yes. But *for the most part, technical issues are not obviously insurmountable. I don't see anything that would preclude us from launching any of those things that we had listed earlier on the call."*

(e) On August 8, 2023, in a press release announcing the Company's second quarter results, the Company revealed that it had completed its FDA submissions for Savanna. On that same day, during Q3 2023 Earnings Call, Defendant Bryant stated: *"Our initial menu includes our RVP4 respiratory viral panel and HSV/VZV lesion panel to be followed throughout 2024 by RVP11 and HSV/VZV syphilis panel, a panel for sexually transmitted infections including chlamydia, gonorrhea, Mycoplasma genitalia and Trichomonas vaginalis, plus two gastrointestinal panels; one bacterial and/or viral and a second parasitic panel. A pharyngitis panel that test for four bacterial pathogens, and, finally, a vaginitis panel On behalf of our customers and shareholders, I'm thrilled that the US Savanna launch is progressing as the platform is robust, the total addressable market is huge and the outlook is very exciting."*

338. Defendants' statements identified in ¶¶337(a) – (e) that the Company's RVP11 and additional panels, including sexually transmitted infections, parasites and gastrointestinal panels were in development, were "very much on track," and would be introduced "throughout 2024" were false and misleading (*see supra*, ¶¶337(a) – (e)) because, in truth, those additional panels were not in development for Savanna's "initial menu" but rather, described by FE-4 were "nearly impossible" and nothing more than a "pipe dream." *See supra*, ¶¶168-69.

C. Defendants Misrepresented the Company's Ability To Manufacture Savanna at a Scale Necessary To Achieve Over \$75 Million in Revenue Synergies and \$300 Million in Overall Revenue Throughout the Class Period

339. Throughout the Class Period, Defendants made a series of objectively false and misleading statements regarding the Company's manufacturing capabilities and Savanna's ability to contribute \$75 million in revenue synergies and \$300 million in overall annual revenue in the near term. Specifically, Defendants made the following false and misleading statements throughout the Class Period:

(a) On February 17, 2022, on the Q4 2021 Earnings Call, Defendant Bryant stated: ***“we’ve identified \$100 million in expected revenue synergies by 2025 with approximately 80% to come from cross-selling opportunities and our expanded geographical footprint to sell Savanna and other products in ex-U.S. markets.”***

(b) On April 11, 2022, in Quidel’s prospectus on Form 424(b)(3) (the “April 11, 2022 Prospectus”), Defendants represented that they would achieve revenue synergies in the following amounts (a) \$5 million by the end of 2022; (b) \$28 million in 2023; (c) \$61 million by end of 2024; (d) \$105 million by end of 2025; and (e) \$149 million by end of 2026. Of these totals, Defendants communicated that ***“75% of revenue synergies attributable to Savanna***, with the remainder from Triage and QuickVue products.”

(c) In the Definitive Proxy Statement on Form DEF14A filed April 11, 2022 (the “2022 Proxy Statement”), Defendants stated: ***“This resulted in Ortho’s assumption, from a product perspective, of approximately 75% of revenue synergies attributable to Savanna***, with the remainder from Triage and QuickVue products.”

(d) On May 4, 2022, during the Q1 2022 Earnings Call, an analyst asked Defendant Bryant whether the Company was “able to build some inventory as we head into this U.S. launch?” In response, Bryant stated: ***“the only constraint with the launch, honestly, being our ability to get enough instruments into the market as quickly as possible as well as our ability to manufacture cartridges at very, very high volumes.”***

(e) Also on the Q1 2022 Earnings Call, Defendant Bryant stated: ***“Once online in the fall, our Savanna cartridge automated manufacturing line is expected to begin its ramp-up and outfit to over 1 million cartridges per month with \$300 million annual revenues and anticipated within 3 years of U.S. launch.”***

(f) On August 4, 2022, in the Company's earnings release for the second quarter 2022 (the "Q2 2022 Earnings Release"), Defendant Bryant stated: "With regard to integration, we've already generated considerable momentum and *have a clear path forward to reaching our targeted cost and revenue synergies, and positioning the combined business for long-term growth and enhanced shareholder value.*"

(g) Also on August 4, 2022, during the Q2 2022 Earnings Call, Defendant Bryant stated: "*As discussed on prior calls, we expect to realize* cost synergies from the transaction of \$90 million and *cross-selling revenue synergies of over \$100 million by the end of year 3, following transaction close* though we do expect the commercial momentum to continue beyond that timeframe. *While our integration is still in the early days, the pieces are aligning and the chemistry is even better than expected, which is remarkable given our high expectations.*"

(h) During the same call, an analyst asked about the prior guidance provided for 2022 and what Defendants were "thinking about next year." In response, Defendant Bryant stated: "*we feel very comfortable* both on the clinical chemistry and immunoassay systems *as well as on the Savanna. And what I would point to, I think, generally, is to be S-4 in those forecasts and suggest to you that those are solidly intact.*"

(i) On November 2, 2022, during the Q3 2022 Earnings Call, Defendant Bryant stated: "Lastly, over the past couple of months, *we've overcome Savanna instrument supply chain challenges, begun ramping our instrument manufacturing capacity and completed the setup and validation of the first of two low-volume cartridge manufacturing lines. This allows us to expand our Europe, Middle East and Africa commercialization for the current respiratory season.* Our second low volume line is expected to be run online during the fourth quarter. *We believe these two lines should be more than sufficient to meet pull-through demand given the*

number of instruments we expect to ship. Our two automated high-volume lines are expected to be up and running by mid-2023, ahead of our US commercial launch.”

(j) During the same call, Defendant Bryant responded to an analyst question about whether the Company needed to revise “the \$300 million guide out there for a three-year period” for Savanna revenues assuming that the US launch “gets pushed out,” to which Bryant responded: “*We’re not making any change to the \$300 million plus target that we had over the 3-year period. We’re just shifting where we’re sending the product based on the availability.*”

(k) On December 13, 2022, during QuidelOrtho’s 2022 Investor Day, an analyst asked why Defendants “talked about pretty confidently kind of a \$300 million number in that three-year timeframe” and “[i]t’s now \$250 million . . . can you just talk about what changed in the last few months? Is it slower adoption in Europe? Is it the fact that US got push out again on the quarter?” In response, Defendant Bryant stated: “*I would say that the number that Tammi showed was 250 or better. And remember, that’s – I have too many mics now. Sorry. That’s three years post the US launch. So it’s sometime call it mid-to-late-2023; three years beyond that is where you’ll see that number. I would argue it’s largely the same number, Patrick. I mean, it’s greater than 250.*”

(l) On February 15, 2023, during the Q4 2022 Earnings Call, Defendant Bryant stated: “For cartridge manufacturing, *we are in the process of increasing manual manufacturing lines, hiring additional staff and installing high volume automated lines that will produce the millions of cartridges that will be required.* The first two panels that we’ll launch are RVP4 and the HSV/VZV lesion panel.”

(m) Also during the Q4 2022 Earnings Call, Defendant Bryant stated: “*I’m pleased to say that we are nearly there, nearly ready for an expanded global launch ahead of*

the next respiratory season. Supply chain and instrument manufacturing issues that were a challenge for us are largely resolved, and we now have the capacity to begin to ship the analyzers that we had anticipated all along.”

(n) On the same day, the investor presentation accompanying the Q4 2022 Earnings Call stated that the Company “[e]xpect[s] Savanna instrument placements of ~1,000 and *\$30 to \$50 million of Savanna respiratory revenue, primarily in the fourth quarter of 2024.*”

(o) On March 7, 2023, during the Raymond James Annual Institutional Investors Conference, analyst Andrew Cooper asked about Savanna since “[w]e’re almost two years out from CE mark” and the “latest and greatest” feedback now that the product has been through a full respiratory season. In response, Defendant Bryant stated: *“[A] lot of the issues, Andrew, that we were working through early on have now largely been resolved. And I think we have the ability to have an effective global launch of Savanna, assuming we can get the cartridge manufacturing to where we want. We’ve started with a low volume line. We’re doubling that now with another low volume line. And we expect to have our higher volume line that will produce the millions of cartridges that we’re going to need to support the market. That should be validated sometime in the first quarter of 2024.”*

(p) On May 3, 2023, during the Q1 2023 Earnings Call, in response to an analyst question regarding Defendants’ confidence in a Savanna U.S. launch, Defendant Bryant stated: *“In addition, I think our confidence comes from having solved supply chain issues and now more reliably making and stocking instruments. So that’s not going to be a challenge for us. And we now have the second line nearly validated on the cartridge manufacturing, which puts us in really good shape in terms of the volumes that we require in 2023 and 2024. So we’re pretty confident.”*

(q) On the same Q1 2023 Earnings Call, Defendant Bryant stated: *“We are currently in a stocking position for both the Savanna Instrument and the RVP4 cartridge, and our second cartridge manufacturing line is in the final stages of validation, as we work to build inventory in anticipation of Savanna’s launch in the US, following regulatory clearance.”*

(r) Also on the Q1 2023 Earnings Call, in response to an analyst question regarding “what’s included in the guide for the year for Savanna[,]” Defendant Busky stated: *“[t]here’s really no change with what we said on the Q4 call related to Savanna guidance. We are going to be -- we’re going to continue to ramp in Europe, and we are expecting regulatory clearance in the U.S. So we’re expecting to have products available for the Q4 respiratory season. So there -- I wouldn’t say there’s no change really to the guidance that we gave in Q4 related to Savanna.”*

(s) On June 6, 2023, during the William Blair Growth Stock Conference, in response to an analyst question regarding “How important is Savanna” and what will drive the “6% to 9%” growth at QuidelOrtho, Defendant Busky stated: *“[W]e expect three years post-launch that will be greater than \$250 million of revenue on that Savanna product.”*

(t) On August 8, 2023, during the Q2 2023 Earnings Call, Defendant Bryant stated: *“We completed validation of our second low volume Savanna cartridge manufacturing line during Q2 and are currently building inventory in anticipation of Savanna’s launch in the US, following regulatory clearance.”*

(u) During the same Q2 2023 Earnings Call, Defendant Bryant stated: *“[W]e’re just finished standing up our second low volume manufacturing line for the cartridges for both clinical trials and launches. And that’s going well, too. So I think we’re in really good shape from an office supply chain and launch perspective.”*

(v) On November 1, 2023, during an earnings call to discuss the Company's third quarter 2023 financial results ("Q3 2023" Earnings Call), Defendant Bryant stated: "***I am confident we will receive Savanna instrument clearance by the end of this year, and launch commercially in the U.S. very quickly thereafter. We have instrument inventory, and I expect that we will launch at pace.***"

(w) On the same call, an analyst asked Defendants to talk about their "confidence in rapid menu expansion and then placement install expectations?" In response, Defendant Bryant stated that the Company "***ha[s] instruments in inventory. We've recently completed the software update. We are fully manufacturing cartridges and so I don't see any other constraint other than US FDA clearance.***"

(x) On the same call, an analyst asked for "an update on the high volume cartridge manufacturing line." In response, Defendant Bryant stated: "***We're still targeting everything on track for midyear next year.***"

(y) On November 30, 2023, during the Evercore ISI HealthCONX Conference, an analyst asked Defendants "what is the Savanna thesis, what should we expect from Savanna?" In response, Defendant Bryant stated: "***[W]e think we'll do about 1,000 instruments.*** That's the forecast. I always say to the marketing people that models are rarely right, but it's at least useful to have something that you think you are aiming at. ***And I think that's about an appropriate target for us in 2024.***"

(z) On February 13, 2024, during the Q4 2023 Earnings Call, Defendant Busky stated: "***Our [2024] guidance also assumes a 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.”

(aa) On March 5, 2024, during the Raymond James Institutional Investors Conference, an analyst asked whether the \$250 million run rate goal for Savanna by 2026 was “still the goal?” In response, Defendant Iskra stated: *“So, yeah, look, \$250 million is the goal, and it’s out there And clearly, we are on the timeline that we expected. But, again, I would say the market opportunity is still there But nonetheless, whether it’s \$250 million, \$275 million or \$245 million, it’s a big number, it’s a big opportunity, and we still believe in it.”*

(bb) Also on March 5, 2024, during the same call, an analyst asked Defendants for their “vision” of what the Savanna menu will look like and whether it will include RVP4, RVP11, and other panels. In response, Defendant Bujarski stated: *“So, when you’re thinking about 2024, you’re thinking about our focus, more so than a revenue number for 2024, any of that. You got to have the menu to really make this platform a success, and those are the ones that we’re focused on straight away.”*

340. The above statements were false and misleading when made. For example, Defendants’ statements above in ¶339(c), (d), (i), (l), (m), (o), (p), (q), (t), (u), (w), (x), and (y) were false and misleading when made because, contrary to these statements, at no point during the Class Period was the Company able to *“manufacture cartridges at very, very high volumes,”* that the Company were *“ramping our instrument manufacturing capacity”* *“to be more than sufficient to most pull-through demand,”* that the Company’s instrument manufacturing issues were *“largely resolved,”* that the Company was *“reliably making and stocking instruments,”* and ultimately that they were *“fully manufacturing cartridges.”* To the contrary, as described by FE-14, that the Company now had the capacity to ship the requisite analyzers was false and

misleading because, in truth, as explained by FE-7, production of Savanna RVP4 was largely manual and FE-10 stated that QuidelOrtho's RVP4 production efforts only reached a manufacturing yield—the percentage of non-defective items of all manufactured items—of approximately 50% by Fall 2023, although the ideal yield rate for a product is 90%, meaning that only 10% of manufactured parts should be defective. Moreover, FE-6 explained that production yields for the Savanna were 30 to 40%, meaning only 3 or 4 out of every 10 tests from the production line were useable, although for a good ROI on production the yields needed to be at least 70-80%.

341. Further, Defendants' statements regarding Savanna's automated manufacturing line, namely that it would be "online in the fall" to "outfit over 1 million cartridges per month" and that its "two automated high-volume lines are expected to be up and running by mid-2023," allowing the Company to manufacture 1,000 instruments in 2024 ((¶339(d), (e), (i), (l), (m), (o), (p), (q), (t) – (y)) were false and misleading because, in truth, although QuidelOrtho "constantly" talked about building a large, expensive, automated production line for the test, FE-6 explained it had trouble getting the automated line set up. FE-6 further recalled that the Company "poured millions" into building a fully automated production line for Savanna, but its location was never confirmed, was still "up in the air," and the production line was still not operational as of April 2024, despite the Company having spent "upwards of \$80 to \$100 million" on the incomplete automated production line. Moreover, even after the significant number of tests were scrapped straight from the manufacturing line, an additional material amount of tests proved to be defective when they were sampled prior to shipping out to customers. FE-2 confirmed that up to 50% of the sampled RVP4 tests were scrapped during the final inspection of the product. In fact, as FE-7 explained, problems with Savanna were so bad that every time a new instrument was sent to a

customer, the Company sent them an additional, back-up instrument so that the customer would shift to the back-up instrument if problems arose, which increased the Company's inventory and production costs.

342. FE-6 raised “red flags” about rising and excessive production costs multiple times and during monthly close meetings and that those concerns were raised “up the chain” of reporting to management, including to Plant Controller Missy Holder and Richard Jenkins, Vice President, Finance Global Operations. FE-14 warned that the design was not manufacturable, and he was aware that the design flaws of the Savanna RVP4 test were highlighted to Senior Vice President, Research and Development Werner Kroll as early as 2019. FE-14's concerns were demonstrated in vivid color throughout Savanna's European launch, which suffered from persistent complaints about both the devices and the tests themselves, a huge number of invalid results that generated a one-in-four replacement rate, and an internal CAPA investigation that had not resolved the root cause of Savanna's issues by the end of the Class Period.

343. Moreover, Defendants' statements that the Company would realize “***cross-selling revenue synergies of over \$100 million by the end of year 3***” following the Merger and that Savanna would contribute approximately 75% of those revenue synergies (¶339(a) – (c), (f) – (h), (j), (k), (n), (r), (s), (z) – (bb)) were false and misleading because for the reasons identified above in Section IV.F, Savanna was far from ready for a global launch. Even if Savanna were to be approved by the FDA (an almost impossibility for the reasons stated above), the Company's manufacturing shortcomings would prevent Savanna from contributing any revenue to the Company in the near-term. Indeed, this is true by the Company's own admission. After the Class Period, by the Company's Q3 2024 Earnings Call on November 7, 2024, new QuidelOrtho CEO

Brian Blaser disclosed that the Company did not expect Savanna to enter the U.S. market until the “later part of 2025,” with most of the “ramp-up” occurring in 2026 and 2027.

D. Defendants Misrepresented the Company’s Endemic COVID-19 Revenue During the Class Period

344. Defendants made a series of materially false and misleading statements following the Company’s poorly-received December 13, 2022 Investor Day regarding QuidelOrtho’s representations about revenues from “endemic” COVID-19 test sales following the astronomical revenues generated during the pandemic stage, including doubling the Company’s endemic COVID-19 annual test revenues from \$150 million to \$200 million, to \$200 million to \$400 million. Specifically, Defendants made the following false and misleading statements throughout the Class Period:

(a) On December 13, 2022, during QuidelOrtho’s 2022 Investor Day, Defendant Busky touted demand for the Company’s products, stating: “I think Doug [Bryant] 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.*”

(b) On December 20, 2022, analysts at William Blair published an analyst report titled: “Virtual NDR Takeaways and Additional Thoughts Following Last Week’s Investor Day,” which was written after the analysts “hosted and attended virtual meetings with management from QuidelOrtho and investors across the U.S. and Europe,” specifying that the participating members of QuidelOrtho management were Defendant Busky and Bryan Brokmeier, Vice President of Investor Relations. The analyst report “discuss[ed] in more detail the key takeaways from the meetings” with Defendant Busky and Brokmeier. Specifically, William Blair wrote that: “*[m]anagement provided some thoughts on endemic COVID-19 testing levels, noting that its prior estimate for between \$150 million and \$200 million of endemic COVID-19 testing revenue*

was likely conservative and that something between \$200 million and \$400 million is more realistic.” This unexpected upward revision, unaccompanied by any data or substantiation, doubled the Company’s expectation for endemic COVID-related revenue (up 71% based on a comparison of midpoints for the ranges provided).

(c) On January 26, 2023, Defendant Bryant appeared on an episode of *Repertoire* Podcast entitled “Mergers, Acquisitions and Respiratory season with Quidel.” During the episode, Defendant Bryant assured investors that QuidelOrtho was “humble” when it comes to setting expectations and guidance, stating:

But part of beating expectations is to set the expectations correctly. And so we’re pretty humble with the street. We don’t get ahead of our skis, as they say. We don’t try to... say things that would hype the share price. We just, you know, we call it like we see it. And you can either say that’s not too clever, Doug, or you can say, you know, I would imagine that you have pretty good credibility with the street as a result. And I kind of like to think it’s the latter.

(d) During the same podcast, Defendant Bryant assured investors that demand for COVID testing products was not on the decline, stating: “We also were the beneficiary, to be fair, Scott, of additional COVID shipments in two areas. One, we did receive additional orders from the federal government for a quick few COVID tests. And then, you know, we have seen a little bit of uptick in prevalence, but really it’s been somewhat flat. *It’s definitely not declining though. And so it’s become somewhat steady state.* And I think some people are probably forecasting that that was going to continue to fall.”

(e) On February 15, 2023, QuidelOrtho released its financial results for the fourth quarter and fiscal year 2022 (“Q4 2022 Earnings Release”). In the Q4 2022 Earnings Release, QuidelOrtho reported \$132 million in quarterly revenue for COVID-19 products as compared to \$511.8 million in the fourth quarter of 2021. On the Q4 2022 Earnings Call to discuss these results, Defendant Busky told investors to expect “[r]espiratory revenue of \$610 million to

\$875 million, *which includes COVID revenue of \$300 million to \$500 million*” for fiscal year 2023. Busky further stated: “*We expect to continue to capture and grow our share of the respiratory market, underpinned by our large and growing Sofia placements.*”

(f) On the same day, an analyst asked Defendants whether “there’s the fear that, as COVID comes out, 2024 then takes a step down,” which Defendant Busky responded by assuring investors that QuidelOrtho was set to receive \$200-\$400 million in COVID-related revenue, stating: “*there’s really no change there with that endemic level of annual revenue being it’s \$200 million to \$400 million*, and you’re right, it’s up another \$100 million in 2023 guide because of those government orders, which again, like as you said, doesn’t carry super significant amount of margin.”

(g) During QuidelOrtho’s Q4 2022 Earnings Call, in response to an analyst question about “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 . . . what you just said about some of the seasonality in flu and respiratory in general,” Defendant Bryant responded that “\$300 million to \$500 million” was the range, and Busky stated that: “*We were saying 200 to 400 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.”

(h) Also on the Q4 2022 Earnings Call, in response to an analyst question regarding “how should we think about the total respiratory business size wise,” Defendant Busky stated: “I think we would, again, go back to the *COVID \$200 million to \$400 million. . . .*”

(i) On March 7, 2023, during the Raymond James Annual Institutional Investors Conference, an analyst noted that “You’re pointing folks to \$200 million to \$400 million of endemic COVID” and asked: “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?” Defendant Bryant responded by explaining how the \$200-\$400 million range was based on a “top down” approach “looking at historical data and the professional segment” and a “bottoms up approach” based on “marketers” that is “almost [] an account by account analysis,” concluding:

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.*

(j) Later, during the same conference, an analyst asked Defendant Bryant about “the progression” of the Company’s EBITDA expectations “in terms of COVID rolling off” and whether EBITDA for 2024 should “be higher than 2023, 2025 higher than 2024?” In response, Bryant told investors that the Company’s outlook was improving, stating that: “*your comment about 2024 should be better than 2023 and 2025 better than 2024 I think is a reasonable expectation.*”

(k) On May 3, 2023, during the Q1 2023 Earnings Call, Defendant Bryant reiterated that “*[d]emand for diagnostics across the health care continuum remained strong*” and noted the “*significant increase in global demand for global testing.*”

(l) On the same call, an analyst from Citi asked about the Company’s decision to “maintain the guide for the full year” and whether there was a need to “de-risk” the guidance, Defendant Bryant stated: “But remember, in the endemic state, we had, assuming that we are now in that endemic 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 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."

(m) Defendant Busky followed up on Bryant's response, stating: "just to put a bow on that . . . *[w]e do think that we've de-risked the balance off your forecast for Respiratory and COVID because we're not changing it* and we didn't overachieve in Q1."

(n) On September 12, 2023, during the Morgan Stanley Global Healthcare Conference, an analyst asked about "the guide here on the COVID side of things" with "the public health emergency coming to an end in May." In response, Defendant Bryant stated: "What I would say for the back half total guide though, that this certainly de-risks 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-specific – or COVID-only sales.*"

(o) On November 1, 2023, during the Q3 2023 Earnings Call, Defendant Bryant stated: "*the strong and early respiratory demand in Q3 was mainly driven by high COVID-19 prevalence throughout the United States.*" Bryant continued:

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.

(p) During the same Q3 2023 Earnings Call, Defendant Bryant stated:

Now, I'd like to leave you with *one key takeaway*, and that's we are the same successful respiratory company than 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 standalone 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.

(q) Also on the Q3 2023 Earnings Call, Defendant Busky stated: *“Our Q3 financial performance, which exceeded our plan significantly derisk Q4 and while we can't precisely predict the timing of the respiratory season in advance, we believe it's prudent to plan for a normal or typical season.* In addition, we have excellent visibility into our non-respiratory business and again we expect our lab business to grow high single digits in Q4. *All in all, we are very confident that we can end the year strong.”*

(r) On November 30, 2023, during the Evercore ISI HealthCONx Conference, an analyst asked Defendants about the Company's “new baseline” for COVID assumptions and whether there were any “sensitivities[.]” In response, Defendant Bryant affirmed QuidelOrtho's target of \$200-\$400 million in COVID-related revenue for fiscal year 2024, but added that *“we probably will be higher than the midpoint[.]”* stating: *“Well, I don't know about sensitivities. I would say, our \$200 million to \$400 million, we still think is the right number. I think, for 2024, we probably will be higher than the midpoint for COVID still.”* Additionally, Defendant Busky was asked about the endemic COVID guidance, where he stated: “there's no change in the guidance” and reaffirmed *“you've got the level of endemic COVID and where you end up in that range of \$200 million to \$400 million.”*

(s) On January 8, 2024, during the J.P. Morgan Healthcare Conference. Defendant Bryant stated: “Some other facts about Point of Care. We have 88,000 Sofias on the ground. I've been asked, are you still growing placements? Yes, we are. Through the first nine

months, we placed an additional 3,900 analyzers in the United States. And of those, 48% were brand new customers, right? *So, we continue to do well in this space. I don't want to sound arrogant, but I do want to point out that we do pretty well in this space, so, and it's our highest market share category.* It's our highest margin category as well."

(t) Also on January 8, 2024, during the same call, Defendant Bryant responded to an analyst question about the Company's decision not to pre-announce financial results for 4Q 2023, stating: "Yes, that's quite a question. Let me start by saying *we historically have preannounced when we have something that's materially different than you think.* So, both positive and negative. One of my first things that I did in 2010 was announce – preannounce that we had missed the quarter dramatically. So, we will always endeavor to preannounce when we think it makes sense. And obviously, Savanna was an important enough thing to preannounce, but we had already announced that a few or week or so ago. So, *we didn't actually see a need to do that and we'll have plenty to talk about at the earnings call here in a few weeks.*"

(u) On that call, Defendant Bryant was asked about QuidelOrtho's endemic COVID guidance, with an analyst asking: "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 responded:

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.*

(v) During the same call, in response to an analyst question regarding whether QuidelOrtho's target of \$200-\$400 million in COVID-related revenue was "applicable to 2024," Defendant Bryant stated: "*I think we're very much on track for 2024.*"

345. Defendants' statements identified in ¶344(a) – (v) were materially false or, at a minimum, misleading when made.

346. As explained above, the statements in ¶344(b), (c), (e) – (l), (n), (r) and (u) were all false and misleading because Defendants' decision to double their COVID-19 endemic revenues following the Company's poorly-received 2022 Investor Day and resulting 17% stock drop not only lacked substantiation, but was directly contradicted by actual COVID sales figures, inventory levels, and trends made known to Defendants. *See* Section IV.G. Numerous former employees confirm that the outlook for COVID-19 sales and revenues by the end of 2022 was worsening, not improving. For example: (a) FE-11 confirmed that as early as August 2021, there was a "huge decline" in COVID test sales, distributors pushed back on prices and contract terms with QuidelOrtho, and in August 2021, COVID test customers "trickled off" and QuidelOrtho began seeing "steady declines;" (b) according to FE-17, QuidelOrtho distributors purchased "significantly" fewer COVID tests in 2022 and 2023; (c) FE-3 described how QuidelOrtho's revenue was "grossly declining" by Q1 2023, and that QuidelOrtho missed its COVID and respiratory sales quotas in Q1, Q2, Q3 and Q4 2023; (d) FE-15 confirmed that 30 to 40% of his total customers stopped purchasing COVID tests from QuidelOrtho between Fall 2022 and early Spring 2023, and these declining sales were discussed in monthly sales calls with QuidelOrtho's C-Suite; and (e) FE-16 confirmed that in 2023, he and colleagues throughout the U.S. talked about how no one was buying QuidelOrtho's acute products.

347. In addition to COVID-test product sales declining, QuidelOrtho faced mounting competition, such that Defendants' statements that it would "continue to capture and grow our share of the respiratory markets" and experienced "significant share gains from competitors for us specifically" were false and misleading when made for the reasons described above in ¶346. *See* ¶344(e), (o), (p), (s). Indeed, former employees describe how QuidelOrtho was losing market share to competitors whose tests offered more flexibility or better technology. For example, FE-11 recalled that QuidelOrtho lost COVID-19 test market share to competitors, including Abbott Laboratories, and described that customers preferred Abbott's molecular tests and that Abbott offered customers a larger reimbursement than QuidelOrtho. FE-3 described how he called accounts in 2023 with declining business to "stop the bleeding" and loss in revenue, and these accounts told him that they stopped ordering respiratory tests from QuidelOrtho and switched to competitors because the competitors offered tests with newer technology, more modern analyzers, faster results, and more capabilities. FE-15 confirmed that the market got saturated and flooded with alternative and cheaper COVID tests during this time and that acute and non-acute customers stopped purchasing COVID tests from QuidelOrtho and instead purchased newer, cheaper, and faster tests from competitors. Further, not only did QuidelOrtho's Sofia platform face internal end of life risks that raised "major concerns" about the platform's longevity, but FE-3 explained that by the time of the Merger, he received feedback from his current and prospective customers that Sofia analyzers "did not hold up," resulting in customers purchasing tests from competitors who had more state-of-the-art products. Thus, as FE-3 explained, QuidelOrtho's revenue was "grossly declining" beginning in Q1 2023, and the Company missed its sales quotas for COVID-19 and other respiratory products in every quarter of 2023.

348. Further, Defendants’ statements that they were “still very comfortable that moving forward will be in that 200 to 400 range for COVID,” that the Company was “very much on track for 2024,” and the Company was “set[ting] expectations correctly” also lacked any foundation, which was known (or should have been known) to be false. *See* ¶344(c), (d), (f), (i), (j), (l), (m), (q), (r), (t) – (v). According to FE-16, QuidelOrtho was very aware that the need for COVID testing in hospitals was declining in 2023. Data regarding how far off QuidelOrtho was from hitting its 2023 annual respiratory sales quotas was presented to QuidelOrtho’s Finance team, according to FE-20, and it was reported to Defendant Busky and other leaders that the Company was not going to hit its 2023 respiratory sales quotas during meetings at the end of each quarter in 2023.

349. Moreover, inventory levels were rising, which alerted Defendants to the falsity of the above statements, including, for example, Defendant Bryant’s statement in ¶344(a) that “*we don’t have so much of a demand problem right now. We have a supply problem. We got to get more products.*” FE-10 confirmed QuidelOrtho had a significant amount of excess inventory which was discussed in quarterly Excess and Obsolete (E&O) meetings during his tenure at QuidelOrtho. These meetings, overseen for most of the Class Period by Vice President, Finance Global Operations Richard Jenkins, unveiled the number of tests that were set to expire and that number increased each quarter during FE-10’s tenure. According to FE-10, during peak levels of inventory, QuidelOrtho was selling less than 1 million tests weekly but maintained “tens of millions” of respiratory tests in inventory, and FE-10 discussed QuidelOrtho’s inventory issues with Defendant Busky directly in advance of earnings calls.

350. On February 23, 2023, the Company filed with the SEC a Form 10-K reporting the Company’s financial results for the quarter (“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.

351. Attached to the 2022 10-K were certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), signed by Defendants Bryant and Busky attesting that information in the 2022 10-K "fairly presents, in all material respects, the financial condition and results of operations of the Company." The same or substantially similar language appeared in every subsequent Form 10-Q filed by Defendants during the Class Period, namely the Company's Form 10-Qs filed by Defendants on May 4, 2023, August 9, 2023, and November 2, 2023.

352. Defendants' statements in the above-referenced risk factor disclosure and SOX certifications were materially false or misleading when made. While Defendants acknowledged risks associated with the fluctuations of demand for QuidelOrtho's COVID-19 testing products, Defendants did not disclose that then-known material risks that directly and negatively impacted

the Company's "sales and revenues from its COVID-19 and influenza tests" had already transpired.

353. For example, Defendants did not disclose that, at the time of each of these statements, QuidelOrtho's COVID-19 test sales were significantly declining and the Company was losing market share to competitors who offered cheaper and more reliable COVID tests. For example, as former employees have noted, there was a "huge" and "steady" decline in COVID test sales beginning in August 2021, according to FE-11. FE-11 further confirmed that during this time, QuidelOrtho's customers stopped ordering COVID tests from QuidelOrtho due to inventory pile-up and loss of business to competitors, including Abbott Laboratories. FE-15 recalled that customers told him they stopped buying QuidelOrtho's Sofia COVID tests and instead purchased newer, cheaper and faster tests from competitors. FE-9 confirmed these accounts, explaining the entry of 50 Chinese companies into the European market with significantly cheaper tests caused competitive pressure and things "went down" pretty quickly. *See supra*, Section IV.G.

354. Despite presenting such risks as hypothetical, Defendants were aware and knew of declining demand for its COVID test products and the Company's loss of market share because, *inter alia*, the Company held Excess & Obsolete meetings during FE-10's tenure during which the Company's significant levels of COVID-test inventory was regularly discussed. FE-10 confirmed that during peak levels of inventory, QuidelOrtho was selling less than 1 million tests per week but maintained tens of millions of respiratory tests in inventory, including 30 million QuickVue tests. FE-10 maintained a report called the McKellar Report, which reflected that "nothing is selling" and that inventory levels were increasing, and these numbers were provided to Defendant Busky. FE-10 confirmed that the analysis presented to Busky showed that QuidelOrtho was "carrying way more" Sofia and QuickVue inventory than it should have been. These significant

facts, read together with the Company's contemporaneous doubling of its endemic COVID guidance rendered these statements false and misleading when made. Despite confirmation from several former employees that QuidelOrtho suffered from declining COVID sales and loss of business to its competitors, Defendants raised and repeatedly reiterated its baseless COVID revenue expectations to the market. Indeed, the March 4, 2024 UBS Report downgrading QuidelOrtho's stock recognized that "QDEL's COVID testing revenues in 2023 and 2024 are declining greater than other COVID testing peers."

VI. SUMMARY OF SCIENTER ALLEGATIONS

355. At all relevant times, Defendants acted with scienter. The facts alleged herein support that the Individual Defendants either had actual knowledge of the truthful facts that they omitted to disclose and which contradicted their false or misleading statements, or acted with reckless disregard for the truth or falsity of those statements and omissions. QuidelOrtho has the scienter of its management-level employees, including each of the Individual Defendants.

356. Numerous allegations set forth fully above and summarized below give rise to the strong inference that Defendants intentionally or recklessly misled investors about (a) Savanna RVP4's performance in Europe and the U.S.; (b) Savanna RVP4's manufacturing problems and setbacks; (c) Savanna RVP4's inability to achieve the FDA's requirements for approval; and (d) the Company's endemic COVID-19 revenues that was unsupported by and inconsistent with the Company's actual declining COVID-19 product performance and sales.

357. **First**, the development and commercial launch of the Savanna platform—and specifically the Savanna RVP4 test—was one of the longest and largest investments in the Company's history, with its closely-watched development dating back to 2011. Defendants spoke about Savanna on *every* conference call with investors and repeatedly emphasized its critical importance to the Company's future success and the success of the Merger during the Class Period.

For example, Defendant Bryant referred to Savanna as a “*the most important flagship product in the history of the Company*,” “*a near-term priority*,” and “*near-term growth driver*.” In a January 12, 2022 investor call, just prior to the start of the Class Period, Defendant Bryant spoke of Savanna’s role as a key driver of the Merger, stating that Savanna is “*the most important product in [the Company’s] history*,” and articulated that Quidel needed Ortho’s “commercial wherewithal” to help with Savanna’s launch and the procurement of at least \$75 million of the touted \$100 million of Merger revenue synergies. Similarly, in a later call on January 9, 2023, Bryant stated that Savanna “is *a flagship product for us. If I’m wrong, you won’t see me here next year. I’ll be hiding*.” Likewise, Bryant, on March 7, 2023, referred to Savanna’s U.S. launch as one of three “*things that [] matter most for the business overall*.”

358. The other Individual Defendants were equally invested and directly involved in the Savanna RVP4 launch and development. For example, Defendant Ranalli stated in a September 12, 2022 podcast that her work on Savanna was “*an over 10-year labor of love*” for her. And on March 5, 2024, just days prior to the end of the Class Period, Defendant Iskra stated that: “All three of us [Individual Defendants Iskra, Bujarski and Busky] and others are *heavily focused on [Savanna] and doing all we can to get not just RVP4 out, but the other menu items*. And that’s what we need.” It is clear that the Individual Defendants were intently focused on the launch of Savanna RVP4 before and throughout the Class Period and were intimately familiar with its actual performance and sales at the time they made their misstatements. *See* Section IV.F.

359. *Second*, multiple former employees explain that there was significant pressure on Defendants—and exerted by Defendants onto QuidelOrtho employees—to launch Savanna before it was ready for the European market and before it was ready for submission to the FDA. For example, FE-4 described a “top-down mandate” and “a lot of pressure” to sell Savanna RVP4 in

Europe. In advance of the 2023 FDA 510(k) application for clearance to sell Savanna RVP4, FE-4 described how Shawna Prange, the Associate Director of Assay V&V, R&D whose studies were critical for Savanna's FDA submissions, received "a lot of pressure" from a "top-down mandate" at the Company to approve Savanna "no matter the cost," even while Prange told FE-4 that the Savanna RVP4 test "does not work" and that it "isn't even a product." FE-12 confirmed that QuidelOrtho's management kept "pushing aggressively" to generate data for all departments to release the assays as soon as possible, as Savanna was supposed to be a "money maker" for the Company.

360. FE-14, an Engineer with the Company from before the Class Period to the second half of 2023, explained how the pressure to force through Savanna started before the Class Period. FE-14 explained that the Company would not be able to manufacture the RVP4 design requirements and was aware that the design flaws of the Savanna RVP4 test were highlighted to Senior Vice President, Research and Development Kroll, Defendant Bryant's direct report, as early as 2019. Kroll "chose to ignore" these warnings and decided to "push through" the identified manufacturing challenges. FE-14 recounted that after the manufacturability warnings were ignored, Kroll, together with former CFO, Defendant Steward, and Defendant Bujarski (the three of whom constituted the Company's Executive Steering Committee for the Savanna project) determined in a 2020 meeting to dismantle the large team working on the Savanna RVP4 project and transfer the project to an insular team, which consisted of current Director, Systems Engineering Matthew Morovich, current Director Engineering Bruce Jacono and current Vice President Global Molecular R&D Johannes Kehle. FE-14 elaborated that Kroll, Steward, and Bujarski created the small, insular team to insulate information from the rest of the Company about any issues involving Savanna RVP4. FE-14 stated that Kroll was not concerned about

manufacturing a quality product and he suggested that neither were Defendants Steward and Bujarski.

361. **Third**, the Individual Defendants were responsible for QuidelOrtho's efforts to develop and promote Savanna throughout the Class Period, including through personal oversight of the product's European launch and 510(k) application for FDA approval. In particular, Defendants Bryant, Busky, and Steward in their roles as CEO and CFOs, were required to not only keep themselves informed of the Company's day-to-day operations, but also keep QuidelOrtho's non-management directors apprised of the state of the Company's business, operations, and trends. Further, as Chief Commercial Officer, Defendant Iskra was primarily responsible for driving customer satisfaction and Defendant Bujarski, as COO, led all aspects of quality, manufacturing and operations. As Senior Vice President, Molecular Diagnostics and Point of Care, Defendant Ranalli was responsible for "defining and executive the strategic vision for the QuidelOrtho molecular and point-of-care diagnostics portfolio" and growing revenue—for which Savanna was a crucial part. Moreover, Ranalli herself described how the Savanna project was "*an over 10-year labor of love*" for her over which she had direct oversight.

362. **Fourth**, while Defendants repeatedly praised the capabilities, performance and strong feedback from European clients, a constant stream of customer complaints and failed Savanna analyzers and Savanna RVP4 tests in the European sales market were carefully documented, discussed in weekly meetings attended by Defendant Ranalli, and brought to the attention of the Individual Defendants. *See supra*, Section IV.F.2-3. For example, FE-4 noted that current Director Global Product Management Jim Baldrice held calls at least monthly and that Defendant Ranalli attended these calls. FE-4 noted that Ranalli reported to former CEO Doug Bryant. FE-4 stated that the focus of these calls was Savanna. FE-4 explained that during these

meetings, Jürgen Becker, Scientific Marketing Manager, Europe, discussed that Savanna RVP4 tests were failing in Europe and provided negative customer feedback. FE-7 similarly recalled “many, many” weekly meetings to discuss problems with Savanna. FE-7 described how, in the 20 years he has been in this line of work, he “*didn’t remember any market launch that was so full of issues.*”

363. Accounts of former QuidelOrtho employees confirm Defendants’ knowledge and/or reckless disregard of the significant and unresolved problems with Savanna throughout the Class Period. For example, FE-13 confirmed that issues with Savanna were communicated to the C-Suite “all the time,” given that Savanna was set to be the Company’s next big “money maker.” FE-2 met with Kroll one-on-one on a weekly basis to discuss projects, including Savanna, where they discussed instrument and cartridge issues. According to FE-2, Kroll “knew everything,” and reported directly to the Board on R&D matters during Board meetings. FE-1 added that Kroll’s direct report, Charice Tellez, Vice President, Program Management Office, provided materials presented to the Board of Directors regarding clinical trials, tests, and related materials for Savanna.

364. Further, in order to monitor the development of Savanna and its preparedness for FDA approval, QuidelOrtho documented every performance test and ensured that all problems with Savanna RVP4 were discussed directly with management (*see supra*, at ¶¶183-188, 195, 204-205, 215-219). Specifically, as described by FE-2, the Company’s engineers and scientists would report findings to their managers, who in turn presented these findings to senior management in PowerPoint presentations, which were reviewed by Kroll (*see supra*, at ¶¶218-219). Further, FE-1 confirmed that Kroll regularly reported updates regarding the Savanna application to the Board

and senior management at least monthly. FE-1 confirmed that the application status was reported up to the Board in notes and PowerPoint slides.

365. Indeed, the Individual Defendants' statements confirm Kroll's role in communicating important information on the Company's products directly to them. For example, during QuidelOrtho's 2022 Investor Day, Defendant Busky explained that he had constant communication with Kroll throughout the Class Period, stating that "Werner [Kroll] presented earlier. He and I are very close, our offices are right next to each other and we talk quite a bit."

366. In addition to documenting Savanna's tests and overall development, the Company used Salesforce to record customer complaints for persistent problems associated with Savanna during the EU launch (*see supra*, at ¶177). Specifically, QuidelOrtho had a formal complaint system for registering customer complaints from the EU launch in which the complaints were sent the Company's office in Ireland, where they were compiled into quarterly reports and then sent to U.S. headquarters (*see supra*, at ¶¶183-184). As confirmed by FE-8, the number of customer complaints was significant enough for the Company to launch a field investigation and subsequently open a Corrective and Preventive Action (CAPA), which confirmed there were errors with the Savanna RVP4 test and was escalated to Company managers and directors. On the Company's scale of complaints from "Green," "Yellow," and "Red," FE-8 explained the Savanna RVP4 complaints were graded "Red." And in at least one instance, QuidelOrtho held a special call related to Savanna's performance, in 2023, during which statistics on complaints were presented in a PowerPoint presentation (*see supra*, at ¶188). This presentation revealed that there were more complaints (85) than installed Savanna instruments (80), FE-7 explained.

367. Similarly, FE-6 confirmed that QuidelOrtho documented Savanna's yield problems and cost accounting issues in emails and in the Company's Enterprise Resource Planning ("ERP")

system, which were then summarized into reports and sent to management (*see supra*, at ¶215). This information was presented in month-end financial close meetings to upper management, including the Controller and the Global Operations Finance Senior Manager, who reported directly to Defendant Busky (*see supra*, at ¶215). FE-13 recalled daily “standup” meetings in which members of the Operations team reviewed and presented status information on daily production, material costs, and operations matters to representatives from Purchasing, Manufacturing, Cost Accounting, and Operations. FE-13 confirmed that issues with Savanna came up in these meetings. FE-13 also attended monthly “Leadership Meetings” attended by Brad Smith, Vice President of Operations, Chris Troxil, Director of Technical Operations, FE-6, Cost Accounting Manager, and the Head of Chemistry (whose exact name he did not recall). FE-13 confirmed that at these meetings, it was well-known and discussed that Savanna was very behind schedule.

368. ***Fifth***, one line of European customer complaints was so serious and significant that the Company opened a Corrective and Preventive Actions (CAPA) investigation in August 2023, which confirmed there were errors with the Savanna RVP4 test and was escalated to Company managers and directors. *See supra*, ¶178. On the Company’s scale of complaints from “Green,” “Yellow,” and “Red,” FE-8 explained the Savanna RVP4 complaints were graded “Red.” FE-8 stated that the issue was significant enough for QuidelOrtho to open a field investigation and subsequent CAPA (“Corrective and Preventative Action”) to address these customer complaints, identify the root cause and prevent it from happening again. FE-8 noted that current Director of Operations, Chris Troxil was notified about this CAPA investigation and that Troxil reported to current Vice President, Operations Brad Smith. FE-8 added that the Research and Development team that developed the Savanna RVP4 test was also notified about this CAPA. According to FE-8, information about this CAPA was shared internally in monthly or quarterly internal business

unit reports to upper management. According to FE-8, QuidelOrtho was still investigating the root cause of these error codes at the time of his departure in July 2024.

369. ***Sixth***, the Individual Defendants Bryant, Busky, Steward, Bujarski, and Ranalli held and attended meetings where the status of the European launch and the status of the clinical trials and FDA submission were discussed. *See supra*, ¶¶187-88, 195, 204-05. For example, QuidelOrtho’s Director Global Product Management, Jim Baldrice, held calls at least monthly that were attended by Senior Vice President, Molecular Business Unit, Tamara Ranalli, who reported directly to Defendant Bryant (*see supra*, at ¶185). During these calls held by Baldrice, Jürgen Becker, Scientific Marketing Manager, Europe, disclosed to Defendant Ranalli that the Savanna RVP4 tests were failing in Europe and provided her with negative customer feedback. FE-7 participated in “many, many” weekly meetings with colleagues in San Diego and Athens, Ohio, where Savanna was manufactured, to discuss the problems with Savanna. FE-7 confirmed that Ranalli, Baldrice, and Amanda Zhang, Global Product Manager, participated in these meetings in addition to employees from R&D, Production Planning, and Logistics. FE-4 also recalled Defendant Bryant also held weekly update calls about the Company’s “state of affairs.” FE-7 detailed that the Company had a formal complaint system for registering customer issues in the EU and that complaints logged in that system were sent to Defendant Ranalli, who reported directly to Defendant Bryant. These complaints were sent formally to the Company’s office in Ireland, where Dara O’Connor, currently Sr Manager, Global Service - POC/MDx,5 prepared quarterly reports on the complaints and sent them to the Company’s headquarters in the US.

370. ***Seventh***, according to FE-14, after Bryant’s direct report, Kroll, who reported directly to Bryant and was a member of the Savanna Executive Steering Committee together with Defendants Steward and Bujarski, was directly informed by the team developing Savanna RVP4

that the test had manufacturability concerns that would prevent the test from being reliably manufactured, that team was disbanded. Rather than proceed with a “design review,” the next step on a normal trajectory at a medical device company, Kroll and Defendants Steward and Bujarski held a meeting in 2020 where they “dismantled” the large team working on Savanna to assemble a small, “insular” team to handle it going forward. FE-14 stated that Kroll pulled the project from this larger team to insulate information from the rest of the Company about issues with Savanna RVP4 and “push it” to production and R&D. According to FE-14, Kroll’s goal, agreed to by Defendants Steward and Bujarski, was to get Savanna “over the goal line,” as opposed to manufacturing a quality product.

371. *Eighth*, Savanna RVP4 failed to consistently meet the 95% sensitivity threshold required by the FDA, a fact that was discussed internally, reported to Defendants, and discussed at Board meetings. *See supra*, ¶¶199, 202-05. FE-1 confirmed that the FDA required RVP4 to consistently meet a certain rate of **95% or higher** for detectability and accuracy. As explained by FE-11, Savanna RVP4 “never came close” to the required 95% sensitivity requirement. FE-2 confirmed that the Savanna assay was not generating the needed sensitivity readings and not picking up enough results during validation prior to the test’s submission to the FDA. FE-1 confirmed that the Company knew it was not meeting the FDA’s requirements when it submitted its 510(k) application for clearance to sell Savanna RVP4 in the U.S., or thereafter.

372. *Ninth*, Defendant Busky was focused on the rising costs of Savanna production. Indeed, Savanna costs increased as at least half of the tests produced were defective and scrapped right after manufacturing, another 10% to 50% were deemed invalid during post-manufacture sampling, and then an additional 25% failed in the field and had to be replaced at cost to the Company. Moreover, the Company invested roughly \$100 million into a long-touted automated

manufacturing line that, unknown to investors, did not work. FE-6 confirmed that QuidelOrtho documented Savanna’s yield problems and cost accounting issues in emails and in the Company’s Enterprise Resource Planning (“ERP”) system, which were then summarized into reports and sent to management (*see supra*, at ¶215). This information was presented in month-end financial close meetings to upper management, including the Controller and the Global Operations Finance Senior Manager, who reported directly to Defendant Busky (*see supra*, at ¶215).

373. **Tenth**, Defendants Bryant, Iskra, and Bujarski told investors on February 13, 2024 and March 9, 2024 that, Savanna’s 510(k) application was “on track,” and affirmed that the Company expected “Savanna instrument placements of approximately 1,000 in 2024, which will pave the way for 2025 Savanna revenue growth.” Iskra confirmed that: “[a]ll three of us [Iskra, Busky, and Bujarski] and others are heavily focused on [Savanna] and doing all we can do to get not just RVP4 out, but the other menu items.” Moreover, Busky affirmed that the Company expected revenue from Savanna RVP4 to be primarily in the fourth quarter of 2024, “given the timing of approvals for the respiratory indication, which we expect in Q1.” Only a few weeks later, the Company shocked the market and withdrew its RVP4 FDA submission, claiming that “the final dataset, submitted in February 2024, did not meet our expectations.” Therefore, by Defendants’ own admission, it knew in February that it would need to withdraw its 510(k) submission but continued to mislead investors. Of course, as alleged fully herein, it was not just a “final dataset” from February that did not meet the FDA’s threshold for clearance. As numerous former employees explained, at no point before or during the Class Period was the Company able to consistently achieve a 95% sensitivity, or detectability, percentage—the objective threshold that the FDA clearly established for the test. *See generally supra*, Section IV.F.3. Indeed, a study published on July 11, 2024 by the Institute of Medical Microbiology comparing the diagnostic

sensitivity, validity, and accuracy of Savanna RVP4 to its competitor Cepheid’s product, Xpert Express, based on samples taken from patients in Germany in 2023-2024, only confirmed what was evident to the Company, the Individual Defendants and numerous former employees and their colleagues throughout the Class Period—RVP4 could not consistently, at a 95% level, detect infection with the requisite sensitivity. The study specifically tested for three of the four infections (COVID-19, Flu A and RSV, but not Flu B), and concluded that RVP4’s sensitivity overall was between 85% and 95%, with ranges of (a) 72%-93% (average of 85%) for SARS-COV-2; (b) 75%-98% (average 91%) for Flu A; and (c) 77%-100% (average 95%) for RSV. These ranges and averages were in line with what the Company already knew, as explained by numerous former employees. The study also confirmed the significant number of invalid and defective tests produced—9.9% as compared to 0.7% of its competitor—and noted how that figure made the RVP4 test a poor candidate for acute and point of care testing where the need for immediate and accurate results was paramount. Specifically, the study found that the “proportion of erroneous and invalid RVP4 tests (**9.9%**, or 29 of the 292 swabs tested) was higher compared to Xpert tests (0.7%, or 2 out of 292 swabs tested),” which would “would limit the use of RVP4 as a point of care test, particularly in emergency units, when test runs are not continuously monitored by the staff to re-start the test in case of errors.”

374. Thus, *after* the Company already knew the dataset submitted in connection with Savanna’s FDA application was insufficient, Defendants continued to tout Savanna’s imminent launch and its revenue generation to investors. *See supra*, ¶¶303-04.

375. *Eleventh*, Defendants’ abrupt doubling of its endemic COVID-19 revenues going forward, following the market’s negative market reaction at QuidelOrtho’s December 13, 2022 Investor Day, further supports scienter. As explained above (*see* Section IV.E), prior to the

Company’s Investor Day, Defendants communicated \$150-\$200 million annually in endemic COVID-related revenue moving forward. Defendants reiterated this figure until December 13, 2022, when Defendants hosted an Investor Day—its first as a combined Company—during which Defendants Bryant, Bujarski, Ranalli, Iskra, and Busky participated. During the Investor Day presentation, the Company reported 6% to 9% top line growth excluding COVID, which was down from previously reported 9-11%. QuidelOrtho’s stock price dropped over 17% by market close—the largest intraday drop since November 2020. In response to the abysmal stock price reaction, Defendants immediately scrambled to flip the script, sitting down with analysts. In particular, Defendant Busky spontaneously revised QuidelOrtho’s COVID-revenue guidance upward to \$200 million to \$400 million, **double** the range stated leading up to the Company’s Investor Day just days prior. Analysts were pleased (*see supra*, ¶119), and QuidelOrtho’s stock slowly climbed—rewarding Defendants’ unsubstantiated upward revision of the Company’s endemic COVID-19 revenues throughout the Class Period until February 13, 2024.

376. **Twelfth**, both Defendants Busky and Bryant were responsible for QuidelOrtho’s COVID endemic revenue guidance. Busky routinely communicated the misleading endemic COVID-19 revenues to investors, and Bryant emphasized on November 2, 2022, just before Defendants doubled the endemic COVID-19 revenues, that he was “responsible for our estimate.”

377. **Thirteenth**, Defendant Busky solicited and received reports detailing COVID-19 inventory buildup. For example, FE-10 participated in quarterly Excess & Obsolete (E&O) meetings during his tenure where the Company’s significant levels of COVID-test inventory was regularly discussed. These meetings focused on the number of tests that were set to expire, and according to FE-10, that number increased in every quarter during FE-10’s tenure. FE-10 maintained an updated a report called the McKellar report, which included sales data for raw

materials and finished goods, weekly sales, and inventory levels. This report, according to FE-10 reflected that “nothing is selling” and inventory levels were increasing. Defendant Busky asked FE-10 for solutions to the Company’s inventory problems partially because Busky wanted guidance on “how to spin” this inventory issue on quarterly earnings calls. Defendant Busky similarly asked FE-10 to run numbers and provide analysis before Busky conducted earnings calls with investors, including how much exposure the Company had in terms of inventory and how much the Company would have to scrap. FE-10 noted that he and other finance colleagues smirked while listening to some earnings calls because Busky—who presented on earnings calls alongside Defendant Bryant—painted a “rosy picture” and put a “positive spin on the situation.”

378. **Fourteenth**, Defendant Busky received reports detailing how COVID-19 sales quotas were missed “by a mile” throughout 2023. As FE-19 explained, test sales “dropped off” in 2023 and most sales representatives at QuidelOrtho missed their respiratory sales quotas in 2023, FEs-3, 16, and 20 confirm (*see supra*, at ¶¶236, 254, 256, 258, 260-264). FE-20 explained data showing how far off salespeople were from hitting their 2023 annual respiratory sales quotas was presented to QuidelOrtho’s Finance team, and Vice President, Customer Operations North America, Charles Bellinghausen reported to Busky and other leaders that the Company was not going to hit its sales quotas during meetings at the end of each quarter throughout 2023. Busky also attended a few meetings where end of about quarter commission-based compensation payouts were discussed (*see supra*, at ¶264). FE-20 noted that former Vice President, Head of Global Commercial Finance, Robert Dunn, who provided 2023 compensation targets, reported to Busky, which suggests 2023 sales quotas came from Defendant Busky.

379. **Fifteenth**, Bryant was fired on February 14, 2024 in direct reaction to February 13, 2024 revelations about the Company’s poor financial results and endemic COVID-19 revenue

figures. *See* Section IV.H.2. There is also a colorable inference to be made that his termination was related to the imminent Savanna RVP4 FDA application withdrawal. Moreover, FE-3 recalled that prior to his departure from the Company, Defendant Bryant recorded a video that was emailed to all Company employees in connection with his firing. FE-3 detailed that in the video, it was FE-3's impression that Bryant took the blame or "rap" for the "unrealistic sales targets" that were set for QuidelOrtho in 2023.

380. ***Sixteenth***, Bujarski and Iskra were also fired under suspicious circumstances at the end of July 2024, after the Company lowered COVID-19 endemic guidance further, and the Savanna RVP4 FDA resubmission was stalled again, with Savanna revenue not projected until 2026. *See* Section I.1.

381. ***Seventeenth***, C-suite bonuses were tied to achieving "certain Savanna launch targets," and former employees confirm that compensation structure motivated the unrealistic and intense pressure surrounding Savanna. For example, FE-14 confirmed that Quidel's Executive Committee pushed Savanna RVP4 through even though they knew it was flawed because they wanted to get paid their bonuses and were under pressure to release the product. According to FE-13, confirmed that former Finance Manager James Pierce, explicitly said Savanna needs to "get out the door" because C-suite level bonuses were dependent on its launch. *See supra*, ¶¶136, 213.

382. The facts set forth above, when viewed holistically and together with the other allegations in this Complaint, support a strong and compelling inference that each of the Defendants knew or were severely reckless in not knowing that each of the misrepresentations and omissions alleged herein were materially false and misleading at the time they were made.

VII. LOSS CAUSATION

383. Lead Plaintiff incorporates by reference the allegations set forth above. During the Class Period, Defendants publicly disseminated materially false and misleading statements and

omitted material facts concerning the performance and success of the Savanna European launch, Savanna's readiness for a U.S. launch and its ability to secure FDA approval for U.S. sales, QuidelOrtho's ability to manufacture Savanna at scale to achieve its touted revenue synergies, and the Company's endemic COVID-19 revenue.

384. The conduct alleged and the materially false and misleading statements and omissions made during the Class Period caused QuidelOrtho's common stock to trade at artificially inflated prices, reaching as high as \$120.61 per share during the Class Period, operating as a fraud on investors in the Company's common stock.

385. When the truth was revealed through disclosures between February 13, 2024 and April 2, 2024, QuidelOrtho's common stock price declined significantly, as the artificial inflation was removed from the common stock price.

386. On February 13, 2024 (after market close), Defendants disclosed, *inter alia*, dismal earnings for Q4 2023 and fiscal year 2023, and disappointing guidance for fiscal year 2024, including primarily that it was slashing its previously disclosed endemic COVID-related revenues from \$200-\$400 million to only \$200 million.

387. On this news, QuidelOrtho's common stock price fell dramatically over the following trading days. After closing at \$66.77 per share on February 13, 2024, QuidelOrtho's common stock price plummeted over 32% on February 14, 2024 to a closing price of \$45.27 per share, on unusually high trading volume of over 10 million shares. On February 15, 2024, QuidelOrtho's common stock price resumed its downward slide as investors continued to digest the shocking news in the earnings announcement for Q4 and year-end 2023, closing at \$43.98 per share, after another atypically high trading volume day with nearly 3.4 million shares traded. This marked a new all-time low for QuidelOrtho's share price since the Merger.

388. QuidelOrtho's stock price slid further on February 16, 2024 after QuidelOrtho filed a Form 8-K with the SEC disclosing a "correction to its 2024 Guidance to widen the range for adjusted diluted EPS to align with 2024 Guidance for unadjusted EBITDA. . . ." On this news, QuidelOrtho's stock price dropped over 5%, falling an additional \$2.22 per share to close at \$41.76 per share at an unusually high trading volume of nearly 2.6 million shares.

389. In reaction to the Company's February 13, 2024 announcement, multiple analysts downgraded QuidelOrtho, expressed shock and surprise, and explained the significance of the disclosure. *See supra*, ¶¶291-92. For example, on February 14, 2024, analysts at Craig-Hallum downgraded QuidelOrtho, noting that "[r]espiratory is still the only thing that matters for this stock" and 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.*"

390. On March 4, 2024, a UBS analyst report was issued, before the market opened, that disclosed for the first time that QuidelOrtho was experiencing sharper declines in COVID-related revenues compared to its peers, revealing the falsity of Defendants' representations that the Company's poor 2023 results were attributable to market-wide decreases in COVID-19 testing and not the loss of market share of the Company's products. This report was cited by several news outlets.

391. In the wake of the March 4, 2024 UBS Report, QuidelOrtho's stock dropped nearly 3%, falling from a close of \$45.53 per share on March 1, 2024 to a close of \$44.33 per share on March 4, 2024. The stock fell an additional \$1.39 on March 5, 2024, closing at \$42.94 per share.

392. Then, on April 2, 2024, at the market open, QuidelOrtho disclosed that the Company was withdrawing its 510(k) submission for Savanna RVP4 because it did not meet the clinical market's expectations. In response to this news, QuidelOrtho's share price sank by **10%**

on unusually high trading volume of over 2.4 million shares, falling \$4.97 per share from a \$47.12 per share opening price on April 2, 2024 to a \$42.15 per share closing price on April 2, 2024.

393. After the April 2, 2024 disclosure, analysts from William Blair stated that: “*[t]he news on Savanna does not help improve sentiment on shares, and we are not all that surprised to see the stock trading down high-single-digits in this morning’s session.*” This William Blair analyst report also explained that this negative news came at a “critical time that is potentially lost for the company” as similar products offered by QuidelOrtho’s competitors recently obtained 510(k) clearance and CLIA-waiver approval. Similarly, a Raymond James analyst report issued on the same day commented on the decline in QuidelOrtho’s share price, stating that this “*news likely represent[s] the proverbial last straw for some holders.*”

394. The timing and magnitude of QuidelOrtho’s stock price declines evidence the impact that Defendants’ statements had on the Company’s stock price during the Class Period and negate any inference that the loss suffered by Lead Plaintiff and other Class members was caused by changed market conditions and macroeconomic, industry, or Company-specific factors unrelated to Defendants’ fraudulent conduct.

VIII. PRESUMPTION OF RELIANCE

395. To the extent that Lead Plaintiff alleges that Defendants made affirmative misstatements, Lead Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (b) the omissions and misrepresentations were material;
- (c) QuidelOrtho’s common stock traded in an efficient market;

(d) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of QuidelOrtho common stock;

(e) Lead Plaintiff and other members of the Class purchased QuidelOrtho common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts;

(f) QuidelOrtho common stock met the requirements for listing, and was listed and actively traded on the Nasdaq, a highly efficient and automated market;

(g) as a regulated issuer, QuidelOrtho filed periodic public reports with the SEC and the Nasdaq;

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

(i) QuidelOrtho was followed by securities analysts employed by major brokerage firms who wrote reports, which were distributed to those brokerage firms' sales force and certain customers and that were publicly available and entered the public marketplace; and

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

396. As a result of the foregoing, the market for QuidelOrtho common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in the price of QuidelOrtho common stock. All persons and entities who or which purchased or otherwise acquired QuidelOrtho common stock during the Class Period

suffered similar injuries through their purchase of QuidelOrtho common stock at artificially inflated prices, and thus, the presumption of reliance applies.

397. A class-wide presumption of reliance is also appropriate in this action under the United States Supreme Court holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), to the extent the claims asserted herein against Defendants are predicated upon omissions of material fact for which there is a duty to disclose.

IX. CLASS ACTION ALLEGATIONS

398. Lead 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 of all persons and entities who or which purchased or otherwise acquired the publicly traded common stock of Quidel and/or its successor QuidelOrtho during the period from after market close on February 17, 2022 through April 1, 2024, inclusive (the “Class Period”), and were damaged thereby (the “Class”). Excluded from the Class are: (i) Defendants; (ii) members of the immediate family of any Defendant who is an individual; (iii) any person who was an officer, director or control person of Quidel and/or QuidelOrtho during the Class Period and their immediate family members; (iv) any firm, trust, corporation, or other entity in which any Defendant has or had a controlling or beneficial interest; (v) Quidel and/or QuidelOrtho’s employee retirement and benefit plan(s), if any, and their participants or beneficiaries, to the extent they made purchases through such plan(s); and (vi) the legal representatives, affiliates, subsidiaries, heirs, successors-in-interest, or assigns of any such excluded person or entity, in their capacities as such.

399. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, QuidelOrtho’s shares actively traded on the Nasdaq. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are at least

hundreds or thousands of members in the proposed Class. Over 66 million QuidelOrtho shares were traded publicly during the Class Period on the Nasdaq. Record owners and other members of the Class may be identified from records maintained by 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.

400. Lead 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.

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

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

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

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, earnings, demand for its products, and specifically, whether Defendants' statements and omissions misrepresented (i) the progress and success of Savanna RVP4's launch in Europe, (ii) the performance of RVP4 and its ability to satisfy the objective threshold criteria established by the FDA, (iii) the Company's ability to manufacture RVP4 at the scale and cost necessary to bring it to market and achieve projected revenues in the U.S., and (iv) the Company's endemic COVID-19 revenues based on the facts known and knowable to Defendants;

(c) whether, and to what extent, the market price of QuidelOrtho common stock was artificially inflated during the Class Period because of the material misstatements alleged herein;

(d) whether Defendants acted with the requisite level of scienter;

(e) whether Defendants Bryant, Busky, Steward, Bujarski, Iskra, and Ranalli were controlling persons of QuidelOrtho;

(f) whether Defendants engaged in a scheme and participated in a continuous course of conduct that operated as a fraud and deceit upon Lead Plaintiff and the Class in connection with the purchase and sale of QuidelOrtho common stock; and

(g) whether the members of the Class have sustained damages as a result of the conduct complained of herein, and if so, the proper measure of such damages.

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

X. THE INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE

404. The statutory safe harbor applicable to forward-looking statements under certain circumstances does not apply to any of the false or misleading statements pled in this Complaint. The statements complained of herein were: (i) historical statements or statements of purportedly current facts and conditions at the time the statements were made; (ii) mixed statements of present and/or historical facts and future intent; and/or (iii) omitted to state material current or historical facts necessary to make the statements not misleading.

405. Further, to the extent that any of the false or misleading statements alleged herein could be construed as forward-looking, the statements were not accompanied by any meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements. Given the then-existing facts contradicting the Defendants' statements, any generalized risk disclosures made by the Defendants were not sufficient to insulate them from liability for their materially false and misleading statements.

406. Alternatively, to the extent the statutory safe harbor otherwise would apply to any forward-looking statements pleaded herein, the Defendants are liable for those false and misleading forward-looking statements because at the time each of those statements was made, the speaker knew the statement was false or misleading, did not actually believe the statements, had no reasonable basis for the statements, and were aware of undisclosed facts tending to seriously undermine the statements' accuracy.

XI. CONTROL PERSON ALLEGATIONS

407. The Individual Defendants, by virtue of their high-level positions with the Company, directly participated in the management of the Company and were directly involved in the day-to-day operations of the Company at the highest levels, and were privy to confidential proprietary information about the Company, including its business, operations, earnings, revenue, and demand for its products. The Individual Defendants participated in the drafting, preparing, and/or approving the public statements and communications complained of herein and were aware of, or recklessly disregarded, the material misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature.

408. The Individual Defendants, as senior executive officers of the Company, were able to and did control the content of the various SEC filings, press releases, and other public statements issued by or on behalf of QuidelOrtho during the Class Period. These Individual Defendants were

provided copies of the documents and statements alleged herein to be materially false and misleading prior to or shortly after their issuance and/or had the ability and opportunity to prevent their issuance or cause them to be corrected. Accordingly, the Individual Defendants are responsible for the accuracy of the public statements detailed herein.

409. The Individual Defendants, because of their positions of control and authority as senior executive officers, directors, and/or senior management had access to adverse undisclosed information about QuidelOrtho's business through their access to internal corporate documents and information, conversations and associations with other corporate officers and employees, attendance at regularly-held meetings, as well as other management and Board of Directors meetings thereof, and reports and other information provided to them in connection therewith.

410. As senior officers and controlling persons of a publicly held company whose common stock was, during the relevant time, registered with the SEC pursuant to the Exchange Act and traded on the Nasdaq, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to QuidelOrtho's operations and business, and to correct any previously-issued statements that were or had become materially misleading or untrue, so that the market price of QuidelOrtho common stock would be based upon truthful and accurate information. The Individual Defendants wrongdoing during the Class Period violated these specific requirements and obligations.

411. The Individual Defendants are liable as participants in a fraudulent scheme and course of conduct that operated as a fraud and deceit on all persons and entities who purchased or otherwise acquired QuidelOrtho common stock during the Class Period, by disseminating materially false and misleading statements and omitting material adverse facts. The scheme deceived the investing public regarding QuidelOrtho's business, operations, and management, and

the intrinsic value of QuidelOrtho's common stock, and caused Lead Plaintiff and members of the Class to purchase QuidelOrtho's common stock at artificially inflated prices.

412. In making the statements complained of herein, the Individual Defendants, who were senior officers and controlling persons of QuidelOrtho, were acting on behalf of the Company in the regular course of business. Therefore, each of the statements made by the Individual Defendants is attributable to the Company.

XII. CLAIMS FOR RELIEF UNDER THE EXCHANGE ACT

COUNT I

For Violation of Section 10(b) of the Exchange Act and Rule 10b-5(b) Against Defendants QuidelOrtho, Bryant, Busky, Bujarski, Iskra, and Ranalli

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

414. This Count is asserted pursuant to Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5(b), on behalf of Lead Plaintiff and the Class, against Defendants.

415. During the Class Period, Defendants QuidelOrtho, Bryant, Busky, Bujarski, Iskra, and Ranalli made, disseminated or approved the materially false or misleading statements alleged herein, all of which were about QuidelOrtho and its common stock, which they knew or, at minimum, were severely reckless in not knowing, were misleading in that they contained misrepresentations and omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

416. Defendants QuidelOrtho, Bryant, Busky, Bujarski, Iskra, and Ranalli violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they made untrue statements of material

fact and/or disseminated and/or approved and/or omitted to state material facts necessary to make the false or misleading statements specified above not misleading.

417. Defendants QuidelOrtho, Bryant, Busky, Bujarski, Iskra, and Ranalli individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails made various untrue and/or misleading 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 made the above statements and omissions intentionally or with severe recklessness.

418. Defendants QuidelOrtho, Bryant, Busky, Bujarski, Iskra, and Ranalli are liable for all materially false or misleading statements made during the Class Period, as alleged above.

419. During the Class Period, Defendants QuidelOrtho, Bryant, Busky, Bujarski, Iskra, and Ranalli acted with scienter throughout the Class Period, in that they acted either with intent to deceive, manipulate, or defraud, or with severe recklessness. The misrepresentations and omissions of material facts set forth herein, which presented a danger of misleading buyers or sellers of QuidelOrtho common stock, were either known to QuidelOrtho, Bryant, Busky, Bujarski, Iskra, and Ranalli, or were so obvious that they should have been aware of them.

420. Lead Plaintiff and the Class have suffered damages in that, in direct reliance on the integrity of market prices, they paid artificially inflated prices for QuidelOrtho common stock, which inflation was removed from its price when the true facts became known.

421. Defendants QuidelOrtho, Bryant, Busky, Bujarski, Iskra, and Ranalli's wrongful conduct, as alleged above, directly and proximately caused the damages suffered by Lead Plaintiff and other Class members. Had Defendants QuidelOrtho, Bryant, Busky, Bujarski, Iskra, and Ranalli disclosed complete, accurate, and truthful information concerning these matters during the

Class Period, Lead Plaintiff and other Class members would not have purchased or otherwise acquired QuidelOrtho common stock or would not have purchased or otherwise acquired these securities at the artificially inflated prices that they paid. It was also foreseeable to Defendants QuidelOrtho, Bryant, Busky, Bujarski, Iskra, and Ranalli that misrepresenting and concealing these material facts from the public would artificially inflate the price of QuidelOrtho's securities and that the ultimate disclosure of this information, or the materialization of the risks concealed by Defendants QuidelOrtho, Bryant, Busky, Bujarski, Iskra, and Ranalli's material misstatements and omissions, would cause the price of QuidelOrtho common stock to decline.

422. Accordingly, as a result of their purchases of QuidelOrtho common stock during the Class Period, Lead Plaintiff and the Class suffered economic loss and damages under the federal securities laws.

423. By virtue of the foregoing, Defendants QuidelOrtho, Bryant, Busky, Bujarski, Iskra, and Ranalli violated Section 10(b) of the Exchange Act and Rule 10b-5(b), promulgated thereunder.

424. This claim is timely within the applicable statute of limitations and repose.

COUNT II

For Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5(a) and (c) Against All Defendants

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

426. This Count is asserted pursuant to Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5(a) and (c) promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5(a) and (c), on behalf of Lead Plaintiff and the Class, against Defendants.

427. Defendant QuidelOrtho and the Individual Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) in that they: (a) employed devices, schemes, and artifices to defraud; and (b) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon Lead Plaintiff and others similarly situated in connection with their purchases of QuidelOrtho common stock during the Class Period in an effort to maintain artificially high market prices for QuidelOrtho common stock.

428. Defendants QuidelOrtho, Bryant, Busky, Steward, Bujarski, Iskra, and Ranalli, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, employed devices, schemes, and artifices to defraud and engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon Lead Plaintiff and the Class in connection with the purchase and sale of QuidelOrtho common stock; which did: (i) deceive the investing public, including Lead Plaintiff and the Class, regarding, among other things, QuidelOrtho's Savanna product, European launch, Savanna's ability to launch in the United States, and the Company's endemic COVID-19 revenues; (ii) artificially inflate and maintain the market price of QuidelOrtho common stock; and (iii) cause Lead Plaintiff and other members of the Class to purchase QuidelOrtho common stock at artificially inflated prices and suffer losses when the true facts became known.

429. As part of their scheme to defraud investors in violation of Rule 10b-5(a) and (c), the Defendants engaged in, for example, the following course of business conduct:

- (a) Pursuing Company-wide unrealistic sales goals and significant internal pressure to get Savanna RVP4 to market despite concerns from the "beginning" about the product's manufacturing, design and performance issues, *see supra*, Section IV.F;
- (b) Actively misrepresenting and concealing negative feedback, customer complaints and device failures regarding Savanna RVP4's performance in Europe, while knowing that Savanna's European launch was riddled with issues and the

Company had launched an unresolved internal investigation regarding those issues and misrepresenting and concealing the nature of Savanna's performance, *see supra*, Section IV.F.2-3;

(c) Dismantling and downsizing the team working on Savanna RVP4 to contain concerns and persistent issues with its performance and development internally to an "insular" group, *see supra*, Section IV.F.1;

(d) Disseminating false statements overstating the development and availability of additional Savanna panels, including GI, STIs, pharyngitis, and vaginitis panels, when those panels were not in development and described by a former employee as a "nearly impossible" and a "pipe dream," *see supra*, Section V.B;

(e) Failing to remediate issues with Savanna RVP4 before submitting the product for FDA approval and refusing to acknowledge that Savanna RVP4 test results, from its European feedback, clinical trials and internal testing, analysis and validation procedures did not meet the FDA's requirement of a consistent result of 95% detection and sensitivity, *see supra*, Section IV.F.3;

(f) Disseminating numerous false, unsubstantiated and unsupported claims that FDA approval was "a matter of time timing" when the Company was nowhere near ready for its U.S. launch, including because the Company had invested over \$100 million in an automated manufacturing line that did not work at any point during the Class Period, *see supra*, Section V.B-C; and

(g) Knowingly and intentionally revising its endemic COVID-19 revenue guidance without supporting data or substantiation that directly contradicted then-existing demand for QuidelOrtho's COVID-19 test products and competitive landscape, *see supra*, Sections IV.E, V.D.

430. These deceptive acts were part of a course of conduct that operated as a fraud and deceit upon Lead Plaintiff and others similarly situated in connection with their purchases of QuidelOrtho common stock during the Class Period in an effort to maintain artificially high market prices for QuidelOrtho common stock.

431. As described above, Defendants QuidelOrtho, Bryant, Busky, Steward, Bujarski, Iskra, and Ranalli acted with scienter throughout the Class Period, in that they either had actual knowledge of the misrepresentations or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose the true facts, even

though such facts were available to them. Defendants QuidelOrtho, Bryant, Busky, Steward, Bujarski, Iskra, and Ranalli engaged in this misconduct to conceal QuidelOrtho's true condition from the investing public and to support the artificially inflated prices of the Company's common stock.

432. Lead Plaintiff and the Class have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for QuidelOrtho common stock, which artificial inflation was removed from the stock when true facts became known. Lead Plaintiff and the Class would not have purchased QuidelOrtho common stock at the prices they paid, or at all, had they been aware that the market prices for QuidelOrtho common stock had been artificially inflated by Defendants QuidelOrtho, Bryant, Busky, Steward, Bujarski, Iskra, and Ranalli's fraudulent course of conduct.

433. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages attributable to the fraud alleged herein in connection with their respective purchases of the Company's common stock, call options, or put options during the Class Period.

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

COUNT III

For Violation of Section 20(a) of the Exchange Act Against the Individual Defendants

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

436. This Count is asserted pursuant to Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), on behalf of Lead Plaintiff and the Class, against each of the Individual Defendants.

437. As set forth above, each of the Individual Defendants acted as controlling persons of the Company within the meaning of Section 20(a) of the Exchange Act, as alleged herein.

438. By reason of their high-level positions of control and authority as QuidelOrtho's most senior officers and/or management, the Individual Defendants had the authority to influence and control, and did influence and control, the decision-making and activities of QuidelOrtho and its employees, and to cause QuidelOrtho to engage in the wrongful conduct complained of herein. The QuidelOrtho Individual Defendants were able to influence and control, and did influence and control, directly and indirectly, the content and dissemination of the public statements made by QuidelOrtho during the Class Period, thereby causing the dissemination of the materially false and misleading statements and omissions of material facts as alleged herein.

439. The Individual Defendants communicated with investors or the public on behalf of QuidelOrtho during the Class Period. The Individual Defendants were provided with, or had unlimited access to, copies of the Company's press releases, public filings, and other statements alleged by Lead Plaintiff to be misleading prior to and/or shortly after these statements were made and had the ability to prevent the issuance of the statements or to cause the statements to be corrected. Therefore, these Individual Defendants were able to influence and control, and did influence and control, directly and indirectly, the content and dissemination of the public statements made by QuidelOrtho during the Class Period, thereby causing the dissemination of the materially false and misleading statements and omissions of material facts as alleged herein.

440. QuidelOrtho violated Section 10(b) of the Exchange Act by virtue of the acts and omissions of its senior executives and/or management, including the Individual Defendants, as alleged in this Complaint.

441. By virtue of their positions as controlling persons of QuidelOrtho and as a result of their own aforementioned conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act to Lead Plaintiff and the other members of the Class who purchased or otherwise acquired QuidelOrtho common stock during the Class Period. As detailed above, during the respective times, these Defendants served as officers, directors, and/or senior personnel of QuidelOrtho.

442. The Individual Defendants acted as controlling persons of QuidelOrtho within the meaning of Section 20(a) of the Exchange Act by virtue of their executive and/or senior positions and their culpable participation, as alleged above. The Individual Defendants had the power to influence and control and did, directly or indirectly, influence and control the decision making of the Company, including the content and dissemination of the various statements that Lead Plaintiff contends were false and misleading. The Individual Defendants were provided with or had unlimited access to the Company's internal reports, press releases, public filings, and other statements alleged by Lead Plaintiff to be misleading prior to or shortly after these statements were issued, and had the ability to prevent the issuance of the statements or cause them to be corrected.

443. In particular, the Individual Defendants had direct involvement in and responsibility over the day-to-day operations of the Company, and/or intimate knowledge of the Company's actual performance, and had the power and ability to control public statements about QuidelOrtho and the actions of the Company and its employees. Moreover, the Individual Defendants were each directly involved in providing false information and certifying and/or approving the materially false or misleading statements disseminated by QuidelOrtho during the Class Period. As a result of the foregoing, the Individual Defendants each were controlling persons of QuidelOrtho within the meaning of Section 20(a) of the Exchange Act.

444. As alleged above, QuidelOrtho violated Section 10(b) of the Exchange Act by its material misrepresentations and omissions as alleged in this Complaint. By virtue of their positions as controlling persons of QuidelOrtho and as a result of their own aforementioned conduct, the Individual Defendants are each liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Lead Plaintiff and the other members of the Class who purchased or otherwise acquired QuidelOrtho common stock. Moreover, as alleged above, during the respective times that the Individual Defendants served as officers, directors, and/or senior management of QuidelOrtho (or one of the two corporate entities that existed prior to the corporate transaction on May 27, 2022), each of the Individual Defendants culpably participated in the material misstatement and omissions made by QuidelOrtho, as set forth above.

445. As a direct and proximate result of the Individual Defendants' wrongful conduct, Lead Plaintiff and other members of the Class suffered damages in connection with their purchases or acquisitions of QuidelOrtho common stock during the Class Period.

446. This claim is timely within the applicable statutes of limitations and repose.

XIII. PRAYER FOR RELIEF

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

(a) Determining that this action is a proper class action maintainable under Rule 23 of the Federal Rules of Civil Procedure, certifying Lead Plaintiff as class representative, and appointing Labaton Keller Sucharow LLP as Class Counsel pursuant to Rule 23(g);

(b) Awarding Lead Plaintiff and the Class compensatory damages and equitable relief, including all damages and relief provided for under the Exchange Act, against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongful conduct, in an amount to be proven at trial, including interest thereon;

(c) Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including to attorneys' fees and expert fees; and

(d) Awarding any equitable, injunctive, or other further relief that the Court may deem just and proper.

XIV. JURY DEMAND

Lead Plaintiff hereby demands a trial by jury of all issues so triable.

DATED: February 7, 2025

Respectfully submitted,

/s/ Lauren A. Ormsbee

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