

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE QUIDELORTHO CORPORATION
SECURITIES LITIGATION

24-CV-02804 (JAV)

OPINION AND ORDER

JEANNETTE A. VARGAS, United States District Judge:

Court-appointed Lead Plaintiff Central States, Southeast and Southwest Areas Health and Welfare Fund (“Central States”) and Teamsters Local 710 Pension Fund (“Local 710”) (collectively, the “Teamsters Funds” or “Lead Plaintiff”) brings this federal securities class action on behalf of itself and a class consisting of all persons and entities damaged by their acquisition of the publicly traded common stock of Quidel Corporation (“Quidel”) and/or its successor QuidelOrtho Corporation (“QuidelOrtho”) (collectively, the “Corporate Defendant” or the “Company”) during the period from after market close on February 17, 2022, through April 1, 2024 (the “Class Period”). The Teamsters Funds allege material misrepresentations by QuidelOrtho’s senior executives and bring claims for violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (“the Exchange Act”) and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5, against the Corporate Defendant as well as QuidelOrtho’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, “Individual Defendants”). ECF No. 42 (“Amended Complaint” or “Am. Compl.”), ¶¶ 413-446. Presently before the Court are Defendants’ Motion to Dismiss the Amended Complaint (“Motion to Dismiss”), Plaintiff’s motion to strike, and Defendants’ motion to strike. ECF No. 47, 51-52, 57-58.

For the following reasons, the motions to strike are **DENIED** and Defendants’ Motion to Dismiss is **GRANTED IN PART AND DENIED IN PART**.

BACKGROUND

The following allegations from the Amended Complaint are presumed true and construed in the light most favorable to Lead Plaintiff. *Slayton v. Am. Express Co.*, 604 F.3d 758, 766 (2d Cir. 2010) (“In considering a motion to dismiss a 10(b) action, we must accept all factual allegations in the complaint as true and must consider the complaint in its entirety.” (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007))).

A. Quidel’s Pre-Merger Business and the COVID-19 Pandemic

QuidelOrtho is a Delaware corporation that emerged from the 2022 merger of Quidel and Ortho. Am. Compl., ¶ 36. Quidel developed and marketed diagnostic

testing solutions, including rapid immunoassay tests (notably the Sofia platform), cardiometabolic immunoassays, molecular diagnostic solutions (Lyra and Solana platforms), and specialized diagnostic solutions. *Id.*, ¶ 68. Prior to the COVID-19 pandemic, Quidel’s annual revenues were steady, with \$534.9 million reported in 2019. *Id.*, ¶ 69. During this time period, Quidel did not typically provide the market with revenue projections on a yearly basis. *Id.*

With the onset of the COVID-19 pandemic in early 2020, Quidel received Emergency Use Authorization (“EUA”) for several COVID-19 diagnostic tests, including the Lyra, Sofia, and Solana platforms. *Id.*, ¶ 70. COVID-19 test sales drove a dramatic increase in revenues: \$1.163 billion in 2020 (70% of total revenue) and \$1.274 billion in 2021 (75% of total revenue). *Id.*, ¶ 74. The company’s stock price rose accordingly, peaking at \$283.45 per share in November 2020. *Id.*, ¶ 3.

By mid-2021, Quidel anticipated a transition from pandemic to endemic COVID-19, with a reduction in testing demand akin to other, more common respiratory illnesses. *Id.*, ¶ 4. The company sought to maintain its revenue and stock performance as pandemic-driven sales waned. *Id.*

B. Quidel’s Merger with Ortho and the Role of Savanna

In May 2021, Quidel began exploring a merger with Ortho Clinical Diagnostics Holdings PLC (“Ortho”), a leading in-vitro diagnostics company. *Id.*, ¶¶ 5, 75. The merger was publicly announced on December 23, 2021, and completed on May 27, 2022, with QuidelOrtho as the successor entity. *Id.*, ¶ 75. The merger was justified in part by the anticipated synergies from Quidel’s soon-to-launch

Savanna molecular diagnostic platform, which was expected to drive \$75 million of the \$100 million in projected revenue synergies. *Id.*, ¶ 78.

First announced in 2011, the Savanna platform was marketed as a low-cost, rapid, multiplex PCR (Polymerase Chain Reaction) testing solution capable of detecting multiple respiratory pathogens in approximately 30 minutes. *Id.*, ¶ 79. The platform’s flagship laboratory test, the Savanna Respiratory Viral Panel-4 (“RVP4”), was designed to test for influenza A and B, COVID-19, and RSV from a single sample. *Id.*, ¶ 80. According to the Company’s former Senior Director, Regulatory Affairs from January 2020 to April 2024 (“FE-1”),¹ the Company’s ability to be first to market with Savanna’s new molecular diagnostic technologic was critical to its success, as several competitors were similarly attempting to develop products that could provide quick test results with the same high level of accuracy as PCR tests. *Id.*, ¶ 129. FE-1, FE-2 (a former Senior Director, Systems Engineering from February 2020 through September 2023), and FE-4 (a scientist who led Savanna RVP4’s EU launch, among other roles from mid-2020 to fall 2023) added that the Savanna launch faced additional pressure because QuidelOrtho’s dominant point of care immunoassays—the Sofia 1 and Sofia 2 analyzers—were reaching their production “end of life.” *Id.*, ¶¶ 138-146. Defendant Bryant repeatedly characterized Savanna as “***the most important product introduction in our history***” and attributed most of the \$100 million in expected revenue

¹ Former employees are hereinafter referred to, per the Amended Complaint, as “FE-___.” See Am. Compl. at 2 & ¶¶ 46-66.

synergies to Savanna’s launch. *Id.*, ¶ 82.

Quidel obtained limited European approval for Savanna and its RVP4 test in July 2021, allowing sales and marketing in certain European countries (the “European launch” or “EU launch”). *Id.*, ¶ 83. In the lead-up to the merger, Defendants made several statements regarding the European launch, citing “***very positive customer feedback***” and positioning Savanna as a major growth driver for the merged company.² *Id.*, ¶¶ 7, 84.

C. Public Statements and Disclosures Regarding Savanna RVP4, Manufacturing Capabilities, and COVID-19 Revenues

Throughout the Class Period, QuidelOrtho and its executives made numerous public statements asserting that the European launch of Savanna RVP4 was successful, that customer feedback was positive, and that the platform was ready for U.S. Food and Drug Administration (“FDA”) approval and to launch in the United States. For example, on February 17, 2022, CEO 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.***” *Id.*, ¶¶ 7, 91. On March 9, 2022, during the Raymond James Annual Investors Conference, Bryant reported 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.***” *Id.*, ¶ 93. Similar statements were made in earnings calls, investor conferences, and analyst presentations throughout 2022 and 2023. *Id.*, ¶¶ 321-322.

² Certain reproduced statements are bolded and italicized, per the Amended Complaint, to distinguish alleged misrepresentations from unchallenged text

Defendants appeared to assure investors that Savanna RVP4 was on track for FDA approval and that the company would achieve \$75 million in merger revenue synergies and \$300 million in annual Savanna revenues within three years of U.S. launch. *Id.*, ¶¶ 95, 222, 327-328. These assurances were reiterated as the Company struggled to meet the FDA’s requirements. *Id.*

Essential to achieving these synergies was the Company’s ability to manufacture the RVP4 test at scale. *Id.*, ¶ 222. Bryant represented that QuidelOrtho would be prepared to manufacture Savanna RVP4 at scale, with automated production lines capable of producing over one million cartridges per month. *Id.*, ¶¶ 222, 339-340. The Company invested \$100 million in this manufacturing capability. *Id.*, ¶ 222.

In mid-2022, QuidelOrtho initially guided investors to expect \$150-\$200 million in annual endemic COVID-19 revenues, a significant reduction from pandemic levels. *Id.*, ¶¶ 109-110. Following a negative market reaction to the company’s December 13, 2022 Investor Day, however, CFO Busky doubled the guidance to \$200-\$400 million without providing supporting data. *Id.*, ¶¶ 114-16, 429. This higher guidance was repeated throughout 2023. *Id.*, ¶ 116. Despite internal reports of declining COVID-19 test sales and mounting inventory, Defendants continued to publicly assert that demand remained strong and that the company was “very comfortable” with the \$200-\$400 million range. *Id.*, ¶¶ 20, 120.

D. Internal Reports and Complaints Underlying Public Statements

FE-10, Finance Director throughout the Class Period until Fall 2023, detailed

that prior to the Merger, employees at QuidelOrtho turned from optimistic about Savanna to perceiving that it was “not a real thing.” *Id.*, ¶ 195. 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.” *Id.* In 2022, FE-10 heard from a former Finance Manager and current Chief Operations Officer—who attended Savanna production meetings, weekly meetings with Savanna manufacturing, and regular meetings with Defendant Ranalli—that Savanna was failing tests, that it was not doing what it was supposed to do, and that the Company was spending money on a product that was not going to work. *Id.* FE-11, a senior sales manager, affirmed that these issues were “widely known.” *Id.*, ¶ 197. 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. *Id.*, ¶ 193. FE-10 recalled that Savanna RVP4 had issues throughout his entire tenure. *Id.* FE-10 stated that he never thought Savanna would be in production and that every test ran for Savanna was “bad news.” *Id.*, ¶ 194. FE-6 understood that the Company would halt production of Savanna RVP4 in April 2024, the month he left the company. *Id.*, ¶ 189.

1. EU Launch Failures

Twenty-one former employees involved in Savanna’s development and launch—several of whom held senior positions at the Company—described significant, unresolved design and manufacturing flaws, including high rates of

invalid test results and device failures. *Id.*, ¶¶ 21, 46-66, 160-209. FE-14, an engineer at the Company until the second half of 2023, described “fundamental flaws” in the manufacturing of the Savanna RVP4 assay cassette that the Company “chose to ignore” prior to the Class Period, instead choosing to transfer Savanna RVP4 to a smaller team that would stop providing cross-functional information within the Company and instead “push” the product to production. *Id.*, ¶¶ 132-34. FE-14 added that the Company skipped quality assurance measures like reliability testing because the Savanna instrument and cartridge would break and fail if subjected to them. *Id.*, ¶ 135. FE-6, a Cost Accounting Manager throughout the Class Period, described the process of bringing Savanna to market as “flying a plane while building it.” *Id.*, ¶ 165. FE-4 described the EU launch as a “defining moment” full of technical challenges from its “beginning.” *Id.*

FE-4 characterized himself as having the “best pulse” on the EU launch performance of all his United States-based colleagues because he worked directly with colleagues in Italy and Germany and communicated with them weekly. *Id.*, ¶ 171. Along with FE-4, FE-7 drafted promotional marketing materials used for Savanna sales in Europe, which FE-4 said included “claims about the Savanna RVP4 test performance and capabilities” that were “just a wish or a dream.” *Id.*, ¶¶ 166-67. After 20 years in “this line of work,” FE-7 “didn’t remember any market launch that was so full of issues.” *Id.*, ¶ 190.

Demand for Savanna in Europe was limited and restricted to late 2021 and the first quarter of 2022. *Id.*, ¶ 170. FE-4 recalled, and FE-7 corroborated, that the

Company sold only about 40 to 55 Savanna devices from the July 2021 launch through mid-2023. *Id.* Customers throughout this period included about six hospitals across Austria and eastern Germany around December 2021 and 16 hospitals in Italy in mid-2022. *Id.*

In their positions, FE-4 and FE-7 were updated weekly on all of the complaints and issues with Savanna RVP4 in the European market. *Id.*, ¶ 171. FE-7 also noted “issues with Savanna from the beginning.” *Id.*, ¶ 172. FE-4 personally became aware of the device’s “widespread failure” between June 2022 and November 2022. *Id.*, ¶ 173. The test’s assay did not work “from the very beginning,” and one in every four Savanna RVP4 instruments sold in Europe had to be replaced at cost due to invalid results—a “depressing” outcome for the Company. *Id.*, ¶¶ 172-73. Indeed, there were times the replacement tests also failed. *Id.*, ¶ 173. The Company’s inventory and production costs increased as it began to send backup tests with every instrument in case problems arose. *Id.*, ¶ 188. The industry standard for invalid results is 1-2%, but the invalid rate for Savanna was between 10 and 30%. *Id.*, ¶ 176. Jürgen Becker, Scientific Marketing Manager, Europe, informed FE-4 that Savanna RVP4 customers were “irate.” *Id.* ¶ 173. Other manufacturing errors also plagued the rollout, with one in four Savanna RVP4 test instruments failing due to overheating, frozen screens, and/or spring ejection issues. *Id.*, ¶ 179.

European customer complaints stayed steady, and even increased, as the Class Period progressed. *Id.*, ¶ 177. FE-8, a former member of the Quality

Assurance team throughout the Class Period, recalled an “uptick” in complaints from European Savanna customers in approximately August 2023. *Id.*, ¶ 177.

Whereas the Company had previously received between 11 and 13 Savanna RVP4 complaints per month from European customers, it received over 30 such complaints in August 2023, all recorded in Salesforce. *Id.* On a scale measuring the seriousness of customer complaints from “Green” to “Yellow” to “Red,” the Company assigned the August 2023 Savanna RVP4 complaints a “Red” grade, significant enough to open a Corrective and Preventative Action (“CAPA”) investigation in summer 2023 to address the complaints, identify their root cause, and prevent it from reoccurring. *Id.*, ¶ 178. Those notified of this CAPA included the research and development team for Savanna RVP4, the Company’s Vice President of Clinical, Regulatory & Quality Assurance, and the Company’s Director of Operations, who reported to the Company’s Vice President, Operations Brad Smith. *Id.* Further, information about this CAPA was shared internally in monthly or quarterly internal business unit reports to upper management. *Id.* FE-8 reported that the Company was still investigating the root cause of the error codes behind the CAPA when he left in July 2024. *Id.* Likewise, FE-9, former Vice President, Sales and Marketing, Europe throughout the Class Period, confirmed that the steady stream of customer complaints about Savanna’s invalid results, failing assays, and failing controls were still being addressed when he left the Company in June 2024. *Id.*, ¶¶ 178-79.

Senior management was informed of European customer complaints, which

continued from the start of the EU launch through the end of the Class Period. *Id.*, ¶¶ 182-188. In an effort to prevent reputational damage, the Company found itself “firefighting.” *Id.*, ¶ 182. It enacted a formal complaint system to register customer issues in the EU, which were then sent to Defendant Ranalli, who reported to Defendant Bryant. *Id.*, ¶¶ 183, 185. Generally, customers complained to sales representatives, who then submitted complaint paperwork to the head of service in the EU, who then reported on complaint statistics for Europe. *Id.*, ¶ 184. All complaints were also formally reported to the Company’s office in Ireland, where leadership prepared quarterly reports on the complaints and sent them to the Company’s United States headquarters. *Id.*, ¶ 183. According to FE-7, there was no lack of visibility regarding Savanna’s problems, and every single issue with Savanna was reported to Irish leadership. *Id.*, ¶ 184. Former Vice President, Sales and Marketing, Europe from October 2017 through June 2024, FE-9, confirmed Irish leadership was in “constant contact” with the Company’s U.S. Headquarters, particularly Senior Vice President, Research and Development Werner Kroll, who then—according to FE-9—relayed such discussions to Defendants Ranalli, Bryant, and Bujarski. *Id.*, ¶¶ 54, 184.

After Savanna launched in Europe in late 2021, the Director of Global Product Management held “many, many . . . Zoom-style” calls about Savanna at least monthly with a regular group of fewer than ten people, including Defendant Ranalli and FE-7. *Id.*, ¶¶ 185-87. At these calls, Becker disclosed to Ranalli that the Savanna RVP4 tests were failing in Europe and provided her with the negative

customer feedback. *Id.*, ¶ 186. Between 60 and 80% of European customer feedback on Savanna was negative. *Id.* FE-7 recalled, during one of these calls in 2023, a PowerPoint presentation that included a quarterly report showing 80 units of Savanna in distribution and 85 complaints. *Id.*, ¶ 188.

2. FDA Approval

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. *Id.*, ¶ 194. As Finance Director, FE-10 added that longtime Financial Planning & Analysis, Accounting and Operations Finance colleagues told him that the Company had worked on the Savanna test for years and their “consistent sentiment” was that they did not think the test “would ever work.” *Id.* QuidelOrtho nonetheless pushed for FDA clearance even though employees who worked directly or indirectly with the Savanna RVP4 test knew that the test had “glaring issues.” *Id.*, ¶ 206.

Internal regulatory and validation teams reportedly informed management that Savanna RVP4 could not consistently achieve the 95% sensitivity required for FDA approval, yet the company proceeded with its FDA required form 510(k) application for clearance to sell Savanna. *Id.*, ¶¶ 200-204, 359-360, 371. FE-11 reported that the test “never came close” to reaching the 95% sensitivity threshold. *Id.*, ¶ 199.

As Senior Director, Regulatory Affairs during the Class Period, FE-1 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), who reported to Kroll. *Id.*, ¶ 198. FE-1 reported that Kroll, Lollar, and Bodien—and likely, in his estimation, Defendant Bryant—made the decision to make the FDA submission in the second quarter of 2023. *Id.* Conversations FE-1 had in late 2023 confirmed that Company management—including Kroll and Defendants Bryant and Bujarski—knew that Savanna RVP4 was not consistently meeting the FDA’s detectability requirements. *Id.*, ¶¶ 198, 204.

The Company kept written documentation of the feedback and discussions with the FDA, including minutes of meetings with the FDA prior to submission. *Id.*, ¶ 205. Status updates in the form of notes and PowerPoint slides regarding the Savanna FDA application were also reported regularly to the C-suite and the Board of Directors, at least monthly. *Id.* FE-1 recalled Defendant Bryant’s practice of “open dialogue” with the FDA and that he was typically involved in discussions with the FDA regarding the Company’s COVID test-related products. *Id.*

Associate Director of Assay Verification & Validation, Research & Development Shawna Prange was responsible for validating Savanna for FDA submission. *Id.*, ¶¶ 206-08. As part of the validation process prior to submission, RVP4’s chemistry was subjected to a variety of viral loads to test its sensitivity under varying conditions and extremes. *Id.*, ¶ 208. According to FE-2, Savanna could not achieve the needed sensitivity readings or pick up enough results as part of that process. *Id.* In summer 2023, Prange—whose studies were core to the Company’s FDA submission—commented to FE-4 that the Savanna RVP4 test “does

not work” and that it “isn’t even a product.” *Id.*, ¶ 206. Senior scientist FE-12, who worked on Savanna throughout 2023 and the first half of 2024, confirmed that detectability issues like high rates of invalid test results and false positives—in addition to issues with Savanna on a molecular level—persisted “across the board” through the end of the Class Period. *Id.*, ¶¶ 209-10.

According to FE-4, Prange knew the product could not achieve the required 95% confidence interval and “will never get it” but received “a lot of pressure” from a “top-down mandate” at the Company to approve Savanna “no matter the cost.” *Id.*, ¶ 207. Several other employees expressed concern to management over the “many shortcuts” it was taking to rush Savanna to market. *Id.*, ¶ 211. In FE-4’s scientific opinion, Savanna would not receive FDA clearance, and if it managed to, it would get recalled. *Id.*, ¶ 212. In September 2023, he told a high-level senior executive who reported directly to Defendant 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.” *Id.*

3. Scale

QuidelOrtho’s ability to automate Savanna RVP4 production was essential to its projected profits after achieving FDA approval. *Id.*, ¶ 222. Indeed, Defendant Bryant identified the Company’s ability to quickly manufacture and get to market instruments and cartridges “**at very, very high volumes**” as the “**only constraint**” on Savanna RVP4’s U.S. launch. *Id.*, ¶ 339(d). He estimated the Company would “**outfit . . . over 1 million cartridges per month . . . within 3 years.**” *Id.*,

¶ 339(e). Specifically, from the start of the Class Period, Defendants told investors that the Company would realize \$75 million of Merger revenue synergies by 2025 in connection with the Savanna launch, another \$30-\$50 million in Savanna revenues by the end of 2024, and \$300 million per year within three years of launch. *Id.*, ¶ 222.

The Company's efforts to build an automated manufacturing line for Savanna were never close to successful. *Id.*, ¶¶ 221-228. The Company's manual production of Savanna tests yielded usable tests far below the expected, normal threshold. *Id.*, ¶ 223. These issues were reported to senior management. *Id.*, ¶ 229. Indeed, FE-4 explained that QuidelOrtho was forced to scrap a "very alarming" 50-80%, and sometimes 90%, of the Savanna assays it manufactured due to defects. *Id.*, ¶ 223. FE-12 advised that the Savanna test suffered from both possible contamination issues and problems on a molecular level. *Id.*, ¶ 210. In the process of scaling up from pilot batches of assays of about 500 units to production scale, the tests produced rates of invalid or false positives that were too high for even in-house use. *Id.* By the time FE-10 left in fall 2023, RVP4 production efforts had only reached a manufacturing yield of 50%, "way below" the Company's ideal yield rate of 90%. *Id.*, ¶ 223. FE-6 confirmed that production yields for Savanna were 30-40% when they should have been 70-80%. *Id.*

After scrapping nearly half of its RVP4 manufacturing yield, the Company also needed to scrap many RVP4 tests during final inspection due to a high level of invalid test results—"the worst result for a clinician." *Id.*, ¶¶ 174, 224. FE-2

confirmed that, for example, in a production batch of 1000 units, maybe 500 needed to be scrapped immediately due to manufacturing errors, and of about 50 selected for random quality testing from that pool, an additional 10% to 50% would fail. *Id.*, ¶ 225. The Company was thus scrapping up to 50% of the entire production line, compared to a 5% standard industry failure rate. *Id.*, ¶ 224. There were times the Company had to shut the entire production line down because everything was failing. *Id.* Meanwhile, the Company's manual production line increased costs and the potential for human error and contamination. *Id.*, ¶ 226. The Company ultimately spent upwards of \$80-100 million on the incomplete automated production line, for which there was never a concrete location. *Id.*, ¶ 228. FE-6 indicated that he raised "red flags" "up the chain" about rising costs associated with production issues multiple times. *Id.*, ¶ 229. Each month, FE-6 told Defendant Busky that the Company would charge costs to Research & Development because Savanna still needed adjustments and research to address its failures. *Id.*

4. Sales

By late 2022 and throughout 2023, internal reports and sales data for products such as the Sofia analyzer showed that QuidelOrtho's COVID-19 test sales were in decline, with the company losing market share to competitors offering more advanced or cost-effective products. *Id.*, ¶¶ 236-237, 240-41. Sales teams consistently missed quotas, and inventory of unsold tests accumulated to concerning levels. *Id.*, ¶¶ 251-268, 270. These negative trends were communicated to senior management, including Defendant Busky, through regular reports, meetings, and

direct conversations. *Id.*, ¶¶ 276-277. Finance and sales personnel provided detailed analyses of missed quotas and excess inventory and sought guidance from the C-suite on how to address or “spin” these issues for investors. *Id.*

FE-13, a Cost Accountant at the Company from February 2022 through March 2023, confirmed that Savanna was not passing the Company’s internal qualifications or testing in 2022 and early 2023. *Id.*, ¶ 213. FE-13 explained that she learned of the Company’s goal to get Savanna on the market by the end of 2023 and the product’s testing problems during daily “standups” for Triage and monthly leadership meetings. *Id.*

FE-6, another Cost Account Manager, knew that problems with the Savanna test instrument and chemical assay “always” amounted to a “huge situation” that doubled the unit cost for the instrument due to quality control issues. *Id.*, ¶ 214. Whereas FE-6 cited a strong return-on-investment for production as yielding 70-80% usable tests, Savanna’s yield was only 30-40%. *Id.*, ¶ 215. These poor yield rates and the amount of scrap material generated by the tests were recorded, including in emails and the Enterprise Resource Planning system used by the company, and reported every month to senior management. *Id.* He input information regarding cost accounting issues for Savanna into a system that generated reports for month-end financial close meetings with upper management, including the Company’s Controller and Global Operations Finance Senior Manager, who reported directly to Defendant Busky. *Id.*

FE-13 corroborated that, because Savanna was supposed to be the Company’s

next big “money-maker,” issues with Savanna were communicated to the C-Suite “all the time,” and “everyone” knew about its problems. *Id.*, ¶ 216. FE-2 elaborated that “every test” of Savanna’s performance was documented, and any change to its engineering or assay was required to be documented in a design review. *Id.*, ¶ 217. “[S]tandard practice” was for engineers and scientists to report findings to their managers, who reported findings through PowerPoints to senior management such as Kroll and Defendant Ranalli, who then reported information to Defendants Bujarski, Bryant, and Iskra. *Id.*, ¶ 217-18. Kroll personally reviewed all findings. *Id.*, ¶ 219. FE-2 met weekly with Kroll before and during the Class Period until his September 2023 departure. *Id.* Kroll met quarterly with the Board and senior management to provide project updates on Savanna, such that senior management—specifically, Defendant Bryant—was made aware of Savanna’s failure rate and assay problems when it was submitted to the FDA in mid-2023 and thereafter. *Id.* FE-5, a Territory Account Manager and Acute Account Manager at the Company who pre-sold a high volume of RVP4 tests to customers in 2022, recalled that the Company wanted salespeople to generate interest but could “never actually back it up with an actual product.” *Id.*, ¶ 220.

E. Corrective Disclosures and Market Reaction

After close of market on February 13, 2024, QuidelOrtho reported disappointing earnings for fourth quarter and fiscal year 2023 and cut guidance for endemic COVID-related revenue. *Id.*, ¶ 386. Previous guidance put this revenue between \$200 and \$400 million, while the February 13 disclosure moved the

guidance to \$200 million. *Id.* Defendants Bujarski, Bryant, and Iskra continued to make positive statements about Savanna RVP4’s FDA approval prospects. *Id.*, ¶ 373. The next day, on February 14, 2024, QuidelOrtho’s stock price fell 32% in a single trading session, moving from \$66.77 per share on the 13th to \$45.27 on the 14th. *Id.*, ¶ 387. Two market analysis firms downgraded the stock, each citing communications by QuidelOrtho executives. *Id.*, ¶¶ 291-292. The Company announced the termination of CEO Bryant a week later, with analysts attributing the move to the week’s disappointing financial results. *Id.*, ¶¶ 300-301.

On March 4, 2024, UBS released an analyst report that downgraded QuidelOrtho stock to “sell.” *Id.*, ¶ 296. The report suggested that the Company was losing market share in COVID-related sales. *Id.* On April 2, 2024, QuidelOrtho disclosed that it had withdrawn its FDA 510(k) submission for Savanna RVP4, citing failure to meet performance expectations. *Id.*, ¶ 303. The stock price dropped another 10% after this announcement. *Id.*, ¶ 306. On July 31, 2024—after the Company lowered COVID-19 endemic guidance further, the Savanna RVP4 FDA resubmission was stalled again, and Savanna revenue projections were pushed out to 2026—Defendants Bujarski and Iskra were fired. *Id.*, ¶¶ 27, 380.

F. Roles of Individual Defendants

Douglas Bryant served as CEO throughout the Class Period and occupied a public-facing role for the company’s communications regarding Savanna and COVID-19 revenues. *Id.*, ¶¶ 4, 37, 344. He oversaw the Executive Steering Committee for the Savanna project, signed SEC filings, and was directly involved in

decisions regarding product launch, regulatory submissions, and public guidance. *Id.*, ¶¶ 37, 43, 205, 357.

As CFO, Joseph Busky was responsible for financial reporting and revenue guidance, including the abrupt doubling of endemic COVID-19 revenue projections. *Id.*, ¶¶ 38, 108. He received reports on sales, inventory, and financial risks and participated in public statements and earnings calls. *Id.*, ¶¶ 43, 215, 376-378.

Former CEO Randall Steward, COO Bujarski, CCO and Interim CEO Iskra, and SVP of Molecular Diagnostics Ranalli each played key roles in the development, marketing, and oversight of Savanna and were recipients of internal reports detailing product issues and sales trends. *Id.*, ¶¶ 39-43, 360-362. For these and the other C-suite executives, compensation was allegedly tied to Savanna's launch. *Id.*, ¶¶ 136 ("Kroll, Defendant Steward, and Defendant Bujarski had large incentives in their employment contracts that were tied to Savanna RVP4 advances."), 381 (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.).

G. Procedural History

On April 12, 2024, Bristol County Retirement System filed a class action complaint against QuidelOrtho and three of its executives on behalf of all investors who purchased or otherwise acquired QuidelOrtho common stock during the Class Period ("the Securities Action"). ECF No. 1. About two weeks later, individual QuidelOrtho shareholder Matthew Whitfield separately filed a shareholder

derivative action on behalf of QuidelOrtho against several members of the Company's board of directors and the QuidelOrtho executives named as Defendants in the Securities Action. *In Re Quidelortho Corporation Derivative Litigation*, No. 24-CV-03176 (S.D.N.Y.). The following day, Whitfield filed a Statement of Relatedness to the Securities Action. *In Re Quidelortho Corporation Derivative Litigation*, No. 24-CV-03176, ECF No. 3 (S.D.N.Y. April 26, 2024). Two months later, individual QuidelOrtho shareholder Steven Pinkney also separately filed a shareholder derivative action and a Statement of Relatedness to the Securities Action. *In Re Quidelortho Corporation Derivative Litigation*, No. 24-CV-04753, ECF Nos. 1, 4 (S.D.N.Y. June 21, 2024). The Court accepted the shareholder derivative actions filed by Whitfield and Pinkney (collectively, the "Derivative Actions") as cases related to the Securities Action.

On December 16, 2024, following oral argument on competing motions for appointment of Lead Plaintiff and Lead Counsel, the Court appointed the Teamsters Funds as Lead Plaintiff and Labaton Keller Sucharow LLP as Lead Counsel. *See generally* ECF No. 34. The Court also consolidated the two Derivative Actions, declining to consolidate them with the Securities Action, and stayed the Derivative Actions for purposes of judicial economy. *Id.* at 10-11. The case was subsequently reassigned to the undersigned. ECF No. 41. On February 7, 2025, the Teamsters Funds filed the Amended Complaint. ECF No. 42. Defendants moved to dismiss on April 4, 2025, ECF No. 47, and the parties filed their cross-motions to strike in June and July 2025, ECF Nos. 51, 57.

LEGAL STANDARDS

A. Pleading Requirements

On a Rule 12(b)(6) motion to dismiss, the Court must “accept[] all factual allegations in the complaint [as true] and draw[] all reasonable inferences in the plaintiff’s favor.” *ATSI Commc’ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007). “To survive a motion to dismiss, a complaint must plead ‘enough facts to state a claim to relief that is plausible on its face.’” *Ruotolo v. City of New York*, 514 F.3d 184, 188 (2d Cir. 2008) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); see *ATSI Commc’ns*, 493 F.3d at 98 & n. 2 (applying the *Twombly* standard in the context of a securities fraud claim).

Securities fraud claims brought under Section 10(b) and Rule 10b-5 are subject to additional, heightened pleading requirements. Federal Rule of Civil Procedure 9(b) requires that “the circumstances constituting fraud . . . shall be stated with particularity.” *Novak v. Kasaks*, 216 F.3d 300, 306 (2d Cir. 2000) (citation omitted). Under Rule 9(b), a complaint must “(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” *Id.* (internal quotation marks omitted). The Private Securities Litigation Reform Act of 1995 (“PSLRA”) further requires a complaint to (i) “specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, . . . state with particularity all facts on

which that belief is formed,” *ATSI Commc’ns*, 493 F.3d at 99 (quoting 15 U.S.C. § 78u 4(b)(1)), as well as (ii) “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind,” *id.* (quoting 15 U.S.C. § 78u-4(b)(2)). In sum, the heightened pleading standards of Rule 9(b) and the PSLRA require that plaintiffs “do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so.” *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004).

B. Section 10(b), Rule 10b-5, and Section 20(a) Liability

Under Section 10(b) of the Exchange Act, it is unlawful to “use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe.” 15 U.S.C. § 78j(b). SEC Rule 10b-5, promulgated under section 10(b), further dictates:

It shall be unlawful for any person . . . (a) [t]o employ any device, scheme, or artifice to defraud, (b) [t]o make any untrue statement of a material fact or to omit to state a material fact . . . or (c) to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

Under Section 20(a) of the Exchange Act, “[e]very person who, directly or indirectly, controls any person liable under any provision of this chapter . . . shall also be liable jointly and severally with and to the same extent as such controlled person,” unless the purported control person can demonstrate that he “acted in good faith and did not directly or indirectly induce the act or acts constituting the

violation or cause of action.” 15 U.S.C. § 78t(a).

C. Motion to Strike

Federal Rule of Civil Procedure 12(f) states that “[t]he court may strike from a *pleading* an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f) (emphasis added). This rule “excludes motions from the definition of pleadings, and courts in this district have held that Rule 12(f) does not authorize this court to strike documents other than pleadings.” *In re AppHarvest Sec. Litig.*, 684 F. Supp. 3d 201, 238 (S.D.N.Y. 2023) (cleaned up).

DISCUSSION

In the 191-page Amended Complaint, Lead Plaintiff imputes to Defendants four types of misrepresentations, comprising 104 statements in total. Am. Compl., ¶¶ 321(a)-(s), 327(a)-(w), 337(a)-(e), 339(a)-(bb), 344(a)-(v), 350, 351.³ Defendants respond that many of the alleged misrepresentations are protected by the PSLRA’s statutory safe harbor, are inactionable puffery, or lack falsity. *See, e.g.*, ECF No. 48 (“MTD Mem.”) at 2.

To succeed on a Section 10(b) claim in the Second Circuit, “a plaintiff must prove (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or

³ In appendices to their respective briefs, the parties have each indexed the statements alleged in the Amended Complaint, *see* ECF Nos. 48-1, 50-1, which the Court has reproduced in modified form as an appendix to this Opinion. The Court refers to alleged misstatements with citations both to the Amended Complaint and by “Statement number,” as identified in its appendix. As noted *supra*, *see* note 2, reproduced statements are bolded and italicized, per the Amended Complaint, to distinguish alleged misstatements from unchallenged text.

sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.” *Gimpel v. Hain Celestial Grp., Inc.*, 156 F.4th 121, 136 (2d Cir. 2025). Defendants challenge only the first two of these prongs. *See generally* MTD Mem. The Court begins with the parties’ cross-motions to strike, as these motions address what materials the Court may properly consider in ruling on the Motion to Dismiss.

A. Motions to Strike

Defendants move to strike Appendix A to Lead Plaintiff’s memorandum of law in opposition to Defendants’ motion to dismiss, ECF No. 50-1 (the “Appendix”), and to partially strike the Glossary of Defined Terms (“Glossary”) included in that same memorandum, ECF No. 50 (“Opp’n”). Lead Plaintiff moves to strike the Declaration of Colin B. Davis and the forty-six exhibits attached thereto, ECF No. 49 (“Davis Declaration”), as well as “Appendix A” attached to Defendants’ memorandum in support of their motion to dismiss, ECF No. 48-1, pursuant to Federal Rules of Civil Procedure 12(d) and 12(f). ECF No. 52 (“Pl. Mem. Str.”) at 1.

1. Lead Plaintiff’s Motion to Strike

The Teamsters Funds argue that (1) Defendants’ request for the Court to take judicial notice of the forty-six exhibits attached to the Davis Declaration and incorporate them by reference into the Amended Complaint is insufficient because it is argued in a footnote; (2) eight of Defendants’ exhibits do not satisfy the standard for judicial notice; (3) Defendants improperly attempt to cast doubt on the content of investor calls; (4) Defendants improperly attempt to utilize several exhibits as

“factual rebuttal”; and (5) Appendix A should be stricken because it relies on these exhibits. *Id.* at 1-2. Defendants respond that the Teamsters’ Funds’ motion is procedurally improper, that Defendants’ exhibits meet the legal standards for either judicial notice or incorporation by reference, and that Appendix A may be properly considered by the Court. ECF No. 62 at 1-2. Because Lead Plaintiff’s motion seeks to strike materials other than pleadings, its motion is procedurally improper. The Court thus turns to whether these materials may be considered in deciding Defendants’ pending motion to dismiss.

a. Documents Incorporated by Reference

Federal Rule of Civil Procedure 12(d) provides, in relevant part, that courts may not look to materials extrinsic to the complaint without converting the instant motion to dismiss to a Rule 56 motion for summary judgment. Fed. R. Civ. P. 12(d). A court may, however, rely upon documents attached to the complaint as exhibits, documents which the complaint incorporates by reference, and documents “upon which [a complaint] . . . relies and which [are] integral to the complaint.” *Cloister E., Inc. v. N.Y. State Liquor Auth.*, 563 F. Supp. 3d 90, 105 (S.D.N.Y. 2021) (citations omitted); *accord Ark. Public Emps. Ret. Sys. v. Bristol-Myers Squibb*, 28 F.4th 343, 357 n.3 (2d Cir. 2022). A document cannot be incorporated by reference through the Defendants’ motion papers, whether mentioned in a footnote or otherwise. Rather, the Court must look to whether the Complaint “make[s] a clear, definite and substantial reference to the documents.” *Mosdos Chofetz Chaim, Inc. v. Vill. of Wesley Hills*, 815 F. Supp. 2d 679, 691 (S.D.N.Y. 2011) (cleaned up).

Of the forty-six exhibits, it is undisputed that thirty-eight are incorporated by reference in the Complaint. Pl. Mem. Str. at 11-12. Of those exhibits, Lead Plaintiff contests the Courts' consideration of Defendants' Exhibits 3-4, 7, 9-29, 31-32, 34, 35, 38-42, and 44 on the basis that "it is improper to assume the truth of an incorporated document if such assumptions only serve to dispute facts stated in a well-pleaded complaint." *Id.* at 12 (quoting *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1003 (9th Cir. 2018)). Certainly, "defendants may not use plaintiffs' sources as an archive from which to build what amounts to a factual rebuttal." *In re Int. Rate Swaps Antitrust Litig.*, 261 F. Supp. 3d 430, 481 (S.D.N.Y. 2017). Yet the "principle" permitting a Court to consider documents "incorporated by reference" on a Rule 12(b)(6) motion "has its greatest applicability in cases alleging fraud." *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007). Indeed, "when the complaint alleges that such a document made a particular representation, the court may properly look at the document to see whether that representation was made." *Id.* Accordingly, the Court will consider these exhibits for this limited purpose.

Lead Plaintiff similarly does not dispute that the transcripts of investor calls and conferences provided by Defendants in Exhibits 30, 33, 37, and 43 are incorporated by reference into the Amended Complaint. *See* Pl. Mem. Str. at 11-12. Rather, the dispute is as to which version of the transcripts should be considered. Lead Plaintiff accuses Defendants of submitting incomplete transcripts and submits competing versions to the Court. *Id.*; ECF No. 53, Exs. A-D. Defendants contend that they obtained the transcripts from Bloomberg Law, a reputable source, and

questions the authenticity of Lead Plaintiff's exhibits. ECF No. 62 at 15-16. As the Court must "accept all factual claims in the complaint as true and draw all reasonable inferences in the plaintiff's favor," *Emps.' Ret. Sys. of Gov't of the V.I. v. Blanford*, 794 F.3d 297, 307 (2d Cir. 2015) (cleaned up), and "[f]act specific questions cannot be resolved on the pleadings," *Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 185 (2d Cir. 2012) (cleaned up), the Court looks to Lead Plaintiff's submissions for purposes of resolving this motion to dismiss.

b. Judicial Notice

With respect to the remaining eight exhibits, Defendants request that the Court take judicial notice. ECF No. 61. Federal Rule of Evidence 201(b) provides that a district court ruling on a motion to dismiss may judicially notice a fact that is not subject to reasonable dispute because it is "generally known within the trial court's territorial jurisdiction" or "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). The Court may take notice on its own and must take judicial notice if "a party requests it and the court is supplied with the necessary information." *Id.* These documents are "relevant not to prove the truth of their contents but only to determine what the documents stated." *Kramer v. Time Warner Inc.*, 937 F.2d 767, 774 (2d Cir. 1991).

"Under Federal Rule of Evidence 201, a court 'may take judicial notice on its own' of 'a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and

readily determined from sources whose accuracy cannot reasonably be questioned.” *Johnson v. McKay*, No. 14-CV-00803 (BKS) (TWD), 2015 WL 1735102, at *4 (N.D.N.Y. Apr. 16, 2015) (quoting Fed. R. Evid. 201(b)-(c)). “Still, as it always does, the Court examines Defendants’ exhibits to determine whether they are properly considered to resolve this motion to dismiss,” *Bazzelle v. Novocure Ltd.*, No. 23-CV-05146 (GHW), 2025 WL 843668, at *6 (S.D.N.Y. Mar. 18, 2025), keeping in mind that “a ruling on a motion for dismissal pursuant to Rule 12(b)(6) is not an occasion for the court to make findings of fact.” *Roth*, 489 F.3d at 509.

The Court determines that Exhibits 1-2, 5-6, 8, 36, and 45-46 are suitable for judicial notice “only to determine what the documents stated.” *Kramer*, 937 F.2d at 774. Exhibits 1 and 8 are excerpts of QuidelOrtho’s Annual Reports on Form 10-K filed with the U.S. Securities and Exchange Commission (the “SEC”); Exhibits 2 and 36 are press coverage of the Savanna launch and QuidelOrtho earnings respectively; Exhibits 5 and 6 are the transcript and accompanying presentation for Quidel’s January 12, 2022 presentation at the Bloomberg J.P. Morgan 40th Annual Healthcare Conference; Exhibit 45 is a transcript of QuidelOrtho’s July 31, 2024 earnings call for the second quarter of 2024; and Exhibit 46 is a chart of the Company’s share prices over time. This public information “can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned,” Fed. R. Evid. 201(b)(2), and is especially important considering Lead Plaintiff’s invocation of Rule 10b-5 to allege that Defendants’ misstatements or omissions have altered the “total mix of information” available to investors, *Basic, Inc. v. Levinson*,

485 U.S. 224, 232 (1988) (cleaned up). “When a complaint alleges, for example, that a document filed with the SEC failed to disclose certain facts, it is appropriate for the court, in considering a Rule 12(b)(6) motion, to examine the document to see whether or not those facts were disclosed.” *Roth*, 489 F.3d at 509.

Accordingly, Lead Plaintiff’s motion is denied.

2. Defendants’ Motion to Strike

In their motion to strike, Defendants argue that Lead Plaintiff attempts to improperly amend the operative complaint and circumvent the Court-ordered page limit through its Glossary, which provides definitions of various terms, and Appendix, which adds two columns of citations from the pleadings to the appendix created by Defendants. ECF No. 58 at 1. This argument both lacks merit and improperly attempts to strike documents outside the pleadings.

Accordingly, Defendants’ motion to strike is denied.

B. Section 10(b) Claims

Section 10(b) and Rule 10b-5(b) protect investors from material misrepresentations in connection with the sale or purchase of securities. “Under Rule 10b-5(b), it is unlawful to[, in connection with the sale of any security,] (1) make any untrue statement of a material fact, or (2) omit to state a material fact necessary in order to make the statements made . . . not misleading.” *Gimpel*, 156 F.4th at 138 (citing 17 C.F.R. § 240.10b-5(b) (cleaned up)). “These prongs correspond to two actionable theories under Section 10(b) and Rule 10b-5: (1) a false statement, *i.e.*, an actual statement that is untrue outright, and (2) a half-

truth, *i.e.*, a representation that states the truth only so far as it goes, while omitting critical qualifying information.” *Id.* (cleaned up). “A false statement . . . must . . . be false at the time it was made, and the plaintiff must demonstrate with specificity why the statement is false.” *Id.*

A half-truth theory relies on a company’s “duty to be both accurate and complete.” *Caiola v. Citibank, N.A., N.Y.*, 295 F.3d 312, 331 (2d Cir. 2002). Rule 10b-5 “does not proscribe pure omissions,” only omissions of “material facts necessary to make the ‘statements made . . . not misleading.’” *Macquarie Infrastructure Corp. v. Moab Partners, L.P.*, 601 U.S. 257, 264 (2024) (quoting 17 C.F.R. § 240.10b–5(b)). While Section “10(b) and Rule 10b-5 do not create an affirmative duty to disclose any and all material information,” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011), once “a company speaks on an issue or topic,” it must “tell the whole truth,” *Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 250 (2d Cir. 2014). “Adequate disclosure” is required alongside such statements to ensure that, “in light of the circumstances under which they were made, [they are] not misleading.” *Id.* (cleaned up). Whether a statement is misleading is an objective inquiry reliant upon its “literal truth” and its “context and manner of presentation.” *Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019).

A securities fraud plaintiff “must also adequately allege that the misstatement or half-truth is ‘material,’ meaning that ‘a reasonable investor would have considered [it] significant in making investment decisions.’” *Gimpel*, 156 F.4th at 139 (quoting *Caiola*, 295 F.3d at 329); *accord Matrixx*, 563 U.S. at 38 (statement

materially misleading if there was “substantial likelihood” that it “would have been viewed by the reasonable investor as having significantly altered the total mix of information made available.” (cleaned up)).

At the pleading stage, allegations from confidential witnesses are taken as true if they “are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged.” *Emps.’ Ret. Sys. of Gov’t of the V.I.*, 794 F.3d at 305 (quoting *Novak*, 216 F.3d at 314); *see also City of Warren Police & Fire Ret. Sys. v. World Wrestling Ent. Inc.*, 477 F. Supp. 3d 123, 132 (S.D.N.Y. 2020) (“This liberal standard make[s] sense; the heightened demands of the PSLRA will often require plaintiffs to rely on the testimony of confidential sources, even where those sources offer indirect knowledge, that is, information and belief that is hearsay but plausible.”).

1. Alleged Misrepresentations

Lead Plaintiff alleges that Defendants Bryant, Busky, Bujarski, Iskra, and Ranalli made materially false and misleading statements and omissions concerning: (i) the status of 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 Court addresses each category of alleged misrepresentations, and defenses raised against statements therein, in turn.

a. Challenged Statements on Savanna RVP4’s European Launch

Lead Plaintiff contends that Defendants Bryant, Ranalli, Busky, and QuidelOrtho altogether made 19 misstatements regarding Savanna RVP4’s European launch during the Class Period. Am. Compl., ¶¶ 321(a)-(s).

i. Falsity

Defendants assert that statements concerning Savanna RVP4’s European launch were not false or misleading because “the number of defective and invalid RVP4 tests, defective Savanna instruments[,] and related string of escalating customer complaints,” *id.*, ¶ 322—all omitted from the total mix of information available to investors—did not contradict Defendants’ statements about positive feedback and high customer demand in Europe, MTD Mem. at 17.

“The test for whether a statement is materially misleading under Section 10(b) . . . is whether the defendants’ representations, taken together and in context, would have misled a reasonable investor.” *City of Hialeah Emps.’ Ret. Sys. v. Peloton Interactive, Inc.*, 153 F.4th 288, 295 (2d Cir. 2025) (quoting *Rombach v. Chang*, 355 F.3d 164, 172 n.7 (2d Cir. 2004)) (internal quotation marks omitted). “A statement or omission is material if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to act.” *IBEW Loc. Union No. 58 Pension Tr.t Fund & Annuity Fund v. Royal Bank of Scotland Grp., PLC*, 783 F. 3d 383, 389 (2d Cir. 2015) (internal quotation marks omitted); *see also City of Hialeah*, 153 F.4th at 295 (“Similarly, for an alleged statement to be ‘material’ under Section 10(b), it must be sufficiently specific for an investor to

reasonably rely on that statement as a guarantee of some concrete fact or outcome.” (cleaned up)).

Applying those standards here, Lead Plaintiff has plausibly alleged material misrepresentations associated with Savanna SVP4’s European launch. Internal reports indicated that the launch was plagued by customer complaints and product returns. Am. Compl., ¶¶ 179-82, 222. From the beginning of Savanna’s EU launch in late 2021, the Company’s Scientific Marketing Manager, Europe reported to Company leadership that “the Savanna RVP4 tests were failing in Europe,” and an employee who felt he had the “best pulse” on Savanna RVP4’s performance in Europe reported that 60-80% of customer feedback was negative. *Id.*, ¶¶ 171, 185-187. A quarterly report in 2023 showed even more complaints (85) than units in distribution (80). *Id.*, ¶ 188. These figures stand in stark contrast to the picture Defendants paint through cited caselaw. *See, e.g., Pearlstein v. BlackBerry Ltd.*, 93 F. Supp. 3d 233, 238 & 240-41 (S.D.N.Y. 2015) (statements that “the launch of BlackBerry . . . marked the beginning of the organization’s transition to becoming a leading mobile computing organization” and “[c]ustomers love the device” were not false or misleading “[e]ven though . . . BlackBerry 10 devices were not selling well” because that fact did not “contradict generally optimistic sentiments”). A market launch so replete with errors and customer discontent, *see, e.g.,* Am. Compl., ¶ 362 (“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”), can hardly be described as yielding “generally optimistic sentiments.”

Accordingly, some, though not all, of the challenged statements would have materially misled investors about Savanna RVP4's promise vis à vis its European launch. Statement 17 provides an illustrative example. In August 2023 during a Q2 2023 Earnings Call,⁴ Defendant Bryant remarked with respect to the decline of QuidelOrtho's molecular diagnostics business: ***“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.”*** Am. Compl., ¶ 321(q). The use of the word “notably” during the Earnings Call indicates Bryant's cue to investors that Savanna's “modest improvement” in sales year-over-year in Europe was material enough to “partially offset” what the Company ultimately reported to be a 67% decrease in year-over-year molecular diagnostics revenue—approximately \$65 million, or an average of about \$16.25 million per quarter. *Id.*, ¶ 295.⁵ Yet the Company generated only \$2.56 million from Savanna RVP4 sales in Europe in all of

⁴ ECF No. 50-1 corrects the Amended Complaint's attribution of this statement to a Q3 2023 Earnings Call.

⁵ QuidelOrtho Corp., Annual Report (Form 10-K), at 55 (Feb. 28, 2024), <https://perma.cc/6NFF-A7LW>; Am. Compl., ¶ 295. *See Tang Cap. Partners, LP. v. BRC Inc.*, 661 F. Supp. 3d 48, 59 (S.D.N.Y. 2023) (“[T]he Second Circuit has consistently held that in the securities context, courts may consider public disclosure documents required by law to be, and that have been, filed with the SEC.” (internal quotation marks omitted) (citing cases)); *ATSI Commc'ns*, 493 F.3d at 98 (“[W]e may consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff and upon which it relied in bringing the suit”).

2023, or an average of about \$640,000 per quarter. *Id.*, ¶ 333. While the pleadings do not provide an exact per-quarter distribution of these losses and gains, they provide enough to suggest that Bryant’s characterization of Savanna’s EU revenues in August 2023 as a “notabl[e] . . . offset” likely materially misled investors. *Id.*, ¶ 321(q).

Other alleged misstatements are not pleaded with this level of specificity. Lead Plaintiff provides no basis of falsity for Statement 9, wherein Defendant Bryant asserted during a Q3 2022 Earnings Call in November of that year, “[W]e 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.” Am. Compl., ¶ 321(i). Although the Amended Complaint alleges facts sufficient to call the European demand for RVP4 into question, *id.*, ¶ 170, the particulars of QuidelOrtho’s shipping practices are not pleaded.

Further, Lead Plaintiff does not allege facts sufficient to explain why Defendant Ranalli’s Statement 12 is misleading. Lead Plaintiff challenges Defendant Ranalli’s assertion during a 2022 Investor Day call in December 2022 regarding the Company’s “*installed base target*,” the “*pull-through in those installed bases*,” and a conclusion based on data from the EU launch that the Company would achieve “*fewer boxes placed, but those boxes are running at a higher rate than our original estimation*.” *Id.*, ¶ 321(l). Although Lead Plaintiff does plead with particularity why certain financial projections for Savanna

RVP4 were misleading, *infra* Discussion § B(1)(b)(iv)(1), the Amended Complaint does not allege facts sufficient to challenge the Company's amendments to its original run rate.

ii. **Puffery**

Defendants challenge 17 statements in this category as inactionable puffery or corporate optimism, “vague[] and enthusiastic[]” statements that are “too general to cause a reasonable investor to rely upon them.”⁶ *Okla. Firefighters Pension & Ret. Sys. v. Xerox Corp.*, 300 F. Supp. 3d 551, 569-70 (S.D.N.Y. 2018).

“Generic, indefinite statements of corporate optimism typically are not actionable” because “reasonable investors [do not] place substantial reliance on generalizations regarding a company's health or the strength of a company's product.” *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 173 (2d Cir. 2020); *ECA, Loc. 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 206 (2d Cir. 2009) (statements “too general to cause a reasonable investor to rely upon them” are inactionable puffery). Such “puffery” is thus “actionable only when the speaker knew that the contrary was true.” *Abramson*, 965 F.3d at 174 (cleaned up).

“Whether a representation is ‘mere puffery’ depends, in part, on the context in which it is made.” *In re Petrobras Sec. Litig.*, 116 F. Supp. 3d 368, 381 (S.D.N.Y. 2015). Moreover, where the context makes it such that “a reasonable investor could rely on them as reflective of the true state of affairs at the Company,” puffery

⁶ These include Statements 2-11 and 13-19. Am. Compl., ¶ 321(b)-(k), (m)-(s).

defenses fail. *Id.* at 381; accord *In re Turquoise Hill Res. Ltd. Sec. Litig.*, 625 F. Supp. 3d 164, 222 (S.D.N.Y. 2022). “The key distinction between [mere puffery] and potentially actionable statements is that these [inactionable] statements were non-verifiable” at the time they were made. *Okla. Firefighters*, 300 F. Supp. 3d at 570. Corporate statements that things are “moving forward well” or “going well,” or that a company is “well positioned, or that its operations are “successful” are “classically non-actionable unless the statements addressed concrete and measurable areas of the defendant company’s performance.” *Id.* (cleaned up).

Half of Statement 6 and all of Statements 7, 13, and 15 fall within this category. On the 2022 Q2 Earnings Call, Defendant Bryant announced, “***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.***” Am. Compl., ¶ 321(f). The latter half of this statement—specifically linking a full European launch to increasing manufacturing capacity and projecting 2023 menu expansions—is neither “generic” nor “indefinite.” *Abramson*, 965 F.3d at 173 (2d Cir. 2020). The first half, however, touting the launch generally as “go[ing] well” and having “early wins,” is entirely “non-verifiable.” *Okla. Firefighters*, 300 F. Supp. 3d at 570; Am. Compl., ¶ 321(f). The same is true of Statement 7, attributable to Bryant at the Morgan Stanley Global Healthcare Conference in September 2022: “***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.” Am. Compl., ¶ 321(g). Phrases like “pretty pleased” applied in generic terms to what the Company had “done in Europe” are “too general to cause a reasonable investor to rely upon them.” *ECA*, 553 F.3d at 206. Statement 15 can be dismissed as inactionable puffery for the same reason.⁷ Statement 13—by Bryant at the 41st Annual J.P. Morgan Healthcare Conference in February 2023—is a bit more concrete, identifying “demand” in Europe.⁸ Yet Bryant in no way quantifies or even characterizes the demand he identifies here, nor does he attach his optimism to any particular deliverable. Accordingly, these statements can be dismissed as inactionable puffery.

Statement 5 offers a telling counterexample to those Defendants successfully challenge on these grounds. At the June 2022 William Blair Annual Growth Stock Conference, Defendant Bryant declared: “*[W]e 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.*” Not only does the phrase “super well” (in contrast to Statement 7’s “pretty well”) imply to reasonable investors that the EU launch was free of catastrophes, but this statement also explicitly ties Savanna’s success to European demand and denies the product’s

⁷ Am. Compl., ¶ 321(o) (Defendant Bryant during the 2022 Q4 Earnings Call in February 2023: “*And I think it would be fair to say that we’ve been reasonably successful in a limited launch in Europe with Savanna too.*”)

⁸ Am. Compl., ¶ 321(m) (“*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.*”)

weakness in that category (“not the issue”), narrowing and concretizing the scope of Bryant’s commentary. Statements 1, 3, 14, and 16 likewise “address[] concrete and measurable areas of the defendant [C]ompany’s performance” and thus cannot be dismissed as inactionable puffery.⁹ *Okla. Firefighters*, 300 F. Supp. 3d at 570.

iii. Inactionable Opinion

Defendants challenge seven statements in this category as inactionable opinions.¹⁰ “A fact is ‘a thing done or existing or an actual happening,’ while an opinion is ‘a belief, a view, or a sentiment which the mind forms of persons or

⁹ Am. Compl., ¶ 321(a) (“***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.***”); *id.*, ¶ 321(c) (“***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.***”); *id.*, ¶ 321 (n) (“***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.***”); *id.*, ¶ 321(p) (“***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.***”).

¹⁰ These include Statements 1 (“***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.***”), 3 (“***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.***”), 5 (“***[W]e 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.***”), and 16 (“***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.***”). MTD Mem. at 11, n. 3; Am. Compl., ¶¶ 321(a), (c), (e), (p). The Court does not include in this subsection any otherwise applicable Statements that have already been addressed on other grounds.

things.” *New England Carpenters Guaranteed Annuity & Pension Funds v. DeCarlo*, 122 F.4th 28, 40 (2d Cir. 2024) (quoting *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 183 (2015)), *cert. denied sub nom. BDO USA, LLP v. New England Carpenters Guaranteed Annuity & Pension Funds*, 146 S. Ct. 261 (2025). Statements 1, 3, 5, 7, 13, 15, and 16 all bear hallmarks of opinions, such as “I think,” “I would say,” “[w]e believe,” or convey a subjective assessment through phrases such as “expected to.”¹¹

Defendants contend these opinion statements are protected from liability because they convey “inherently subjective . . . assessment[s],” ECF No. 59 (“Reply”) at 4-5 (quoting *In re Philip Morris Int’l Inc. Sec. Litig.*, 89 F.4th 408, 418 (2d Cir. 2023)), that are “not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way,” *id.* at 5 (quoting *Omnicare*, 575 U.S. at 189). “[A] sincere statement of pure opinion is not an untrue statement of material fact” giving rise to liability under the securities laws, even if “an investor can ultimately prove the belief wrong.” *Omnicare*, 575 U.S. at 186 (cleaned up). This is because “[r]easonable investors understand that opinions sometimes rest on a weighing of competing facts; indeed, the presence of such facts is one reason why an issuer may frame a statement as an opinion, thus conveying uncertainty.” *Id.* at 189-90.

“But opinions lead double lives.” *New England Carpenters*, 122 F.4th at 41.

¹¹ Am. Compl., ¶¶ 321(a), (c), (e), (g), and (p). Statement 3 is mixed. Only the final sentence in that statement is an opinion.

This is because “an opinion may implicitly convey ‘facts about how the speaker has formed the opinion.’” *Id.* (quoting *Omnicare*, 122 F.4th at 188). “[I]f the real facts are otherwise, but not provided, the opinion statement will mislead” a reasonable investor. *Omnicare*, 575 U.S. at 188. In other words, an “opinion may be false or misleading if the embedded fact is not one as to which reasonable minds can differ.” *New England Carpenters*, 122 F.4th at 42. Accordingly, “whether an omission makes an expression of opinion misleading always depends on context.” *Omnicare*, 575 U.S. at 190.

All of the opinions at issue convey facts about which reasonable minds could not differ. Take, for instance, Defendant Bryant’s March 2022 statement at the Raymond James Annual Institutional Investors Conference that Savanna was ***“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.”*** Am. Compl., ¶ 321(c). Taking the Amended Complaint’s allegations as true, the facts embedded in this opinion—that Savanna was broadly well received in Europe and not plagued with critical design flaws—are not ones about which reasonable minds could differ. Savanna RVP4’s test assay was failing “from the very beginning” of the EU launch; customers were “irate”; and early complaints reflected the fact that one in four tests had to be replaced, devices overheated, and cartridges produced a high level of invalid test results. *Id.*, ¶¶ 170-177. Demand for the product in this market was also limited. *Id.*, ¶ 170. Accordingly, the challenged opinion statements are actionable.

iv. PSLRA Safe Harbor

The PSLRA exempts certain statements from liability if they are “forward looking” and meet one of the two prongs of the PSLRA’s safe harbor analysis. 15 U.S.C. § 78u-4; *see also Slayton*, 604 F.3d at 762 (discussing the “prongs” of analysis under the PSLRA). The first prong is satisfied, and the speaker is thereby exempt from liability for the statement, if the statement is “accompanied by meaningful cautionary statements.” 15 U.S.C. § 78u-5(c)(1). The second prong is satisfied if “the plaintiff fails to prove that the forward-looking statement . . . was made with actual knowledge by that person that the statement was false or misleading.” *Id.*

As a threshold matter, courts determine whether a statement is “forward looking” before inquiring into the PSLRA’s protections. *See Slayton*, 604 F.3d at 766-67. A “forward-looking statement” is one that contains “a projection of revenues, income . . . , [or] earnings,” “a statement of the plans and objectives of management for future operations,” or “a statement of future economic performance.” 15 U.S.C. § 78u-5(i)(1). “A statement may contain some elements that look forward and others that do not,” and “forward-looking elements” may be “severable” from “non-forward-looking” elements.” *In re Vivendi Universal, S.A. Sec. Litig.*, 765 F. Supp. 2d 512, 569 (S.D.N.Y. 2016) (cleaned up) *aff’d*, 838 F.3d 223 (2d. Cir. 2016); *see also Makor Issues & Rights, Ltd. v. Tellabs Inc.*, 513 F.3d 702, 705 (7th Cir. 2008) (“[A] mixed present/future statement is not entitled to the safe harbor with respect to the part of the statement that refers to the present.”).

For a statement to qualify for the protections of the PSLRA under this first prong, “courts must first ‘identify the allegedly undisclosed risk’ and then ‘read the allegedly fraudulent materials—including the cautionary language—to determine if a reasonable investor could have been misled into thinking that the risk that materialized and resulted in his loss did not actually exist.’” *zCap Equity Fund LLC v. LuxUrban Hotels Inc.*, 792 F. Supp. 3d 407, 432 (S.D.N.Y. 2025) (quoting *Halperin v. eBanker USA.com, Inc.*, 295 F.3d 352, 359 (2d Cir. 2002)). A plaintiff may establish that statements are not cautionary if language “did not expressly warn of or did not directly relate to the risk that brought about plaintiffs’ loss.” *Halperin*, 295 F.3d at 359. “Vague” or “mere boilerplate” language does not suffice. *Slayton*, 604 F.3d at 772.

While several of Defendants’ misrepresentations regarding the European launch include forward-looking elements,¹² these statements were not accompanied by meaningful cautionary language. Defendants attempt to invoke safe harbor protection by pointing the Court to warnings “[d]uring earnings calls and at investor conferences . . . that [the Company’s] forward-looking statements were subject to the risk factors identified in the Company’s SEC filings,” which in turn outlined that “there is no assurance . . . our efforts to develop new technologies, products or markets will be successful . . . [or] commercially viable.” MTD Mem. at 13-14. Yet such cautionary language does nothing to mitigate Defendant Bryant’s

¹² These include Statements 1, 6, 10, 13, 14, 16, and 19. Am. Compl., ¶ 321(a), (f), (j), (m)-(n), (p), (s). The Court does not address statements already dismissed.

representation, for instance, that “[b]ased 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.” Am. Compl., ¶ 321(a). This statement, like the other forward-looking statements about the European launch, was premised not upon predictions concerning disclosed risk factors but upon false summaries of already-collected customer feedback on Savanna RVP4’s performance in Europe. These statements thus do not fall within the scope of the first prong of the safe harbor provision. *See Facebook*, 986 F. Supp. 2d at 515 (cautionary language does not “insulate from liability the failure to disclose that the risk ha[d] transpired”); *accord Rombach v. Chang*, 355 F.3d 164, 173 (2d Cir. 2004).

Lead Plaintiff has also plausibly alleged that Defendants had actual knowledge of the product’s lackluster reception among the European market, thus defeating Defendants’ attempt to rely on the second prong of the safe harbor. According to the Amended Complaint, senior executives were regularly informed about the negative feedback and technical problems. The rampant issues with the Savanna European launch were documented and reported up to the C-suite and Board of Directors through regular meetings, PowerPoint presentations, and internal complaint systems. *Id.*, ¶¶ 184-185. In this sense, Lead Plaintiff has “ple[ade]d far more than fraud by hindsight.” *In re Glob. Crossing, Ltd. Sec. Litig.*, 322 F. Supp. 2d 319, 338 (S.D.N.Y. 2004). Accordingly, these statements do not receive safe harbor protection.

b. Challenged Statements on Savanna RVP4's Readiness for a U.S. Launch and FDA Approval

Lead Plaintiff contends that Defendants QuidelOrtho, Bryant, Busky, Iskra, Bujarski, and Ranalli altogether made 29 misstatements regarding Savanna RVP4's development progress toward FDA approval, satisfaction of FDA threshold requirements, and readiness for a U.S. launch during the Class Period. Am. Compl., ¶¶ 327(a)-(w), 337(a)-(e).

i. Falsity

Lead Plaintiff has plausibly alleged material misrepresentations associated with Savanna RVP's readiness for a U.S. launch and FDA approval. *Id.*, ¶¶ 191-229, 328-36. For instance, several accounts from former employees regarding Savanna RVP4's manufacturing yields and sensitivity levels throughout the Class Period squarely contradict Defendant Bryant's statement on the Q1 2023 Earnings Call in May 2023 that "*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.*"¹³ *Id.*, ¶ 327(k) (Statement 30); *see, e.g., id.*, ¶¶ 193 ("FE-2 stated that . . . engineering issues with the RVP4 test were not fixed when it went on sale in

¹³ Defendants dispute the attribution of this statement to Defendant Bryant, instead attributing it to Defendant Busky. ECF No. 48-1 at 10 n.2. Lead Plaintiff maintains that Bryant made the statement, *see* ECF No. 50-1 at 15 n.4, providing a transcript in support of this assertion, ECF No. 53-1. The Court credits Lead Plaintiff's allegation at this stage. *See, e.g., Emps' Ret. Sys. of Gov't of the V.I. v. Blanford*, 794 F.3d 297, 307 (2d Cir. 2015) (on motion to dismiss, Court must "accept all factual claims in the complaint as true and draw all reasonable inferences in the plaintiff's favor") (citation omitted); *Anderson News, L.L.C.*, 680 F.3d at 185 ("Fact specific questions cannot be resolved on the pleadings." (cleaned up)).

Europe in late 2021, . . . not fixed when it was sent to the FDA for approval in the second quarter of 2023, and . . . not fixed when he left the Company in September 2023.”), 194 (“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.”); 199 (“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,” but “FE-1 advised that Savanna could not meet that level of accuracy either directly or through pooled samples”), 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.”), 206 (“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.’”). The Second Circuit has expressly found analogous statements misleading to investors. *Abramson*, 965 F.3d at 178 (“Both because of its posture as a response to a specific question and its categorical nature, . . . a jury could find that, by saying that [the corporate defendant] did not have ‘any reason’ to believe” the negative outcome at issue, the speaker, who was company president and chief medical officer, “implied that there were no competing facts” on this topic.).

Statement 35 is also illustrative on this point. At the Evercore ISI Health CONX Conference in November 2023, Defendant Bryant was asked, “what’s happening with Savanna? It looks like there was some timing pushout.” Am.

Compl., ¶ 327(p). Beginning his statement, “***Let’s be completely open,***” Defendant Bryant elaborated that “***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.***” *Id.*¹⁴ This statement is a classic “half-truth” under Rule 10b-5(b). *See Gimpel*, 156 F.4th at 138-39. Once “a company speaks on an issue or topic,” it must “tell the whole truth.” *Meyer*, 761 F.3d at 250.

Particularly given his representation of “complete[] open[ness],” Defendant Bryant’s omissions here are striking and material. By specifying that the FDA’s concern with Savanna RVP4 wasn’t the “performance of the product” but rather the “perform[ance]” of the “instrument and cartridge” (which some might indeed classify as the “product”) *with* “respiratory season samples,” this statement implied that the product’s FDA clearance hurdle was a routine regulatory check for seasonal incongruency rather than the reality: that RVP4 “never worked properly.” Am. Compl., ¶ 192. Certainly, disclosure of the fact that the “Savanna RVP4 test ‘never came close’” to the 95% sensitivity level required for FDA approval, *id.*, ¶ 199, would have been “substantial[ly] likel[y] . . . [to] have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information made available” about the Company’s FDA submission timeline, *Matrixx*, 563 U.S. at 38 (citation omitted).

The Court dismisses the first half of Statement 23 (“***We continue to focus***

¹⁴ Lead Plaintiff and Defendant again submit warring transcripts with respect to this statement. *See* ECF Nos. 48-1 at 12 n.4, 53-3 at 4. Again, the Court credits Plaintiff’s representations at this stage.

on overcoming manufacturing and supply chain challenges as we ramp up production of both instruments and cartridges”), however, because the Company’s “focus” on overcoming its manufacturing and supply chain challenges in service of its efforts to ramp up production in November 2022 is not materially impacted by its failure to ultimately do so. Statement 40 can be dismissed for the same reason. Am. Compl., ¶ 327(t) (regarding Defendants “*focus*” on “*doing all we can do to get not just RVP4 out, but the other menu items.*”). In contrast, the second half of Statement 23 (“*Additionally, we completed development activities for all Savanna panels planned for launch in 2023.*”) survives, as it directly contradicts former employee accounts. *See, e.g., id.*, ¶ 212 (“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.”).

ii. Puffery

Statements 20, 21, 29, 33, 34, 38, 45, 46, and 48 are too general to have been material to a reasonable investor’s analysis. *Id.*, ¶ 327(a)-(b), (j), (n)-(o), (r); *id.*, ¶ 337(b)-(c), (e). These statements recount the Company’s initial RVP4 Respiratory Viral Panel menu and its anticipated RVP11 menu with no concrete timeline for release, *see, e.g., id.*, ¶ 337(b), (c), (e), or constitute “vague descriptions offer[ing] only generally optimistic opinions,” *see, e.g., id.*, ¶ 327(a)-(b), (j), (n)-(o), (r), and can thus be classified as “inactionable corporate puffery,” *In re Synchrony Fin. Sec.*

Litig., 988 F.3d 157, 170 (2d Cir. 2021). “To be actionably misleading, there must be a sufficiently close nexus between the statement and the allegedly omitted information.” *Buhrke Fam. Revocable Tr. v. U.S. Bancorp*, 726 F. Supp. 3d 315, 340 (S.D.N.Y. 2024) (cleaned up). Such a nexus cannot exist where “exaggerations or overstatements . . . mention nothing specific, but rather amount to general claims of superiority expressed in broad, vague, and commendatory language.” *MacNaughton v. Young Living Essential Oils, LC*, 67 F.4th 89, 96 (2d Cir. 2023) (cleaned up). Accordingly, these statements are dismissed.

iii. Inactionable Opinion

Statement 43, Defendant Bujarski’s challenged statement at the Raymond James Institutional Investors Conference in March 2024, constitutes an inactionable opinion.¹⁵ Like many “statements of opinion,” Statement 43 includes “qualifying language (like ‘I believe’ or ‘I think’) that conveys a lack of certainty about the thing being expressed, marks the statement as reflecting the speaker’s impression or point of view rather than an objective truth, and makes it easier to identify the statement as one of opinion rather than fact.” *New England Carpenters*, 122 F.4th at 40-41. Further, “[c]ertain statements address issues so

¹⁵ Am. Compl., ¶ 327(w) (“*I think the ones that the field, I would say, is most interested [in], 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 . . . 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*”).

plainly subjective . . . that the statement is one of opinion not just by virtue of the words used but also because of the nature of the information conveyed.” *New England Carpenters*, 122 F.4th at 41. Defendant Bujarski’s focus, and his opinion with respect to what makes a product successful, “lacks any objective standard,” *id.* (cleaned up), because it does not implicitly convey facts as to RVP4’s capabilities at that time. Accordingly, this statement is dismissed.

The other statements that Defendants challenge as inactionable opinions are actionable because they “implicitly convey ‘facts about how the speaker has formed the opinion . . . or . . . about the speaker’s basis for holding that view,’” and the pleadings plausibly allege such facts to be both false and material. *Id.* (quoting *Omnicare*, 575 U.S. at 188). *See, e.g.*, Am. Compl., ¶¶ 327(c) (“***it’s just about—it’s a matter of timing in terms of FDA clearance.***”) (conveying that nature of product errors were not so significant as to render FDA approval an “if” rather than a “when”), 327(g) (“***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 largely been 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***”) (conveying, *inter alia*, that “***instrument build issues ha[d] largely been resolved,***” that “***cartridge ramp up***” concerns had supplanted more fundamental concerns regarding widespread detectability failures, that RVP4

performance as of February 2023 did not render FDA 510(k) approval three months later an impossibility, and that the promised automated production line was close enough to producing “*millions of cartridges very shortly*” that it had, for instance, a physical location—which Lead Plaintiff alleges it still did not as of April 2024, *see id.*, ¶ 228).

iv. PSLRA Safe Harbor

Defendants argue that several of the challenged statements in this category are eligible for PSLRA safe harbor protection because they are forward looking, because they were accompanied by adequate cautionary language, and because Lead Plaintiff has not proven that the Defendants who made the statements had actual knowledge that the statement was false or misleading. MTD Mem. at 11-15. These include statements “containing a projection of revenues” or about “future economic performance,”¹⁶ 15 U.S.C. § 78u-5(i)(1)(A), (C), projecting regulatory approval for RVP4 and its subsequent U.S. commercial launch,¹⁷ and anticipated manufacturing capabilities and timeline for development of additional Savanna test panels.¹⁸ Many of the statements already dismissed on other grounds—Statements 20, 21, 34, 38, 43, 46, and 48, for instance—would alternatively qualify for dismissal as immaterial under this doctrine. All of the statements not already dismissed on other grounds, however, remain actionable.

¹⁶ These include Statements 25, 27, 32. *See* Am. Compl., ¶¶ 327(f), (h), (m).

¹⁷ These include Statements 20, 21, 24, 25, 26, 27, 28, 29, 31, 32, 34, 36, 37, 38, 39, 42, and 43. *See* Am. Compl., ¶¶ 327(a), (b), (e), (g)-(j), (l)-(m), (q)-(s), (v), (w).

¹⁸ These include Statements 26, 39, 44, 45, 46, 47, 48. *See* Am. Compl., ¶¶ 327(g), (s), 337(a)-(e).

Defendants point to oral warnings by Defendants that their “forward-looking statements were subject to risk factors identified in the Company’s SEC filings,” which in turn provided cautionary language regarding the Company’s estimated “regulatory clearance for RVP4 and other assays, as well as *underlying assumptions* about development and manufacturability.” MTD Mem. at 13-14 (emphasis added) (citing ECF Nos. 49-6 at 2, 49-7 at 1-2, 49-12 at 1-2, 49-14 at 2, 49-15 at 1, 49-19 at 1, 49-21 at 3, 49-25 at 2, 49-27 at 2, 49-30 at 2, 49-33 at 1-2). Accepting Lead Plaintiff’s well-pleaded allegations as true, however, these “underlying assumptions” were knowingly false. While the Company cautioned that “[f]ailure to obtain FDA clearance or approval would preclude commercialization in the U.S., which could materially and adversely affect our future results of operations,” ECF Nos. 49-28 at 40-41, 49-8 at 33, it did not disclose material facts about the product’s unaddressed incompatibility with those FDA clearance standards that would have meaningfully altered a reasonable investor’s assessment of Savanna RVP4’s commercial viability. “[C]autionary words about future risk cannot insulate from liability an issuer’s failure to disclose that the risk has, in fact, materialized in the past and is virtually certain to materialize again.” *Set Cap. LLC v. Credit Suisse Grp. AG*, 996 F.3d 64, 85 (2d Cir. 2021). As Judge Pollack of this District once noted, “The doctrine of bespeaks caution provides no protection to someone who warns his hiking companion to walk slowly because there might be a ditch ahead when he knows with near certainty that the Grand Canyon lies one foot away.” *In re Prudential Sec. Inc. Ltd. P’ships Litig.*, 930 F. Supp. 68, 72 (S.D.N.Y. 1996).

1. Revenue Projection Statements

Contrary to Lead Plaintiff's assertions, Opp'n at 15, Statements 25, 27, and 32 are forward-looking revenue-projection statements. A statement that references defendant's "current expectation of cash flows," for instance, is forward-looking because it does "not justify the financial projections in terms of any particular aspect of the company's current situation" but instead asserts "only that, whatever that situation is, it makes the future projection attainable." *Gissin v. Endres*, 739 F. Supp. 2d 488, 505-06 (S.D.N.Y. 2010) (cleaned up).

Yet the projections made in these statements were not attainable. Moreover, they were not adequately "accompanied by meaningful cautionary language identifying important factors that could cause actual results to differ materially from those in the forward[-]looking statements." *In re Nokia Oyj (Nokia Corporation) Sec. Litig.*, 423 F. Supp. 2d 364, 400 (S.D.N.Y. 2006) (citing 15 U.S.C. § 78u-5(c)).

Further, as noted *supra*, see Discussion § B(1)(a)(i), Defendants had actual knowledge that—unlike Statements 25 and 27 implied—their European revenue could not offset revenue declines attributable to the delay of Savanna RVP4's U.S. launch. Lead Plaintiff adequately alleges, as to the first half of Statement 32, that Defendant Busky would have known by June of 2023 that "placing . . . boxes" (after FDA approval) by the fourth quarter of that year was not possible. See Am. Compl., ¶¶ 327(m), 332 ("FE-2 further explained that Kroll met with the Board and senior management quarterly to provide project updates on Savanna, and senior

management . . . 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.”). Lead Plaintiff has also shown that Defendant Busky possessed actual knowledge that the second half of Statement 32 was false: “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.*” *Id.*, ¶ 327(m). Savanna revenue projections could not be realized without FDA approval, U.S. launch, and an automated production line. *Id.*, ¶¶ 95, 222, 343; *see also id.*, ¶ 380 (On July 31, 2024, QuidelOrtho bumps Savanna revenue projections to 2026 after RVP4 FDA resubmission stalls). Given Defendant Busky’s alleged knowledge that these milestones would not be possible in the near future, *see, e.g., id.*, ¶¶ 214-220, this statement does not qualify for safe harbor protection at the pleading stage.

2. Regulatory Approval Statements

The remaining challenged statements projecting regulatory approval for RVP4 and its subsequent U.S. commercial launch are ineligible for safe harbor protection for the same reasons as many of the prior statements.¹⁹ *See, e.g.,* Statement 24 (“*There’s nothing really different in terms of the timelines that we’ve communicated before.*”); Statement 28 (“*[F]rom a timing perspective, I think we’re in reasonably good shape to be ahead of the upcoming*

¹⁹ These include Statements 24, 26, 28, 29, 31, 36-37, 39, and 42. *See* Am. Compl., ¶¶ 327 (e)-(j), (l)-(m), (q)-(s), (v).

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. . . ."); Statement 36 (“*[W]e’re in good shape. And I would commit to being in market before the end of the quarter.*”).

Statement 26, made by Bryant in February 2023 during the Q4 2022 Earnings call, is particularly glaring: “*We’re still expecting RVP for EUA in April [2023] 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. . . . [We] expect to have the ability to make millions of cartridges very shortly.*” *Id.*, ¶ 327(g). As alleged, QuidelOrtho’s outlook for FDA clearance was undeniably bleak in February 2023; some of its instrument build issues were never resolved; and the Company was lightyears away from the capacity to make “millions of cartridges.” *See, e.g., id.*, ¶¶ 178 (CAPA investigation ongoing in 2024), 221-229 (automated manufacturing line never built), 325-26 (continuing instrument build failures), 330 (Company “never met” FDA standards).

The Amended Complaint sets forth a wide range of troubling allegations as to Defendants Busky, Bryant, Iskra, and Ranalli’s knowledge that Savanna RVP4 would not receive FDA clearance anywhere near the projected timeframes within the Class Period. *See, e.g., id.*, ¶¶ 16, 194 (Finance Director FE-10, who was one reporting level away from Busky from May 2022 through Fall 2023, *id.*, ¶ 55,

“recounted internal discussions about Savanna where employees joked that the product was a fraud—QuidelOrtho’s ‘Theranos’” and “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,” affirmed by “consistent sentiment[s]” of “longtime FP&A, Accounting and Operations Finance colleagues”), 198-208, 211-12, 216 (“FE-13 corroborated . . . that [because] Savanna was supposed to be the Company’s next big ‘money-maker,’ . . . issues with Savanna were communicated to the C-suite ‘all the time.’”), 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 . . . , specifically . . . Kroll and Defendant Bujarski, and that information was also forwarded on to Defendants Bryant and Ranalli[, and] . . . [to] his understanding[, . . . Defendant Iskra.”), 359-360, 371; *see also id.*, ¶ 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”).

Statement 42 falls outside the PSLRA safe harbor for the same reason as the second half of Statement 32. *See supra* Discussion B(1)(b)(iv)(1); Am. Compl., ¶ 327(v) (“**\$250 million is the goal, and it’s out there . . . 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.**”).

3. Statements Regarding Manufacturing Capacity and Additional Panels

Having already addressed the challenged statements regarding QuidelOrtho's anticipated manufacturing capabilities, the Court concludes that the challenged statements regarding the Company's development of additional Savanna test panels are likewise ineligible for safe harbor protection.²⁰ The Company's RVP11 and additional panels, touted to include sexually transmitted infections, parasites, and gastrointestinal panels, were described by FE-4 as "nearly impossible" and nothing more than a "pipe dream." *See id.* ¶¶ 168-69 ("there was no evidence at the time that Savanna RVP11 was going to launch in the near future[,] and . . . the Company knew this at the time the product overview was published"). Lead Plaintiff has sufficiently pleaded that Defendant Ranalli, as then-Senior Vice President of the Molecular Business Unit, and Defendant Bryant, as then-CEO, were briefed on these topics. For instance,

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.”).

Id., ¶ 217; *see also id.*, ¶¶ 42, 183, 185, 195, 369. These statements survive.

²⁰ Excluding statements already dismissed or deemed ineligible for safe harbor protection, these include only Statements 44 and 47. *See* Am. Compl., ¶ 337(a), (d).

c. Challenged Statements on Savanna RVP4’s Scalability

Lead Plaintiff contends that the Corporate Defendant and Individual Defendants Bryant, Busky, Iskra, and Bujarski altogether made 28 misrepresentations during the Class Period about 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 in the near term. *Id.*, ¶¶ 339-343.

Defendants’ falsity challenge to these statements largely echo their arguments regarding RVP4’s European launch and readiness for the U.S. market. MTD Mem. at 21-22. The Court has already held that Lead Plaintiff plausibly alleges material misrepresentations associated with the Company’s ability to manufacture thousands of devices and millions of RVP4 tests once FDA approval materialized. *See supra* Discussion § B(1)(b)(i), (iv)(2)-(3); *see also* Am. Compl., ¶¶ 174, 194, 221-28. The Court turns to Defendants’ remaining arguments.

i. Inactionable Opinion

All of the statements in this category that Defendants identify as opinions, MTD Mem. at 11 n.3, are actionable.²¹ Though several include phrases akin to “[I] believe” or “[I] think,” “those magic words can preface nearly any conclusion, and the resulting statements, as [the Supreme Court] ha[s] shown, remain perfectly capable of misleading investors.” *Omnicare*, 575 U.S. at 193. Defendant Bryant’s

²¹ These include Statements 52, 57, 63, 64, 69, 71, 73, and 75. *See* Am. Compl., ¶¶ 339(d), (i), (o), (p), (u), (w), (y), (aa).

statement in May 2023 on the Company’s Q1 2023 Earnings Call is illustrative:

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.

Am. Compl., ¶ 339(p) (Statement 64); *see also id.*, ¶ 339(i) (Statement 57) (“***Our two automated high-volume lines are expected to be up and running by mid-2023, ahead of our U.S. commercial launch.***”). Underlying Bryant’s subjective assessment of the origins of QuidelOrtho’s “confidence” are his factual assurances that QuidelOrtho had “solved [its] supply chain issues,” that it was “***more reliably making and stocking instruments,***” that doing so was “***not going to be a challenge for***” the Company, and that the validation of the Company’s second cartridge manufacturing line had put it in “***really good shape in terms of the volumes [the Company would] require in 2023 and 2024.***” *Id.*, ¶ 339(p). As discussed, the pleadings amply allege otherwise. *See, e.g., id.*, ¶¶ 212, 224-228, 340-43. “[O]ne of the more straightforward ways a statement of opinion may be actionable is if it contains an embedded statement of fact that is not true.” *New England Carpenters*, 122 F.4th at 42. As these statements contain several false assertions that do not “turn[] on the exercise of subjective judgment,” *id.* at 41, they are not inactionable opinions.

ii. Puffery

None of the statements in this category that Defendants contend are

inactionable puffery qualify as such.²² In a representative example, Defendant Bryant reported on the Q1 2022 Earnings Call in May 2022 that “***the only constraint with the launch, honestly, [is] 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.***” Am. Compl., ¶ 339(d) (Statement 52). Like the other statements at issue, and unlike inactionable statements of corporate optimism, this statement is verifiably false. *See Oklahoma Firefighters*, 300 F. Supp. 3d at 570; *see also Abramson*, 965 F.3d at 178. Taking Lead Plaintiff’s allegations as true, there were clearly other constraints on the launch besides the speed and volume at which QuidelOrtho could bring Savanna RVP4 to market: namely, that the product didn’t work. *See, e.g.,* Am. Compl., ¶¶ 16 (“person responsible for validating the RVP4 test results for its FDA submissions . . . , at the time when FDA submissions were being filed, [shared] that Savanna RVP4 ‘does not work’ and that it ‘isn’t even a product.’”), 173 (“widespread failure” with Savanna device and test assay “not working ‘from the very beginning’”), 175 (one in four test instruments in Europe did not work), 179 (European customers reported nonworking Savanna devices and invalid results, which persisted through June 2024), 180 (RVP4 “test wasn’t stable enough to launch to market” in May 2024), 192 (FDA submissions had “glaring issues” and RVP4 tests “never worked properly”), 194 (since early 2022, longtime employees’ “consistent sentiment” was

²² These include Statements 52, 55, 56, 61, 64, 69, 70, and 75. *See* MTD Mem. at 16 n.10 (citing Am. Compl., ¶ 339(d), (g), (h), (m), (p), (u), (v), (aa)).

that they did not think the test ‘would ever work’”), 195 (at time of Quidel and Ortho merger, colleagues remarked, “wait until they see [Savanna] doesn’t work” and is “not a real thing”), 372 (“at least half of the tests produced were defective and scrapped right after manufacturing”).

Because all challenged statements in this category are sufficiently specific to cause a reasonable investor to rely upon them, they cannot be dismissed as mere puffery. *See Oklahoma Firefighters*, 300 F. Supp. 3d at 570 (“statements address[ing] concrete and measurable areas of the defendant company’s performance” are not inactionable puffery (citation omitted)).

iii. PSLRA Safe Harbor

Nearly all of the challenged statements about Defendants’ manufacturing capacity, ability to hit the ground running with U.S. production and distribution after FDA approval, and related near-term revenue projections are forward-looking.²³ Again, however, “[c]autionary words about future risk cannot insulate from liability the failure to disclose that the risk has transpired.” *Rombach*, 355 F.3d at 173. As established, Defendants’ cautionary language was insufficient to protect their statements about QuidelOrtho’s manufacturing capacity and resultant revenue projections from liability because those warnings did not disclose that the Company had already failed to achieve necessary predicates to their predictions.²⁴

²³ These include Statements 49-64, 66-67, 69-76. *See* MTD Mem. at 16 & nn.3-7 (citing Am. Compl., ¶ 339(a)-(p), (r), (s), (u)-(z), (aa)-(bb)).

²⁴ *See, e.g.*, Am. Compl., ¶ 339(e) (Defendant Bryant on the Q1 2022 Earnings Call in May 2022: “**Once online in the fall, our Savanna cartridge automated manufacturing line is expected to begin its ramp-up and outfit to over 1**

The Court has also already determined that investors were not adequately warned of risks associated with Defendants' statements about Savanna RVP4's FDA approval timeline,²⁵ *see supra* Discussion § B(1)(b)(iv)(1)-(2), and that Defendants Bryant, Busky, Iskra, Bujarski, and senior executives more broadly had actual knowledge that their statements about the Company's ability to manufacture at scale were misleading, *see supra* Discussion § B(1)(b)(iv)(2). Accordingly, none are protected.

d. Challenged Statements regarding QuidelOrtho's endemic COVID-19 Revenue

Lead Plaintiff contends that the Corporate Defendant and Individual Defendants Bryant and Busky altogether made 28 misrepresentations regarding the Company's endemic COVID-19 revenue during the Class Period. Am. Compl., ¶¶ 344(a)-(v), 350, 351. Many of the statements in this category specifically address QuidelOrtho's multi-year endemic COVID-19 guidance of \$200-400 million annually ("endemic range statements"),²⁶ some address the Company's future endemic

million cartridges per month with \$300 million annual revenues and anticipated within 3 years of U.S. launch.").

²⁵ See, e.g., Am. Compl., ¶ 339(v) (Defendant Bryant on the Q3 2023 Earnings Call in November 2023: "***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.***"); *id.*, ¶ 339(k) (Defendant Bryant on the 2022 Investor Day Call in December 2022: ". . . ***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 [million].***").

²⁶ These include Statements 78, 82-86, 90-92, 97-98, and 101-02. Am. Compl., ¶ 344(b), (e)-(j), (l)-(n), (r), (u)-(v). Statements 82 and 84, *id.*, ¶ 344(e), (g), project an additional \$100 million to account for a secured government contract in 2023.

COVID-19 trends more broadly (“general prospects statements”),²⁷ others characterize the Company’s past or present performance within the respiratory market (“market position statements”),²⁸ and a few discuss respiratory market trends at large (“market trend statements”).²⁹ Two encompass regulatory disclosures and certifications.³⁰

i. Falsity and Puffery³¹

The endemic range statements can be divided into two groups: those that explicitly tie the \$200-\$400 million projection to fiscal years *beyond* 2023³² and those that may be construed as applying to fiscal year 2023 only.³³ Although Lead Plaintiff does not differentiate between these two statement types, the distinction is consequential. As alleged, the statements that reassure investors the \$200-\$400 million projection would hold for years to come are material misrepresentations, whereas those that do not are less likely to have misled investors. This is because Lead Plaintiff has sufficiently alleged that—between missed sales quotas, impending end-of-life concerns for the Sofia line of products, Savanna RVP4’s unviability, QuidelOrtho’s loss of market share, and skyrocketing excess and

²⁷ These include Statements 81 and 87. Am. Compl., ¶ 344(e), (j).

²⁸ These include Statements 77, 79, 93-94, 96, and 99-100. Am. Compl., ¶ 344(a), (c), (o), (q), (s)-(t).

²⁹ These include Statements 80, 88-89, and 95. Am. Compl., ¶ 344(d), (k), (p).

³⁰ These include Statements 103 and 104. Am. Compl., ¶¶ 350-51.

³¹ None of the challenged statements in this category are inactionable opinions.

³² These include Statements include 83, 90, 92, 97, and 102. Am. Compl., ¶ 344(f), (l), (n), (r), (v).

³³ These include Statements 78, 82, 84-86, 98, and 101. Am. Compl., ¶ 344(b), (e), (g)-(i), (r), (u).

obsolete (“E&O”) inventory—there was no path to achieving revenue within the \$200-400 million range after 2023. *See, e.g.*, Am. Compl., ¶¶ 139-45 (end-of-life forecast for Sofia 1 and 2), 213 (Savanna not passing QuidelOrtho’s internal qualifications or testing in 2022 and early 2023), 236-76 (sales quotas missed—and progressively tanked—in every quarter of 2023; commission only paid if salespeople’s percent to forecast hit 93%, but average percent to forecast was 65-68%; E&O hit unprecedented levels), 354 (loss of market share), 378 (“Defendant Busky received reports detailing how COVID-19 sales quotas were missed ‘by a mile’ throughout 2023”).

Throughout fiscal year 2023, however, these realities were still taking shape. *See, e.g., id.*, ¶¶ 237 (sales representatives attempted unsuccessfully to “stop the bleeding” of declining business and revenue loss in 2023), 240 (“COVID test sales at QuidelOrtho began declining in late 2022”), 241 (“FE-15 recalled that he saw ‘significant’ change in the behavior of customers between late Fall 2022 and early Spring 2023,” by which time 30-40% of customers had stopped purchasing from QuidelOrtho because they were “not testing for COVID as frequently” and “purchasing newer tests from competitors”); 244 (“COVID tests sales in hospitals were ‘completely gone’ in 2023 and . . . Quidel’s acute business ‘disappeared overnight’”). Clocking out at \$260 million in endemic COVID revenue, discounting government contracts, *id.*, ¶ 296 n.13, the Company’s final revenue numbers for 2023 were within the projected range—though shocking and disappointing to investors, *see id.*, ¶¶ 291 (2023 “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.”), 292 (William Blair analysts decry “disconnect” between the expectations set by QuidelOrtho management and the Company’s fourth quarter and fiscal year 2023 results” and characterize QuidelOrtho shares as “in the penalty box” until management can “rebuild some credibility”). Accordingly, Statements 78, 82, 84-86, 98, and 101 cannot be considered false and are dismissed.

In contrast, the general prospects statements constitute material misrepresentations because they project a picture of the Company’s respiratory market outlook made impossible by documented realities at the time the statements were made. For instance, during the Q4 2022 Earnings Call in February 2023, Defendant Busky made Statement 81: “***We expect to continue to capture and grow our share of the respiratory market, underpinned by our large and growing Sofia placements.***” *Id.*, ¶ 344(e). By February 2023, Sofia had no chance of “underpinn[ing]” QuidelOrtho’s capture of, or growth in, the respiratory market because Sofia placements were not “large and growing” but rather careening toward obsolescence. *See e.g., id.*, ¶¶ 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.”), 139 (“according to . . . 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.”), 147 (“Sofia analyzers’ sales potential also suffered because customers were choosing more modern technology over what the Sofia platform could offer. . . . [B]y the time of the Merger,” FE-3, a

former salesman and business developer for the Company, “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.”), 148 (“there was less demand for the Sofia analyzer and other immunoassay tests because competitors’ molecular tests had substantially higher reimbursement rates.”). Further, Defendant Bryant’s statement at the Raymond James Annual Institutional Investors Conference in March 2023 that the Company’s EBITDA expectations in “**2024 should be better than 2023 and [in] 2025 better than 2024**,” *id.*, ¶ 344 (j), was materially misleading given the Company’s sales drop-offs and end-of-life concerns for its major COVID-19 products. *See e.g., id.*, ¶¶ 236-76.

Most, but not all, of Defendants’ market position statements were material misrepresentations. For instance, Lead Plaintiff alleges with damning specificity

that Statements 77,³⁴ 94,³⁵ and 100³⁶ materially misled investors. In contrast, Statement 79 is certainly misleading, but it fails on puffery grounds along with Statement 99.³⁷ Because these statements “lack the sort of definite positive

³⁴ Compare Am. Compl., ¶ 344(a) (“**[W]e don’t have so much of a demand problem right now. We have a supply problem. We got to get more products.**”), with *id.*, ¶¶ 233 (“huge decline” in COVID test sales beginning in August 2021, such that distributors couldn’t resell to end-users and “tests kits . . . were never moved from distribution warehouses”), 245 (“Quidel provided the [hospital] 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 [and] Q1 2023”); 246 (FE-16 and his sales colleagues throughout the U.S. “all talked about how no one was buying QuidelOrtho’s acute products” and “asked each other what they were doing with all the Quidel products that they were unable to sell.”), 247 (FE-17, “[a]nother 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 . . . recalled that in 2022 and 2023, ‘no one’ was buying COVID tests.”).

³⁵ Compare Am. Compl., ¶ 344(o) (Defendant Bryant, discussing the “**overall market for respiratory testing and our respiratory business**” in November 2023 during the Q3 2023 Earnings Call, describes “**significant share gains from competitors for us specifically.**”), with *id.*, ¶ 347 (QuidelOrtho was “losing market share to competitors whose tests offered more flexibility or better technology”).

³⁶ Compare Am. Compl., ¶ 344(t) (“**[W]e historically have preannounced when we have something that’s materially different than you think. . . [s]o, 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.**”), with *id.*, ¶ 281 (“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**’ [so] ‘**23 guidance (rev and profits) appears intact**’ . . . and that ‘**Q1 [2024] looks like a normal respiratory season.**’”), and *id.*, ¶ 283 (Defendant Bryant “will not sugarcoat the fact that our fourth quarter numbers fell short of our expectations”), and *id.*, ¶ 286 (“Defendants . . . in January . . . [were] fully aware [that] . . . **total revenue . . . was about 6% or 7% of what we had projected.**”).

³⁷ Am. Compl., ¶ 344(c) (“**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.**”); *id.*,

projections that might require later correction,” *In re Vivendi*, 838 F.3d at 245 (citation omitted), they are inactionable statements of corporate optimism. *See Abramson*, 965 F.3d at 173 (securities laws do not “require[] corporate officials to present an overly gloomy or cautious picture of current performance and future prospects.” (cleaned up)). Statement 93 fails because Lead Plaintiff does not allege facts with specificity to conclude that the third quarter of 2023 did not have “***strong and early respiratory demand***” as Defendant Bryant represented on the Q3 2023 Earnings Call. Am. Compl., ¶ 344(o). Statement 96 similarly fails because Lead Plaintiff does not allege that QuidelOrtho’s 2023 Q2 “***financial performance***” did not “***exceed[] [its] plan significantly.***” *Id.*, ¶ 344(q). While Lead Plaintiff does allege that the Company’s salespeople did not hit their quotas that quarter, *id.*, ¶ 346, the Teamsters Funds do not advance overall Q3 projections against which to measure QuidelOrtho’s ultimate Q3 performance.

Defendants’ market trend statements would not have materially misled reasonable investors because they were not concretely tied to QuidelOrtho’s performance.³⁸ Accordingly, these statements are dismissed.

¶ 344(s) (“***So, we continue to do well in this space*** [with respect to Sofia]. ***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.***”).

³⁸ See Am. Compl., ¶ 344(d) (COVID-19 is “***definitely not declining though. And so it’s become somewhat steady state.***”), (k) (“***Demand for diagnostics across the health care continuum remained strong.***”), (k) (“***significant increase in global demand for global testing.***”), (p) (“***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***”).

Finally, Statements 103 and 104 are QuidelOrtho's regulatory disclosures and certifications. Am. Compl., ¶¶ 350-51. While these 10-Ks, 10-Qs, and Sarbanes-Oxley Act of 2002 ("SOX") certifications are insufficient to shield many of the other statements from liability, *see infra* Discussion § B(1)(d)(ii), they are not in and of themselves false. Accordingly, they are dismissed.

ii. PSLRA Safe Harbor

The remaining forward-looking statements not already dismissed address Defendants' market share and endemic COVID-19 revenue projections for fiscal year 2023 and beyond.³⁹ Defendants point to their SEC filings as providing "[m]eaningful cautionary language" with "detailed warnings about risks to QuidelOrtho's future financial performance and business." MTD Mem. at 13-14. QuidelOrtho's 2022 Form 10-K filed on February 23, 2023 ("2022 10-K") is illustrative, as the Company's quarterly 10-Qs for 2023 incorporate it by reference through November 2023.⁴⁰ The 2022 10-K provides, in relevant part:

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.").

³⁹ These include Statements 81, 83, 87, 90, 92, 97, and 102. Am. Compl., ¶ 344(e)-(f), (j), (l), (n), (r), (v).

⁴⁰ *QuidelOrtho Corp.*, Quarterly Report (Form 10-Q), at 36 (filed May 4, 2023), <https://www.sec.gov/Archives/edgar/data/1906324/000190632423000033/qdel-20230402.htm> ("There has been no material change in our risk factors as previously disclosed in our Annual Report on Form 10-K for the fiscal year ended January 1, 2023."); *QuidelOrtho Corp.*, Quarterly Report (Form 10-Q), at 35 (filed Aug. 9, 2023), <https://www.sec.gov/Archives/edgar/data/1906324/000190632423000046/qdel-20230702.htm> (same); *QuidelOrtho Corp.*, Quarterly Report (Form 10-Q), at 36 (filed Nov. 2, 2023), <https://www.sec.gov/Archives/edgar/data/1906324/000190632423000058/qdel-20231001.htm> (same).

. . . 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.

Am. Compl., ¶ 350. Because several of the hypothetical risks listed in this disclosure (e.g., market share loss and obsolescence) had already manifested by the time many of these SEC filings were released, such cautionary language does not offer safe harbor protection.

The Amended Complaint is also replete with allegations that Defendants Busky and Bryant were aware that QuidelOrtho's sales and E&O metrics rendered their revenue and market share projections fantastical. *See, e.g., id.*, ¶¶ 144 (“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”), 232 (“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.”), 236-238 (“FE-3 noted that he logged feedback from [his] conversations” with customers who “purchased tests from competitors because they

had more state-of-the-art products . . . in CRM Salesforce and shared the feedback in weekly meetings” with his team and supervisor who reported to VP of Sales John Meckles. “According to FE-3, [his supervisor] thereafter attended business manager meetings where sales were discussed with senior management”), 251 (“the inflated sales quotas were identified at the start of 2023 and brought to the attention of senior management, including the Individual Defendants”), 257 (“upper management utilized Microsoft Power BI to analyze data and ‘see the bigger picture,’ *i.e.*, all of the Company’s territories,” where the “huge decline in the Quidel side of the business . . . was seen ‘easily and obviously.’”), 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.”), 265 (Defendant Busky attended meetings about the Company’s sales analysis throughout 2023), 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.”), 278 (FE-10 discussed inventory analysis and data directly with Defendant Busky); *see also id.*, ¶ 265. Accordingly, the PSLRA’s safe harbor does not shelter these statements.

2. Scienter

The Supreme Court has instructed that a “strong inference” of scienter “must be more than merely plausible or reasonable—it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.” *Tellabs*, 551 U.S. at 314 . This inference need not be “irrefutable,” of the “smoking-gun genre,” or the “most plausible of competing inferences,” rather, courts consider “whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.” *Id.* at 323-24. “Courts in this district generally conclude that the scienter of ‘management level’ employees can be attributed to the corporation.” *In re ASML Holding N.V. Sec. Litig.*, 825 F. Supp. 3d 208, 239 (S.D.N.Y. 2026) (citation omitted); *Thomas v. Shiloh Indus., Inc.*, No. 15-CV-07449 (KMW), 2017 WL 2937620, at *3 (S.D.N.Y. July 7, 2017) (same) (collecting cases).

In this Circuit, “[a] plaintiff may establish scienter by alleging facts showing that (1) the defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness.” *Gimpel*, 156 F.4th at 144 (cleaned up). If plaintiffs cannot make a showing of motive, “the strength of the circumstantial allegations must be correspondingly greater.” *ECA*, 553 F.3d at 198-99 (cleaned up). Further, “personal financial gain may weigh heavily in favor of a scienter inference.” *Slayton*, 604 F.3d at 776 (quoting *Tellabs*, 551 U.S. at 325).

a. Motive and Opportunity

To raise an inference of scienter under motive and opportunity, a plaintiff must show that the corporation or its officers “benefitted in some concrete and personal way from the purported fraud.” *zCap Equity Fund LLC*, 792 F. Supp. 3d at 440 (quoting *Novak*, 216 F.3d at 307-08). The Amended Complaint imputes such a motive to the Individual Defendants, alleging that “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.” Am. Compl., ¶ 381 (internal quotation marks omitted); *see also id.*, ¶ 136 (“[T]he Executive Steering Committee[, which included Defendants Steward and Bujarski,] 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, . . . [and] Kroll, Defendant Steward, and Defendant Bujarski had large incentives in their employment contracts that were tied to Savanna RVP4 advances. . . . Defendant Bryant oversaw Quidel’s Executive Steering Committee for the Savanna project.”).

b. Circumstantial Evidence of Conscious Misbehavior or Recklessness

For 10b-5 actions in this Circuit, recklessness is defined as “at the least, . . . an extreme departure from the standards of ordinary care . . . to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it.” *zCap*, 792 F. Supp. 3d at 440 (cleaned up). As relevant here, pleadings must that show Defendants “knew facts or had access to

information suggesting that their public statements were not accurate” or “failed to check information they had a duty to monitor” give rise to an inference of scienter. *Id.* (cleaned up). The Court has discussed at length the extent to which Defendants Bryant, Busky, Iskra, and Ranalli “knew facts or had access to information suggesting that their public statements were not accurate.” *See supra* Discussion § B(1)(a)(iv), (b)(iv), (c)(iii), (d)(ii).

Further, “[t]he timing of terminations and resignations, in relation to the magnitude of corrections in a restatement, also can be a strong inference of scienter, approaching recklessness or even conscious malfeasance as to the targeted individuals.” *In re Pareteum Sec. Litig.*, No. 19-CV-09767 (AKH), 2021 WL 3540779, at *17 (S.D.N.Y. Aug. 11, 2021) (cleaned up). Taken alongside the rest of the Amended Complaint, CEO Bryant’s termination a week after the corrective market reaction to QuidelOrtho’s 2023 Form 10-K, Am. Compl., ¶ 300-01, and Defendants Bujarski and Iskra’s firings that July after the Company continued to perform below touted expectations, *id.*, ¶¶ 27, 380, are probative of these Individual Defendants’ recklessness.

Accordingly, the Court finds that Lead Plaintiff has adequately alleged scienter as to both the Individual Defendant and QuidelOrtho.⁴¹ *See Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital, Inc.*, 531 F.3d 190, 195 (2d Cir. 2008) (“In most cases, the most straightforward way to raise such an inference

⁴¹ Finding Lead Plaintiff’s alternate arguments sufficient to plead scienter, the Court does not address the parties’ core operations doctrine arguments. *See* MTD Mem. at 31; Opp’n at 28.

for a corporate defendant will be to plead it for an individual defendant.”).

C. Scheme Liability under Rule 10b-5(a) and (c)

To state a scheme liability claim, a plaintiff must allege “(1) manipulative acts; (2) damage (3) caused by reliance on an assumption of an efficient market free of manipulation; (4) scienter; (5) in connection with the purchase or sale of securities; (6) furthered by the defendant’s use of the mails or any facility of a national securities exchange.” *ATSI*, 493 F.3d at 101. “Unlike a misrepresentation or omission claim under Rule 10b-5(b), [a] scheme liability claim is aimed at inherently deceptive conduct and does not require a misleading statement or omission.” *In re AT&T/DirecTV Now Sec. Litig.*, 480 F. Supp. 3d 507, 534 (S.D.N.Y. 2020) (cleaned up), *aff’d sub nom., Steamfitters Loc. 449 Pension Plan v. AT&T Inc.*, No. 21-2698-CV, 2022 WL 17587853 (2d Cir. Dec. 13, 2022) (summary order). Instead, “scheme liability is triggered where the defendant performed an inherently deceptive act that was distinct from an alleged misstatement: *i.e.*, sham agreements, sham transactions, sham companies.” *SEC v. Farnsworth*, 692 F. Supp. 3d 157, 189 (S.D.N.Y. 2023) (cleaned up). Accordingly, while “misstatements and omissions can form *part of* a scheme liability claim, . . . an actionable scheme liability claim also requires something *beyond* misstatements and omissions.” *SEC v. Rio Tinto PLC*, 41 F.4th 47, 49 (2d Cir. 2022).

While the misrepresentations set forth in the Amended Complaint certainly augment Lead Plaintiff’s scheme liability claim, *see* Am. Compl., ¶ 429(a)-(g), they are not its only support. Lead Plaintiff’s other allegations in support of scheme

liability include, *inter alia*, inflated sales goals, concealing the CAPA investigation and negative customer feedback in Europe, dismantling and downsizing the Savanna RVP4 team in favor of a more insular team, advertising additional Savanna panels that did not exist, doubling endemic COVID revenue projections without substantiation, and submitting Savanna RVP4 to the FDA despite known insufficiencies. *Id.*, ¶¶ 115, 168-69, 178-79, 183-84, 198, 200-04, 207, 359-60, 429; *see also, id.*, ¶¶ 134-35 (to “push” Savanna “over the goal line,” “Defendant Steward and Defendant Bujarski . . . ‘championed’ cutting corners on the RVP4 project . . . through the second half of 2023,” including by “skipp[ing] quality steps like reliability testing . . . because there were flaws with the Savanna RVP4 instrumentation, [such that] the RVP4 instrument and cartridge would break and fail and therefore the Company could not run a reliability test.”), 201 (employees believed the Company made its Savanna RVP4 FDA submission in 2023 to boost the Company’s stock price), 370 (After team developing Savanna RVP4 told Kroll the test had manufacturability concerns that would prevent it from being reliably manufactured, QuidelOrtho did not “proceed with a ‘design review,’ the next step on a normal trajectory at a medical device company.” Instead, “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,” allegedly to “insulate information from the rest of the Company about issues with Savanna RVP4 and ‘push it’ to production and R&D.”). Accordingly, this claim survives.

D. Control Person Liability Under Section 20(a)

Section 20(a) of the Exchange Act assigns joint and several liability to every person who controls any person liable under any provision of the Exchange Act. 15 U.S.C. § 78t(a). To state a claim under section 20(a), “a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person’s fraud.” *Okl. Firefighters*, 300 F. Supp. 3d at 569-70 (cleaned up).

Defendants’ sole argument for dismissal of this claim is that Lead Plaintiff fails to plead a “primary violation” under Section 10(b) that would allow for a claim under Section 20(a). MTD Mem. at 35. As discussed at length, Lead Plaintiff’s Section 10(b) claims survive Defendants’ motion, so its claims arising under Section 20(a) may proceed as well. *See, e.g., Ark. Pub. Emps. Ret. Sys.*, 28 F.4th at 356-57 (2d Cir. 2022).

CONCLUSION

Accordingly, Defendants’ Motion to Dismiss is **GRANTED IN PART AND DENIED IN PART**. Both motions to strike are **DENIED**. The Clerk of Court is respectfully directed to terminate ECF Nos. 47, 51, and 57.

SO ORDERED.

Dated: September 30, 2026
New York, New York


JEANNETTE A. VARGAS
United States District Judge

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
European Launch of Savanna RVP4				
1	321(a)	2/17/2022 Q4 2021 Earnings Release	Bryant	<i>“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.”</i>
2	321(b)	2/17/2022 Q4 2021 Earnings Call	Bryant	<i>“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.”</i>
3	321(c)	3/9/2022 Raymond James Annual Institutional Investors Conference	Bryant	<i>“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.”</i>
4	321(d)	3/9/2022 Raymond James Annual Institutional Investors Conference	Bryant	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. <i>We’re receiving some really nice feedback.</i> But that’s just RVP4 at the moment.”
5	321(e)	6/8/2022 William Blair Annual Growth Stock Conference	Bryant	<i>“[W]e 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.”</i>
6	321(f)	8/4/2022 Q2 2022 Earnings Call	Bryant	<i>“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.”</i>
7	321(g)	9/12/2022 Morgan Stanley Global Healthcare Conference	Bryant	<i>“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.”</i>
8	321(h)	9/13/2022 Repertoire Podcast	Ranalli	<i>“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>

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
9	321(i)	11/2/2022 Q3 2022 Earnings Call	Bryant	<i>“[W]e 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.”</i>
10	321(j)	11/2/2022 Q3 2022 Earnings Call	Bryant	<i>“[W]e are seeing demand in Europe and are increasingly confident that Savanna placements and revenue will accelerate throughout 2023.”</i>
11	321(k)	12/13/2022 2022 Investor Day Presentation	QO	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 .”
12	321(l)	12/13/2022 2022 Investor Day Call	Ranalli	<i>“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.”</i>
13	321(m)	1/9/2023 41st Annual J.P. Morgan Healthcare Conference	Bryant	<i>“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.”</i>
14	321(n)	2/15/2023 Q4 2022 Earnings Call	Busky	<i>“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.”</i>
15	321(o)	2/15/2023 Q4 2022 Earnings Call	Bryant	An analyst asked Defendant Bryant a question regarding the “cross-selling excitement” that he referred to earlier. In response, Bryant stated: <i>“And I think it would be fair to say that we’ve been reasonably successful in a limited launch in Europe with Savanna too.”</i>

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
16	321(p)	5/3/2023 Q1 2023 Earnings Call	Busky	<i>“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.”</i>
17	321(q)	8/8/2023 Q2 2023 Earnings Call	Bryant	Defendant Bryant described how, while the molecular diagnostics business had declined because of declining Lyra assay sales, <i>“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.”</i>
18	321(r)	11/30/2023 Evercore ISI HealthCONx Conference	Bryant	Defendant Bryant was asked about “longer term, what is the Savanna thesis, what should we expect from Savanna?” 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 super competitive. And that’s what our marketing data says. <i>And we do have customers in Europe, we do have IUO customers in the US and the feedback at this point has been encouraging.</i> ”
19	321(s)	1/8/2024 J.P. Morgan Healthcare Conference	Bryant	<i>“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.”</i>
Savanna’s Readiness for a U.S. Launch and FDA Approval Throughout the Class Period				
20	327(a)	2/17/2022 Q4 2021 Earnings Release	Bryant, QO	<i>“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.”</i>
21	327(b)	2/17/2022 Q4 2021 Earnings Call	Bryant	<i>“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.”</i>

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
22	327(c)	3/9/2022 Raymond James Annual Institutional Investors Conference	Bryant	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. <i>And then here, it’s just about -- it’s a matter of timing in terms of FDA clearance.</i> ”
23	327(d)	11/2/2022 Q3 2022 Earnings Call	Bryant	<i>“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.”</i>
24	327(e)	11/2/2022 Q3 2022 Earnings Call	Bryant	<i>“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.”</i>
25	327(f)	11/2/2022 Q3 2022 Earnings Call	Bryant	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: <i>“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.”</i>
26	327(g)	2/15/2023 Q4 2022 Earnings Call	Bryant	An analyst asked Defendant Bryant for an update on the Savanna timeline. In response, Defendant Bryant stated: <i>“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.”</i>

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
27	327(h)	3/7/2023 Raymond James Institutional Investors Conference	Bryant	Defendant Bryant responded to questions about the Savanna FDA approval process during the Raymond James Institutional Investors Conference, where the analyst asked, “[i]s 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: <i>“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>
28	327(i)	5/3/2023 Q1 2023 Earnings Call	Bryant	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. <i>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</i> , which puts us in really good shape in terms of the volumes that we require in 2023 and 2024. So we’re pretty confident.”
29	327(j)	5/3/2023 Q1 2023 Earnings Call	Bryant	<i>“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.”</i>
30	327(k)	5/3/2023 Q1 2023 Earnings Call	Bryant	<i>“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.”</i>
31	327(l)	6/6/2023 William Blair Growth Stock Conference	Bryant	<i>“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.”</i>

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
32	327(m)	6/6/2023 William Blair Growth Stock Conference	Busky	In response to an analyst question regarding “How important is Savanna” to achieving “6% to 9%” growth, Defendant Busky stated: “And then finally, Molecular, <i>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.</i> We haven’t really talked too much about the slope of that revenue ramp in 2024 and 2025. But we have said that <i>we expect three years post-launch that will be greater than \$250 million of revenue on that Savanna product.</i> ”
33	327(n)	8/8/2023 Q2 2023 Earnings Call	Bryant	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 <i>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.</i> ”
34	327(o)	9/12/2023 Morgan Stanley Global Healthcare Conference	Bryant	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. . . . <i>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.</i> ”
35	327(p)	11/30/2023 Evercore ISI HealthCONX Conference	Bryant	An analyst asked Defendant Bryant “what’s happened with Savanna? It looks like there was some timing pushout.” In response, Bryant stated: “ <i>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.</i> The one issue which we’ve agreed was that we needed to run some samples during respiratory season. And <i>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...</i> ”
36	327(q)	1/8/2024 J.P. Morgan Healthcare Conference	Bryant	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?” Defendant Bryant responded: “ <i>Well, we’re in good shape. And I would commit to being in market before the end of the quarter.</i> ”

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
37	327(r)	2/13/2024 Q4 2023 Earnings Call	Bryant	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.”
38	327(r)	2/13/2024 Q4 2023 Earnings Call	Bryant	“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.”
39	327(s)	2/13/2024 Q4 2023 Earnings Call	Busky	“We continue to expect Savanna instrument placements of approximately 1,000 in 2024, which will pave the way for 2025 Savanna revenue growth.”
40	327(t)	3/5/2024 Raymond James Institutional Investors Conference	Iskra	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 folks [sic 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.”

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
41	327(u)	3/5/2024 Raymond James Institutional Investors Conference	Iskra	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: <i>“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.”</i>
42	327(v)	3/5/2024 Raymond James Institutional Investors Conference	Iskra	An 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: <i>“\$250 million is the goal, and it’s out there”</i> and “net-net, we are driving to that number, but we’re watching a lot of things that will factor into it. But nonetheless, <i>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.”</i>
43	327(w)	3/5/2024 Raymond James Institutional Investors Conference	Bujarski	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>“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.”</i>

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
44	337(a)	9/13/2022 Repertoire Podcast	Ranalli	<i>“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 .”</i>
45	337(b)	2/15/2023 Q4 2022 Earnings Call	Bryant	<i>“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 .”</i>
46	337(c)	5/3/2023 Q1 2023 Earnings Call	Bryant	<i>“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 .”</i>

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
47	337(d)	5/3/2023 Q1 2023 Earnings Call	Bryant	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: <i>“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.”</i>
48	337(e)	8/8/2023 Q2 2023 Earnings Call	Bryant	<i>“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.”</i>
Company’s Ability To Manufacture Savanna at a Scale Necessary To Achieve Over \$75 Million in Revenue Synergies and \$300 Million in Overall Revenue				
49	339(a)	2/17/2022 Q4 2021 Earnings Call	Bryant	<i>“[W]e’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.”</i>

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
50	339(b)	4/11/2022 April 11, 2022 Prospectus	QO	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.”
51	339(c)	4/11/2022 2022 Proxy Statement	Bryant	“ 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.”
52	339(d)	5/4/2022 Q1 2022 Earnings Call	QO	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 . ”
53	339(e)	5/4/2022 Q1 2022 Earnings Call	Bryant	“ 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 . ”
54	339(f)	8/4/2022 Q2 2022 Earnings Release	Bryant	“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 . ”

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
55	339(g)	8/4/2022 Q2 2022 Earnings Call	Bryant	<i>“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.”</i>
56	339(h)	8/4/2022 Q2 2022 Earnings Call	Bryant	An analyst asked about the prior guidance provided for 2022 and what Defendants were “thinking about next year.” In response, Defendant Bryant stated: <i>“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>
57	339(i)	11/2/2022 Q3 2022 Earnings Call	Bryant	<i>“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.”</i>
58	339(j)	11/2/2022 Q3 2022 Earnings Call	Bryant	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: <i>“[W]e’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.”</i>

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
59	339(k)	12/13/2022 2022 Investor Day Call	Bryant	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>“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 .”</i>
60	339(l)	2/15/2023 Q4 2022 Earnings Call	Bryant	<i>“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.”</i>
61	339(m)	2/15/2023 Q4 2022 Earnings Call	QO	<i>“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 .”</i>
62	339(n)	2/13/2024 Q4 2023 Earnings Call Investor Presentation	Bryant	The investor presentation accompanying the Q4 2023 Earnings Call stated that the Company <i>“[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 .”</i>

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
63	339(o)	3/7/2023 Raymond James Annual Institutional Investors Conference	Bryant	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.”
64	339(p)	5/3/2023 Q1 2023 Earnings Call	Bryant	“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.”
65	339(q)	5/3/2023 Q1 2023 Earnings Call	Bryant	“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.”
66	339(r)	5/3/2023 Q1 2023 Earnings Call	Busky	In response to an analyst question regarding “what’s included in the guide for the year for Savanna[,]” Defendant Busky stated: “there’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.”

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
67	339(s)	6/6/2023 William Blair Growth Stock Conference	Busky	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: <i>“we expect three years post-launch that will be greater than \$250 million of revenue on that Savanna product.”</i>
68	339(t)	8/8/2023 Q2 2023 Earnings Call	Bryant	<i>“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.”</i>
69	339(u)	8/8/2023 Q2 2023 Earnings Call	Bryant	<i>“[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.”</i>
70	339(v)	11/1/2023 Q3 2023 Earnings Call	Bryant	<i>“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.”</i>
71	339(w)	11/1/2023 Q3 2023 Earnings Call	Bryant	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 <i>“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.”</i>
72	339(x)	11/1/2023 Q3 2023 Earnings Call	Bryant	An analyst asked for “an update on the high volume cartridge manufacturing line.” In response, Defendant Bryant stated: <i>“We’re still targeting everything on track for midyear next year.”</i>
73	339(y)	11/30/2023 Evercore ISI HealthCONX Conference	Bryant	An analyst asked Defendants, “what is the Savanna thesis, what should we expect from Savanna?” In response, Defendant Bryant stated: <i>“[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.”</i>

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
74	339(z)	2/13/2024 Q4 2023 Earnings Call	Busky	<i>“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.”</i>
75	339(aa)	3/5/2024 Raymond James Institutional Investors Conference	Iskra	An analyst asked whether the \$250 million run rate goal for Savanna by 2026 was “still the goal?” In response, Defendant Iskra stated: <i>“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.”</i>
76	339(bb)	3/5/2024 Raymond James Institutional Investors Conference	Bujarski	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: <i>“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.”</i>
Endemic COVID-19 Revenue During the Class Period				
77	344(a)	12/13/2022 2022 Investor Day Call	Busky	<i>“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.”</i>

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
78	344(b)	12/20/2022 William Blair analyst report relaying QuidelOrtho management statements “Virtual NDR Takeaways and Additional Thoughts Following Last Week’s Investor Day”	Busky	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: “Management 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 .”
79	344(c)	1/26/2023 Repertoire Podcast	Bryant	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.
80	344(d)	1/26/2023 Repertoire Podcast	Bryant	“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.”
81	344(e)	2/15/2023 Q4 2022 Earnings Call	Busky	“We expect to continue to capture and grow our share of the respiratory market, underpinned by our large and growing Sofia placements .”
82	344(e)	2/15/2023 Q4 2022 Earnings Call	Busky	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 with \$300 million to \$500 million .”

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
83	344(f)	2/15/2023 Q4 2022 Earnings Call	Busky	An analyst asked Defendants whether “there’s the fear that, as COVID comes out, 2024 then takes a step down,” which Defendant Busky responded: “[T]here’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.”
84	344(g)	2/15/2023 Q4 2022 Earnings Call	Bryant & Busky	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.”
85	344(h)	2/15/2023 Q4 2022 Earnings Call	Busky	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. . . . ”
86	344(i)	3/7/2023 Raymond James Annual Institutional Investors Conference	Bryant	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 .

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
87	344(j)	3/7/2023 Raymond James Annual Institutional Investors Conference	Bryant	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 stated: “ <i>your comment about 2024 should be better than 2023 and 2025 better than 2024 I think is a reasonable expectation .</i> ”
88	344(k)	5/3/2023 Q1 2023 Earnings Call	Bryant	“ <i>Demand for diagnostics across the health care continuum remained strong .</i> ”
89	344(k)	5/3/2023 Q1 2023 Earnings Call	Bryant	The “ <i>significant increase in global demand for global testing .</i> ”
90	344(l)	5/3/2023 Q1 2023 Earnings Call	Bryant	In response to Citi analyst question 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, <i>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 .</i> ”
91	344(m)	5/3/2023 Q1 2023 Earnings Call	Busky	“[J]ust to put a bow on that . . . <i>[w]e do think that we’ve de-risked the balance off your forecast for Respiratory and COVID because we’re not changing it</i> and we didn’t overachieve in Q1.”
92	344(n)	9/12/2023 Morgan Stanley Global Healthcare Conference	Bryant	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. <i>And we should expect, therefore, moving forward, 2024 and beyond, to see \$200 million to \$400 million in COVID-specific – or COVID-only sales. .</i> ”
93	344(o)	11/1/2023 Q3 2023 Earnings Call	Bryant	“ <i>[T]he strong and early respiratory demand in Q3 was mainly driven by high COVID-19 prevalence throughout the United States .</i> ”

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
94	344(o)	11/1/2023 Q3 2023 Earnings Call	Bryant	<i>“Both the overall market for respiratory testing and our respiratory business became significantly larger due to more testing in general, and significant share gains from competitors for us specifically . We have a strong position in this market and our respiratory diagnostic capabilities play an important role in combating both early and seasonal upticks of COVID-19, RSV and influenza, among others. We’re also well positioned to manage any seasonal fluctuations, given our operations team’s agility to respond to meet customer demand.”</i>
95	344(p)	11/1/2023 Q3 2023 Earnings Call	Bryant	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 .
96	344(q)	11/1/2023 Q3 2023 Earnings Call	Busky	<i>“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 .”</i>
97	344(r)	11/30/2023 Evercore ISI HealthCONx Conference	Bryant	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 .”
98	344(r)	11/30/2023 Evercore ISI HealthCONx Conference	Busky	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 .”

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
99	344(s)	1/8/2024 J.P. Morgan Healthcare Conference	Bryant	“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? <i>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.</i> It’s our highest margin category as well.”
100	344(t)	1/8/2024 J.P. Morgan Healthcare Conference	Bryant	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 <i>we historically have preannounced when we have something that’s materially different than you think</i>. 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, <i>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.</i>”
101	344(u)	1/8/2024 J.P. Morgan Healthcare Conference	Bryant	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, <i>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.</i>
102	344(v)	1/8/2024 J.P. Morgan Healthcare Conference	Bryant	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>“I think we’re very much on track for 2024.”</i>

Statement #	Complaint ¶	Date and Source	Speaker	Alleged Misrepresentation
103	350	2/23/2023 Form 10-K	QO, Bryant, Busky	<i>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 .</i> 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.
104	351	2/23/2023 Form 10-K 5/2/2023 Form 10-Q 8/9/2023 Form 10-Q 11/2/2023 Form 10-Q SOX Certifications	Bryant, Busky	Attestations by Defendants Bryant and Busky that information in the 2022 10-K “<i>fairly presents, in all material respects, the financial condition and results of operations of the Company .</i>”