UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

Case No. 22-cv-00105-SI

IN RE: TALIS BIOMEDICAL CORPORATION SECURITIES LITIGATION,

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS CONSOLIDATED CLASS ACTION COMPLAINT WITH LEAVE TO AMEND

Re: Dkt. No. 83

On November 4, 2022, the Court held a hearing on defendants' motion to dismiss the consolidated complaint. For the reasons set forth below, the Court GRANTS the motion and GRANTS leave to amend. The amended complaint must be filed by **January 13, 2023**.

INTRODUCTION

Co-lead plaintiffs Martin Dugan, Leon Yu, and Max Wisdom Technology Ltd., on behalf of a putative class of shareholders, allege that Talis Biomedical Corporation ("Talis") and various current and former Talis officers and board members misled the investing public about Talis's ability to bring its first product – a molecular diagnostic platform for COVID-19 tests called the "Talis One" – to market. Plaintiffs allege that defendants misled investors about Talis's initial application for an Emergency Use Authorization ("EUA") from the Food and Drug Administration ("FDA"); the accuracy and functionality of the Talis One; and about Talis's ability to manufacture the Talis One on a commercial scale on projected timelines. Plaintiffs allege that defendants made numerous false and misleading statements and omissions in connection with Talis's February 2021

initial public offering ("IPO") and in post-IPO filings with the Securities and Exchange Commission ("SEC") and during quarterly investor calls from March 2021 until March 2022.

Defendants move to dismiss the consolidated complaint ("CC"), asserting that Talis consistently disclosed to investors that it faced extraordinary circumstances bringing its first product to market, including supply-chain and other manufacturing challenges arising from the COVID-19 pandemic; uncertainty about receiving approval for an EUA from the FDA; challenges related to launching a new instrument system and COVID-19 test at the same time; and building and scaling complex manufacturing processes operated by third party contractors. Defendants contend, *inter alia*, that none of the statements challenged by plaintiffs were false or misleading when made, that plaintiffs have not pled fraud with particularity, and that many of the challenged statements are inactionable corporate optimism, forward-looking, or opinions.

BACKGROUND

I. Factual Background

Talis is a biotechnology company that was founded in 2010 to develop point-of-care ("POC") diagnostic tests for infectious diseases. CC ¶ 27.[1] Talis developed the Talis One System, a diagnostic platform comprised of (1) single-use test cartridges that prepare and store patient samples, (2) a box-shaped instrument that analyzes the samples, and (3) software. *Id.* ¶¶ 34-35; Defs' Request for Judicial Notice Ex. B at 2-3 (Excerpts from Talis's Final Amended Registration Statement on Form S-1/A, filed with the SEC on February 11, 2021).[2]

In 2018, Talis was developing rapid POC diagnostic tests for sexually transmitted infections ("STIs") such as chlamydia and gonorrhea. CC ¶ 28. After the onset of the COVID-19 pandemic in early 2020, Talis abandoned its original focus on STI testing, and by summer 2020 started to

[1] Talis was originally named SlipChip LLC. POC testing "refers to medical diagnostic testing that takes place at or near the time and place of patient care, rather than in a central laboratory." *Id.*

[2] As discussed *infra*, the Court grants defendants' request for consideration of this document as well as several others under the "incorporation by reference" doctrine.

develop a molecular test for COVID-19. *Id.* ¶¶ 28, 32.[3] Talis's COVID-19 test was slated to be the source of "[s]ubstantially all" of Talis's initial revenue. *Id.* ¶ 216.

A. IPO/Registration Statement

By late 2020, Talis was moving to conduct an IPO. Plaintiffs allege that defendants were motivated to do so because Talis was required to issue a "going concern" warning in October 2020. *Id.* ¶ 38. Talis's first draft registration statement, which was confidentially filed with the SEC on October 15, 2020, stated "Our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm on our financial statements as of and for the year ended December 31, 2019, included an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern." *Id.*[4]

Talis also sought to capitalize on a rapidly closing window to sell a new COVID-19 test before demand cooled due to the FDA's approval of the Pfizer and Moderna COVID-19 vaccines in December 2020, and before competing tests captured the market. *Id.* ¶ 40. Talis would need to persuade investors that its product provided fast, accurate, reliable results and could be manufactured at scale. *Id.* ¶¶ 35, 40-41.

Talis conducted its IPO on February 11, 2021. *Id.* ¶ 72. Shares of Talis common stock were offered at $16 per share, and the IPO raised $253.9 million. *Id.* Plaintiffs allege that the Registration Statement was false and misleading because (1) Talis was not capable of producing Talis One to scale; (2) the Talis One was non-functional due to design issues; and (3) Talis had botched its crucial application for an EUA from the FDA.

[3] The CC explains that there "are two basic types of COVID-19 diagnostic tests. Antigen tests (like those widely available at drugstores) detect specific viral proteins (antigens), but provide only a simple "yes" or "no" and sacrifice accuracy for speed. By contrast, molecular diagnostic tests amplify genetic material to detect viral nucleic acid (viral RNA), offering greater accuracy but generally lower speed than antigen tests." *Id.*

[4] Talis temporarily staved off its auditor's "going concern" warning by raising $126 million in private financing in November 2020. *Id.* ¶ 39.

1. Manufacturing Issues

When Talis pivoted from its original focus on STI testing to COVID-19 testing, it substantially accelerated its timeline for bringing Talis One to market. *Id.* ¶ 43. According to FE-1,[5] a former Talis R&D engineer who worked at Talis from August 2016 to March 2021, "had COVID not happened, the original cartridge for STI testing was slated to go into production in 2022." *Id.* Plaintiffs allege that Talis did not have a realistic timeline to manufacture the Talis One and that the process was plagued by production problems:

> 45. . . . FE-2—a senior scientist with a Ph.D. in molecular genetics—confirmed that Talis did not have a realistic timeline to manufacture its product, let alone bring it to market. Indeed, FE-2 explained that for much of the period when FE-2 worked at Talis (February to October 2020), Talis only had one person and a supporting technician working on the COVID-19 test, but was aggressively applying for grants. FE-2 described an amalgamation of incompetency at every level within the Company – marketing, alignment with R&D, and even creating a plan or timeline.
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> 46. Similarly, FE-3—an engineer who worked at Talis for over four years before the IPO—stated that Talis's timelines were overly aggressive, citing company culture as one of the drivers. When FE-3 mentioned concerns about the overly aggressive timelines to a scientific advisor on Talis's Board, the advisor responded that the aggressive timelines were "inspirational." FE-3 was infuriated and thought the timelines had no basis.
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> 47. In the view of FE-1, a senior mechanical R&D engineer, Talis management ignored many of the technical challenges with bringing the Talis One to market. FE-1 explained that all the engineering wasn't there, and the Talis One was a concept model. FE-1 further explained that to go from prototype to full production at volume—a 100-fold increase—was not possible at the time of the IPO.
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> 48. Overall, FE-1 said that the combination of manufacturing, design, and supply chain issues was like running without your pants pulled up all the way. In the second quarter of 2020, FE-1 raised flags, especially about an issue with leaking cartridges that only began to be fixed in December of 2020, after being known for a year. Management knew about the leaking cartridges, FE-1 stated, because Talis had conducted a user study and the feedback was given to all of management.
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> 49. FE-1 also highlighted Tony Cunningham, the senior director of supply chain starting in July 2020. Starting around August 2020, FE-1 spoke directly about supply issues to Cunningham, who reported to CFO Roger Moody, but Cunningham ignored and downplayed FE-1's concerns. FE-1 also explained that Talis's executive team knew what was being purchased and they knew the testing results.
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> 50. Talis was also significantly behind its internal deadlines shortly before the February 2021 IPO. FE-1 explained that Cunningham posted a weekly schedule of production that indicated a Q4 2020 goal of producing 1,000 instruments for beta

[5] The CC relies on five confidential witnesses who are former employees ("FE") of Talis.

> testing and to prove Talis's manufacturing capability, but Talis produced far fewer instruments in the quarter.
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> 51. FE-1—who was responsible for sourcing component vendors for Talis's cartridge manufacturing—indicated that it was not possible for Talis to produce 1 million cartridges per month. There was no contingency planning due to the company's fatal flaw of not building in a scheduling buffer to account for issues that might arise. FE-1 recalled that CEO Coe was notorious for not having any scheduling buffer, which failed to recognize that in the engineering and operations world, things happen.

Plaintiffs allege that the Registration Statement misleadingly stated that concrete steps toward production of the Talis One had been taken and were scheduled in 2021. For example, it stated that Talis had "ordered 5,000 instruments" to be delivered beginning in "the first quarter of 2021" and stated that "automated cartridge manufacturing lines capable of producing one million cartridges per month" were "scheduled to begin to come on-line in the first quarter of 2021" and expected to "scale to full capacity through 2021," a year earlier than the original STI project. *Id.* ¶ 153.

2. Design Issues

Plaintiffs allege that the Talis One suffered from serious design issues and a high invalid rate, meaning that the tests did not yield usable results. The CC alleges that these issues were known within the company before the IPO. For example,

> 53. According to FE-2, it was known well before the Company submitted its first EUA application that the test had a high invalid rate. FE-2 indicated that this should have been no surprise, as the Talis One was not developed with the biology in mind, and was developed by engineering without much input from the assay department that developed the biological testing.
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> 54. Specifically, FE-2 described poor communication between the engineering and assay teams, resulting in a lack of pretesting in the Talis One design and design issues such as the size of the cartridges. FE-2 indicated that the chamber sizes in the Talis One's cartridges were created without sufficient volume for proper Limits of Detection (the lowest concentration that a test can consistently identify with high probability) because some of the chambers were too small.

The CC alleges that notwithstanding these issues, the Registration Statement touted the Talis One as a "highly accurate" product with safety and convenience features, while advising that Talis's "diagnostic tests may contain errors or defects or be subject to reliability issues," omitting any mention of the high invalid rates already known to the company. *Id.* ¶¶ 158-62.

3. Emergency Use Authorization from FDA

Talis was required to obtain an EUA from the FDA before marketing or selling the Talis One COVID-19 test.[6] *Id.* ¶ 59. Obtaining and maintaining an EUA was also required under a contract Talis had received from the National Institutes of Health. *Id.* ¶ 60.[7]

Talis submitted its EUA application for "CLIA-moderate" authorization on January 29, 2021, shortly before the February 11, 2021 IPO. *Id.* ¶ 62; Defs' Ex. B at 39.[8] According to plaintiffs, "[b]y that time, the EUA process was well-established; the FDA had granted EUAs to other COVID-19 molecular diagnostic tests as early as April 2020, and authorized dozens of such tests by the end of the year." *Id.* ¶ 62. "The FDA's Molecular Diagnostic Template for Commercial Manufacturers (July 28, 2020) provided specific guidance to companies like Talis seeking EUAs. Applicants were required to submit various studies, some of which measure data about the percentages of specimens that the test correctly identifies as positive or negative relative to a prior test, known as a comparator assay." *Id.* ¶¶ 63-64. Because the testing is comparative in nature, the resulting data is only valid if the benchmark comparator assay is reliable. *Id.* ¶ 65. Due to the importance of the comparator assay, the FDA stated that applicants should use "only" a "high sensitivity" comparator assay. *Id.* ¶ 67. The CC cites the FDA's Molecular Diagnostic Template for Commercial Manufacturers (July 28, 2020), which stated:

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[6] Under Section 564 of the Federal Food, Drug and Cosmetic Act, the FDA "may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening disease." This provides medical device manufacturers with an expedited, less costly mechanism for obtaining marketing authorization for their products. The U.S. Department of Health and Human Services originally authorized the FDA to grant EUAs related to COVID-19 on February 4, 2020. CC ¶ 59 n.3.

[7] On July 31, 2020, Talis issued a press release titled "Talis Awarded NIH RADx Contract to Launch Talis One™ System for Point-of-Care COVID-19 Testing and Further Strengthens Financial Position and Leadership Team," announcing that Talis had been awarded a $25 million National Institutes of Health ("NIH") contract through the NIH's Rapid Acceleration of Diagnostics ("RADx") initiative (the "RADx Contract"). *Id.* ¶ 33.

[8] The Clinical Laboratory Improvement Amendments of 1988 ("CLIA") categorizes tests as waived, moderate complexity, or high complexity. Defs' Ex. B at 39. The Registration Statement stated that Talis's "regulatory strategy is to initially submit for the equivalent of CLIA-moderate authorization to be followed shortly thereafter with a subsequent filing for the equivalent of CLIA-waived authorization for use in non-laboratory settings." *Id.* at 18.

> a) "We recommend using only a high sensitivity EUA RT-PCR assay which uses a chemical lysis step followed by solid phase extraction of nucleic acid (e.g., silica bead extraction)."
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> b) "If available, FDA recommends selecting a comparator assay that has established high sensitivity with an internationally recognized standard or the FDA SARSCoV 2 Reference Panel. Please contact CDRH-EUA-Templates@fda.hhs.gov to discuss options to establish sensitivity."

Id. Plaintiffs do not allege that the FDA set additional criteria for what did or did not constitute a "high sensitivity" assay.

Plaintiffs allege that contrary to the FDA's guidance, "Talis used a weak comparator assay as a benchmark for its EUA submission." *Id.* ¶ 212(i) (citing FE-2).[9] However, the Registration Statement extensively touted positive information about the Talis One's testing and the EUA submission, stating that the Talis One had been tested against an "FDA-authorized"[10] comparator assay and that the Talis One displayed "high PPA and NPA [that] is suggestive of clinical sensitivity and specificity." *Id.* ¶ 69. The Registration Statement also stated that the "Talis One test results exactly matched the central lab results with 100% positive percentage agreement (PPA) and 100% negative percentage agreement (NPA) for detection of COVID-19," touted "the very low limits of detection possible on the Talis One platform," and claimed that the Talis One "demonstrated a limit of detection for SARS-CoV-2 of ≤500 viral particles per milliliter." *Id.* Plaintiffs do not claim that Talis misrepresented the test results, but rather that the submission "was deceptive because it compared the Talis One's performance to a useless benchmark." *Id.*

The Registration Statement also disclosed, under "Risk Factors," that during the FDA's "preliminary review" of Talis's EUA submission, the FDA asked Talis to "provide it with additional information" regarding Talis's test "prior to initiating its substantive review," and that Talis expected to "promptly provide" that information. *Id.* ¶ 70.

4. Risk Disclosures

Talis's Offering Documents contained numerous risk disclosures. Defs' Ex. B at 9-10

[9] FE-2 worked at Talis as a senior scientist on infectious disease diagnostics and assay development from February 2020 to October 2020. *Id.* ¶¶ 68, 212.

[10] Plaintiffs do not allege that the comparator assay was not FDA-authorized.

("Summary of Risk Factors"); *id*. at 18-41 ("Risk Factors"). These included:

- "There can be no assurance that the COVID-19 test we are developing for the detection of the SARS-CoV-2 virus will be granted an Emergency Use Authorization by the U.S. Food and Drug Administration. . . . if we do not receive an EUA for our Talis One platform with COVID-19 test, the commercial launch of such products could be significantly delayed, which would adversely impact our business[.]" *Id.* at 18.
- "We have no products approved for commercial sale. We have no or limited experience in developing, marketing and commercializing diagnostic platforms and tests, and we are continuing to evaluate the sales model for the Talis One platform which may make it difficult to evaluate the success of our business and to assess our future viability." *Id*. at 22.
- "We rely, and expect to continue to rely, on third parties for the manufacture of the Talis One platform and our tests, as well as for commercial supply . . . . This reliance exposes us to significant risk that we will not have sufficient quantities of our products at an acceptable cost or quality, which could delay, prevent or impair our clinical trials and commercialization efforts." *Id.* at 20.
- "[T]he [automated cartridge assembly] lines are not complete and could incur substantial delays, costs and may not perform as anticipated, and any failure to perform as anticipated could require us to make significant capital expenditures to make adjustments. Any such delays or required expenditures could prevent us from launching our Talis One platform with COVID-19 test[.]" *Id.*
- "In order to commercialize our products . . . we will need to manufacture them in large quantities. We, or our manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our products in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities." *Id.* at 22.
- "There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our product deliveries increase[.]" *Id.* at 25.
- "Our products use a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. For example, the Talis

One platform . . . may contain undetected errors or defects when first introduced[.]" *Id.*

- "Our diagnostic tests may contain errors or defects or be subject to reliability issues, and while we have made efforts to test them extensively, we cannot assure that our current diagnostic tests . . . will not have performance problems. An operational, technological or other failure in one of these complex processes or fluctuations in external variables may result in sensitivity or specificity rates that are lower than we anticipate . . . or they may cause our products to malfunction." *Id.* at 25-26.

B. Withdrawal of Initial EUA Application and Second EUA Application

Talis' IPO was conducted on February 11, 2021. On March 8, 2021, Talis issued a press release disclosing that in late February, the FDA had informed the company that it "[could not] ensure the comparator assay used in [Talis's] primary study has sufficient sensitivity to support Talis's EUA application." CC ¶ 75. The press release also announced that Talis had withdrawn its initial EUA application for CLIA-moderate classification and would focus on a new EUA for its previously planned CLIA-waived setting. *Id*. The press release also stated that "Talis intends to initiate its previously planned clinical validation study in a point-of-care environment, with plans to submit an EUA application . . . early in the second quarter of 2021" and "[t]he planned clinical validation study was designed with a different comparator assay, which Talis believes will address the FDA's concerns." *Id.* Plaintiffs allege that this news drove a 12.3% decline in Talis's share price, to $12.85 per share. *Id*. ¶ 76.

On July 23, 2021, Talis submitted a second EUA application. Defs' Ex. H at 5. On an investor call held August 10, 2021, Talis reported that the data from its clinical validation study in support of the EUA application "exceed[ed] the FDA's guidance for 95% concordance with the comparator test results, including both the positive and negative percent agreements." Defs' Ex. J at 4. Plaintiffs do not challenge any statements made by Talis regarding this second EUA application.

On November 8, 2021, Talis announced that the FDA had approved its EUA. CC ¶ 102.

C. Post-IPO

Plaintiffs' Exchange Act claims are based on a number of statements that Talis and senior management made to investors between March 30, 2021 and March 15, 2022. Plaintiffs claim that throughout this period, Talis's senior management continued to mislead the market by touting Talis's progress towards manufacturing at scale and "terrific" results, when in reality Talis was not ready to begin manufacturing and the Talis One continued to suffer from design issues and a high invalid rate.

For example, plaintiffs challenge as false then-CEO Coe's answer during a May 11, 2021 earnings call to an analyst's question asking "hypothetically, after [FDA approval of the EUA], how soon can you ship the product out to customers?" CC ¶ 190. Coe responded, "We feel we'll be in a position to ship product in a very timely manner following an approval. We're certainly spending quite an effort on commercial preparedness. And as we've already commented as well, we have a commercial team in place. And we feel very much ready to go on our end." *Id.* Plaintiffs allege that Coe's May 2021 claim that Talis was "ready to go" into production upon receiving an EUA had no basis because Coe "knew there were serious issues with the manufacturing timelines for the Talis One, as FE-3 [who was working on the design of cartridges for testing] had briefed Coe on the topic over several weeks in May 2021." CC ¶ 213(ii). In addition, FE-1, who also worked on the cartridge until his/her departure in March 2021, "recalled a rumor that in or around May 2021, then SVP-of R&D Ramesh Ramakrishnan had provided a new timeline to Coe, who rejected it; Ramakrishnan resigned within days." CC ¶¶ 90; 211(vi).

On August 10, 2021, Talis reported its second quarter earnings and senior management held an earnings call with investors. Coe discussed Talis's recent submission of its second EUA application and stated that "we cannot predict the FDA's timing for authorization, and we still need to finalize validation of our automation lines," and "our development timelines have been extended by delays in the launching of our COVID-19 test and manufacturing scale." CC ¶ 92; Defs' Ex. J at 4-5. Coe announced that Talis would be executing a "controlled launch, beginning with target customers to evaluate Talis One followed by a broader market launch," and COO Liu stated that "[d]uring the second quarter, we modified and improved the first set of automated lines . . . At this

time, we have completed installation and are in the final stages of validation. . . . We are making final adjustments and expect to have the cartridges from these lines for commercial launch upon receiving our EUA." Defs' Ex. J at 5-6. Liu also announced that while they were "pleased" with the progress on manufacturing, "we have decided to take a phased approach similar to our commercial launch for implementing the second and third sets of automation lines in order to ensure that our first line provides customers with exceptional product quality and to align production with sales [and] [w]e will prepare and deploy additional lines as needed." *Id*. at 6.

Plaintiffs claim that defendants sought to blunt this negative information with misleading affirmations of progress. In response to an analyst's question asking "what can you say to give us confidence that the longer-term opportunity is there?", Coe responded "[Y]es, the timelines are later than we'd anticipated in the IPO model. And on the other hand, our results really look terrific. From a company perspective, we're way ahead on our ability to produce product relative to almost any company our size historically." CC ¶ 94. Plaintiffs allege that Talis did not have "terrific" results and was not "way ahead" because the Talis One continued to suffer from a high invalid rate that foreclosed and/or dramatically delayed commercial production.

Plaintiffs also allege that the statements about the automated cartridge lines being in the "final stages of validation"[11] were false and misleading because "in the medical device industry, 'validation' is a technical term that indicates an extensive degree of scrutiny such that a successful result is practically assured." *Id*. ¶ 97. Plaintiffs allege that Talis was nowhere near the "final stages of validation" on the automated cartridge manufacturing lines in August 2021 because Talis later admitted (at a March 15, 2022 earnings call, discussed *infra*) that Talis was "beginning to evaluate the performance of cartridges" in November 2021. *Id*. ¶ 110. Plaintiffs also cite FE-5, an associate director of technical implementation based in Dallas from September 2021 until March 2022, who "explained that Talis had not validated its production lines, which was significant and one of the major factors in not launching the Talis One" *Id*. ¶ 215(iii).

On August 30, 2021, Talis announced that CEO Coe had "stepped down" effective

[11] The 2Q21 quarterly report also stated that Talis was in the "final stages of validation for the first set of automated cartridge production lines." *Id*. ¶ 96.

immediately. *Id.* ¶ 101. Plaintiffs allege that "Coe's unplanned departure just six months after the IPO signaled that Talis's production problems and delays were potentially much more serious than Defendants' public statements had revealed." *Id.*

On November 15, 2021, one week after announcing that the FDA had approved Talis's second EUA application, Talis filed a Form 8-K with the SEC and announced that Brian Blaser had been appointed as President, CEO and Director of Talis, effective December 1, 2021. *Id.* ¶ 103. At an earnings call the same day, Interim CEO Popovits stated that Talis would execute a "controlled product rollout" using a "measured approach." *Id.* ¶ 104. Chief Commercial Officer Rob Kelley reiterated that Talis had "decided to take a phased approach for rolling out the Talis One System" with a "limited rollout" to being "in the first quarter of 2022" that would involve "a small number of sites representative of the customers we are targeting . . . ." *Id.* Plaintiffs allege that this delayed timeline and small-scale commercial introduction was a recognition that Talis was unprepared and unable to manufacture the Talis One at scale. *Id.* Plaintiffs allege that at this time, the Talis One "was little more than a 'dummy box' that sales representatives were instructed not to turn on in meetings at doctors' offices and hospitals." *Id.* ¶ 214(iv).

On December 1, 2021, Brian Blaser replaced Coe as CEO. *Id.* ¶ 105. On December 8, 2021, Talis announced that Blaser had "stepped down" from his positions as President, CEO and Director effective immediately. *Id.* Plaintiffs allege, "While Talis publicly claimed that Blaser's departure was due to 'personal matters,' FE-4 later learned from a contact at another company that Blaser left Talis because there was major fraud." *Id.*

The Exchange Act class period ends on March 15, 2022, when Talis reported "a barrage of new, negative information" in its first financial reporting under its new CEO Rob Kelley. *Id.* ¶ 106. On that day, Talis revealed that it "has not started its phased launch of the Talis One COVID-19 Test System due to challenges with manufacturing" and that the company "has engaged in a manufacturing review process to determine appropriate next steps and undertaken initiatives to align resources and preserve cash." *Id.* ¶ 107. Talis's Form 10-K also stated that Talis had "ordered components for up to 5,000 instruments from our instrument contract manufacturing partners," which plaintiffs claim is a "materially different truth" from Talis's previous statements about having

ordered "5,000 instruments." *Id.* ¶ 111. Talis further disclosed that the company had engaged external consultants "to assess product design for manufacturing at scale, evaluate current processes and partners, and determine appropriate next steps and timing for bringing the Talis One system to market," that the company was laying off approximately 25 percent of its workforce, and that COO Liu was stepping down. *Id.* ¶ 112

At a conference call held the same day, CEO Kelley admitted that "the yield and consistency of our current manufacturing process is not yet sufficient to support commercialization" and that "our current process is not yet optimized to produce a minimum monthly yield [of instruments] to support a commercial launch." *Id.* ¶ 108. Kelley also stated that "the rate of invalid or failed tests remains higher than what we believe is acceptable"; plaintiffs allege that Kelley misleadingly implied that this was a recent development where, "[i]n reality, the high invalid rates had plagued the device since before the IPO (FE-2) and continued thereafter (FE-4, FE-5)." *Id.* ¶ 109. Plaintiffs also allege that Kelley conceded that Talis had not been in the "final stages of validation" of Talis's cartridge production in August 2021 when he said, during the March 15, 2022 conference call, "When we spoke with you back in November, we were beginning to evaluate the performance of cartridges coming off our high-yield lines." *Id.* ¶ 110.

On May 10, 2022, CEO Kelley stated during an earnings call that the company did not expect the Talis One to make a "significant revenue contribution " in 2022. *Id.* ¶ 114. Plaintiffs allege that "after 18 months of false promises with no commercially available product, the market has essentially given up on Talis as a viable company." *Id.* ¶ 117. As of June 2022, Talis common stock traded at $0.81 per share. *Id.* ¶ 118.

II. This Consolidated Class Action

In January and February of 2022, two putative class actions were filed against Talis and the individual defendants.[12] In June 2022, those cases were consolidated into the present action, and on July 1, 2022, plaintiffs filed the CC. Plaintiffs bring claims under: (1) the Securities Act of 1933

[12] One of the complaints named additional defendants who have not been named in the CC.

(the "Securities Act"), 15 U.S.C. § 77 *et seq*, on behalf of all persons and entities that purchased or otherwise acquired common stock issued by Talis pursuant and/or traceable to the Registration Statement issued in connection with the Company's February 2021 initial public offering; and (2) the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. § 78 *et seq*., on behalf of all persons and entities who purchased or otherwise acquired Talis common stock between March 30, 2021 and March 15, 2022, both inclusive.

Plaintiffs allege violations of Sections 11 and 15 of the Securities Act, 15 U.S.C. § 77k, against Talis and nine individuals who signed the Registration Statement: Brian Coe (co-founder, former CEO, President and member of the Board); CFO Roger Moody; and current and former members of the Board of Directors (Rustem Ismagliov, Felix Baker, Raymond Cheong, Melissa Gilliam, Kimberly Popovits, Matthew Posard, Randal Scott) ("Securities Act defendants"). Plaintiffs allege that Talis, as the issuer, is strictly liable under the Securities Act, and that the individual defendants – who are "experienced medical diagnostics investors, executives, and scientists" – are liable because they acted negligently and failed to perform any reasonable investigation before the offering. CC ¶ 169. Plaintiffs allege that the Securities Act defendants are liable for issuing materially false or misleading statements and/or failing to disclose material facts concerning the testing performed on the Talis One and the data submitted to the FDA; Talis's ability to manufacture the Talis One at commercial scale, including a false claim that Talis had ordered 5,000 instruments before the IPO; and the performance, reliability, safety, and convenience of the Talis One. In addition, plaintiffs allege that the Registration Statement omitted material information about known uncertainties and specific risks in violation of Items 105 and 303 of SEC Regulation S-K. Plaintiffs further allege violations of Section 15 of the Securities Act, 15 U.S.C. § 77o, against the individual Securities Act defendants in their roles as control persons of Talis.

Plaintiffs allege violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), against Talis, Coe, Moody and current CEO Rob Kelley. They allege that these defendants acted knowingly or were deliberately reckless in making false and misleading statements regarding the progress, production levels, and validation of the Talis One cartridge manufacturing lines; Talis's ability to ship the Talis One promptly following FDA approval; the quality of results; the reasons for Talis

adopting a "phased approach" to launching the Talis One; and Talis's purported order of 5,000 Talis One "instruments." Plaintiffs also allege violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), against defendants Coe, Moody and Kelley by virtue of their role as control persons of Talis.

LEGAL STANDARD

To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). This "facial plausibility" standard requires the plaintiff to allege facts that add up to "more than a sheer possibility that a Defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While courts do not require "heightened fact pleading of specifics," a plaintiff must allege facts sufficient to "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555, 570. "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.' " *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.' " *Id*. (quoting *Twombly*, 550 U.S. at 557). "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." *Id*. at 679.

In reviewing a Rule 12(b)(6) motion, a district court must accept as true all facts alleged in the complaint, and draw all reasonable inferences in favor of the plaintiff. *See al-Kidd v. Ashcroft*, 580 F.3d 949, 956 (9th Cir. 2009). However, a district court is not required to accept as true "allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *In re Gilead Scis. Sec. Litig*., 536 F.3d 1049, 1055 (9th Cir. 2008).

As a general rule, the Court may not consider any materials beyond the pleadings when ruling on a Rule 12(b)(6) motion. *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001). However, the Private Securities Litigation Reform Act ("PSLRA") permits courts considering a motion to dismiss governed by the PSLRA to consider "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd*., 551 U.S. 308, 322 (2007).

If the Court dismisses a complaint, it must decide whether to grant leave to amend. The Ninth Circuit has "repeatedly held that a district court should grant leave to amend even if no request to amend the pleading was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." *Lopez v. Smith*, 203 F.3d 1122, 1130 (9th Cir. 2000) (citations and internal quotation marks omitted).

DISCUSSION

I. Requests for Incorporation by Reference

The "incorporation-by-reference doctrine is a judicially created doctrine that treats certain documents as though they are part of the complaint itself." *Khoja v. Orexigen Therapeutics, Inc*., 899 F.3d 988, 1002 (9th Cir. 2018). A document may be incorporated into a complaint "if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *Id.* at 1002 (quoting *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003)). Courts have not set a bright line for what constitutes "sufficiently extensive under *Ritchie*." *Khoja*, 899 F.3d at 1003. While brief reference in a footnote that "convey[ed] only basic historic facts" did not incorporate a document by reference, a "single reference" "may be sufficiently 'extensive' if [it] is relatively lengthy." *Id*. The incorporation-by-reference doctrine is designed to prevent plaintiffs from selectively citing "only portions of documents that support their claims, while omitting portions of those very documents that weaken—or doom—their claims." *Id*. A court may generally assume the contents of a document incorporated by reference "are true for purposes of a motion to dismiss under Rule 12(b)(6)." *Id*. However, "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*.

Defendants request consideration of twenty documents consisting of SEC filings, earnings call transcripts, analyst reports, and press releases. Kirby Decl. Ex. A-T (Dkt. No. 83). The Court finds it is appropriate to consider the SEC filings and the earnings call transcripts, as the CC quotes extensively from all of these materials and because plaintiffs challenge various statements within these documents as false or misleading, but the CC often does not contain the surrounding context of the statements at issue and/or omits cautionary language contained in those materials.

Accordingly, the Court GRANTS defendants' request for consideration of Exhibits B, C, D, E, F, G, H, I, J, L, M, O, P, and Q on the ground that those documents have been incorporated by reference in the CC.

The Court DENIES the requests for consideration of the balance of defendants' exhibits. These documents are only briefly referenced in the CC, consideration of the documents would not add anything to the Court's review of the present motion, and/or the Court cannot consider the documents for the reasons sought by defendants. For example, defendants' Exhibit K is a press release announcing the departure of defendant Coe as CEO. Coe's "termination" is mentioned in CC ¶ 16, and the press release is quoted in one paragraph of the CC (¶ 101: quoting press release as saying that Coe had "stepped down"). Defendants assert that the Court should consider Exhibit K because plaintiffs allege that Coe was terminated, while the press release states that Coe "stepped down." Defendants also argue that Exhibit K forms the basis of plaintiffs' claims of fraud because plaintiffs rely on the executive departures as evidence of fraud. The Court finds that the CC does not quote extensively from the press release and therefore is not "sufficiently extensive under *Ritchie*." *Khoja*, 899 F.3d at 1003. Further, while executive departures do form part of the basis of plaintiffs' claims, the claims do not turn on what Talis said in this press release. *Id*. Finally, to the extent defendants wish to make the point that the press release stated that Coe "stepped down" and not "terminated," that language is quoted in Paragraph 101.

The Court notes that defendants' request for consideration of certain documents prompted plaintiffs to seek consideration of eight documents "to provide context to the arguments made in Defendants' motion to dismiss . . . and to provide a complete picture in light of the twenty documents subject to Defendants' request for judicial notice." Pls' Request for Judicial Notice at 2 (Dkt. No. 90). The Court discourages the "[t]he overuse and improper application of judicial notice and the incorporation-by-reference doctrine" and advises the parties to be judicious with regard to any future requests for judicial notice in connection with motions to dismiss. *Khoja*, 899 F.3d at 998.

The Court DENIES plaintiffs' request for judicial notice. The asserted relevancy of some of the documents has been mooted by the Court's denial of defendants' request for judicial notice of certain documents. For example, plaintiffs' Exhibit D is a separation and consulting agreement

between Coe and Talis, which plaintiffs asserted was relevant to rebut defendants' Exhibit K; plaintiffs and defendants ask the Court to draw different and disputed inferences from these documents that are inappropriate at this stage of the litigation. Other documents post-date the filing of the CC, and other documents could have been, but were not, quoted in the CC. "It is difficult to understand how documents not referenced in a complaint and on which the allegations of the complaint do not necessarily rely can be relevant to the Court's determination." *In re Calpine Corp. Sec. Litig.*, 288 F. Supp. 2d 1054, 1076-77 (N.D. Cal. 2003).

II. Securities Act Claims

"[S]ection 11 of the 1933 Securities Act creates a private remedy for any purchaser of a security if 'any part of the registration statement, when such part became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading.'" *In re Daou Sys., Inc.*, 411 F.3d 1006, 1027 (9th Cir. 2005) (quoting 15 U.S.C. § 77k(a)). Section 11 "require[s] a plaintiff adequately to allege a material misrepresentation or omission." *In re Stac Electronics Secs. Litig.*, 89 F.3d 1399, 1403 (9th Cir. 1996) (citation, internal quotation marks, and alteration omitted). "The plaintiff in a § 11 claim must demonstrate (1) that the registration statement contained an omission or misrepresentation, and (2) that the omission or misrepresentation was material, that is, it would have misled a reasonable investor about the nature of his or her investment." *Id.* "No scienter is required for liability under § 11; defendants will be liable for innocent or negligent material misstatements or omissions." *Id.* at 1404. To state a claim under Section 11, plaintiffs must show that the challenged statement was false at the time of the offering and "cannot use the benefit of 20-20 hindsight to turn management's business judgment into securities fraud." *In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407, 1419 (9th Cir. 1994).

The parties disagree on whether plaintiffs' Section 11 claims sound in fraud, and thus whether a heightened pleading standard applies. "Although section 11 does not contain an element of fraud, a plaintiff may nonetheless be subject to Rule 9(b)'s particularity mandate if his complaint 'sounds in fraud.'" *Daou*, 411 F.3d at 1027. Defendants argue that the Section 11 claim sounds in

fraud because the Section 11 and Section 10(b) claims rely on the same factual allegations and plaintiffs describe the entire course of conduct in fraudulent terms, such as "adverse facts were concealed in the Registration Statement." CC ¶ 6. Plaintiffs counter that Section 11 imposes liability for material omissions and "misleading" statements, and they argue that the Section 11 claims are based on different statements made at different times than the Section 10(b) claims.

The Court finds it unnecessary to resolve this issue at this time because the Court agrees with defendants that plaintiffs' Section 11 allegations do not meet Rule 8 as explicated in *Iqbal* and *Twombly*. For the most part, the allegations in support of falsity are based on FE allegations that are conclusory, state opinions without factual support, sometimes based on vague hearsay and rumors, and are often vague or silent as to time period, and thus plaintiffs have not alleged facts showing that the challenged statements were false or misleading at the time of the IPO. In addition, the Court concludes that many of the challenged statements appear to be protected by the bespeaks caution doctrine, as the Registration Statement contained fulsome risk disclosures. When amending, the Court encourages plaintiffs to add as much specificity as possible to cure the defects identified in this order and to show that the challenged statements were false or misleading when made (particularly since plaintiffs rely on the same FE allegations for both the Section 11 and 10(b) claims).

A. "Ordered 5,000 Instruments" CC ¶ 155

Plaintiffs challenge the statement that "We have ordered 5,000 instruments from our instrument contract manufacturing partners to be delivered beginning in the fourth quarter of 2020 through the first quarter of 2021." CC ¶ 155; *see also* Defs' Ex. B at 118 (Registration Statement). Plaintiffs allege that this statement was materially false and misleading when made "because it indicated that (a) Talis had ordered 5,000 instruments, and (b) the 5,000 instruments would be delivered between the fourth quarter of 2020 and the first quarter of 2021." CC ¶ 156. Plaintiffs allege that "[b]oth aspects of the statement were false" because Talis's Form 10-K filed on March 15, 2022, admitted that it had ordered "components for up to 5,000 instruments," not the completed instruments themselves, and Talis's Form 10-K filed on March 30, 2021 stated that Talis had

"ordered 5,000 instruments from our manufacturing partners to be delivered through the third quarter of 2021" – two quarters after the Registration Statement claimed. *Id.*

Defendants contend that plaintiffs have failed to allege affirmative falsity because the statement about ordering "5,000 instruments" is not "directly contradicted" by ordering instrument components, and the statement "5,000 instruments" is not misleading in light of the disclosures in the Registration Statement that Talis worked with a third party to manufacture and assemble its instruments. With regard to the portion of the statement about timing of delivery, defendants argue that plaintiffs do not allege facts showing that the statement was false when made – that Talis had not actually ordered instruments "to be delivered beginning in the fourth quarter of 2020 through the first quarter of 2021," or that delivery had not begun during that time period, and the fact that Talis later stated that instruments would be "delivered through the third quarter of 2021" does not mean that the earlier statement was false when made.

The Court finds that plaintiffs have not sufficiently alleged why "We have ordered 5,000 instruments from our instrument contract manufacturing partners to be delivered beginning in the fourth quarter of 2020 through the first quarter of 2021" is false or misleading. Plaintiffs do not allege, for example, that Talis had not actually "ordered" 5,000 instruments (or components), but they contend it is false or misleading to say "instruments" versus "components for instruments." However, the Registration Statement disclosed that "Our products are manufactured by several third parties, including a single contract manufacturer that provisions the parts and assembles our instrument. The instrument assembly is largely manual with some automation in testing. Our instrument contract manufacturer is scaling up to be able to make up to 500 instruments per week." Defs' Ex. B at 135. Thus, Talis disclosed that a third party manufacturer provisioned the parts and assembled the instruments, that the assembly was "largely manual," and that the manufacturer was "scaling up" to be able to make up to 500 instruments per week. Given these disclosures, plaintiffs have not adequately alleged why stating that Talis was ordering "instruments" rather than "components for instruments" was false or misleading.

Plaintiffs also have not alleged facts showing that the statement that Talis had ordered instruments "to be delivered beginning in the fourth quarter of 2020 through the first quarter of

2021" was false when made. Plaintiffs speculate that the statement was false because Talis later stated that it had ordered instruments "to be delivered through the third quarter of 2021." But plaintiffs do not allege, for example, that Talis either knew that delivery could not begin in the fourth quarter of 2020 through the first quarter or 2021, or that that the order for delivery was actually for a later time. It is not inconsistent to say that instruments had been ordered "to be delivered beginning in the fourth quarter of 2020 through the first quarter of 2021" and to later state that instruments had been ordered "to be delivered through the third quarter of 2021" – particularly when the Registration Statement contained numerous disclosures about the instrument manufacturing process. Without more, plaintiffs cannot rely on the later statement to show that the Registration Statement was false.

B. Manufacturing Statements CC ¶ 153

Plaintiffs challenge the following two statements regarding Talis's manufacturing capability (with the allegedly false or misleading portions bolded):

- "To support our anticipated commercial launch of our COVID-19 test, we have invested in automated cartridge manufacturing lines capable of producing one million cartridges per month, which are scheduled to begin to come on-line in the first quarter of 2021 and we expect **will scale to full capacity through 2021**." CC ¶ 153.
- "*Low cost to manufacture*—We designed the Talis One platform to be **low-cost** and **manufactured at scale**." *Id.*

Plaintiffs allege that these statements were false and misleading because (1) "Talis had no basis to claim that cartridge production 'will scale to full capacity' of 'one million cartridges per month' in 2021" because "production at that scale in 2021 was not possible"; and (2) these statements were misleading because "the Registration Statement omitted the facts that (a) Talis did not have a realistic timeline for production and could not produce one million cartridges per month; (b) Talis was already significantly behind its internal deadlines for beta testing; and (c) the Talis One suffered from design issues and high invalid rates that foreclosed and/or dramatically delayed commercial production." *Id.* ¶ 154. Plaintiffs also contend that the second statement was false and misleading given Talis's existing design problems and inability to perform "low cost"

manufacturing "at scale."

As support, plaintiffs cite FE-1 and FE-4. Opp'n at 12 (citing CC ¶¶ 51 (FE-1) & 214(iii) (FE-4)). FE-1, a senior mechanical R&D engineer, worked at Talis from August 2016 until March 2021, and was responsible for sourcing component vendors for Talis's cartridge manufacturing. *Id.* ¶¶ 51, 211. The CC alleges that FE-1 "indicated that it was not possible for Talis to produce 1 million cartridges per month. There was no contingency planning because of the company's fatal flaw of not building in a scheduling buffer to account for issues that might arise. FE-1 recalled that CEO Coe was notorious for not having any scheduling buffer, which failed to recognize that in the engineering and operations world, things happen." CC ¶ 51.

FE-4 was a territory account manager at Talis and oversaw the western region from February 1, 2021 to March 15, 2022. FE-4 was based in San Diego and was one of the first members of Talis's salesforce. According to FE-4,

> (iii) Excuses for repeated delays: FE-4 received various excuses as to why the Talis One COVID-19 test had not launched. Initially, FE-4 was told that the launch would happen in April 2021. FE-4 was then told that there was a delay because the FDA wanted Talis to redo its product testing due to the comparator assay issue. In or around April 2021, FE-4 was told it was expensive and difficult to manufacture the machines, which had to be made by hand, and that Talis did not have a manufacturer at full scale.

Id. ¶ 214(iii).

Defendants contend that plaintiffs have failed to allege falsity because plaintiffs have not alleged facts showing that the statements about expecting to scale to full capacity and manufacturing to scale were false when made. Defendants argue that the FE-1 allegations are conclusory, many are opinions without a stated factual basis, and that the allegations are often silent as to timeframe. With regard to FE-4's allegation about manufacturing (which was cited in plaintiffs' opposition but not in the CC as a reason why the statements were misleading), defendants contend that an allegation that FE-4 was told in April 2021 that it was expensive and difficult to manufacture the machines (instruments) is irrelevant to cartridge manufacturing, and the fact that Talis did not have a manufacturer at full scale in April 2021 does not contradict a statement about the Talis One platform being designed to be low cost and manufactured at scale.

Defendants also argue that the bespeaks caution doctrine protects statements about when the

lines were "expected" to scale in the future because the Registration Statement contains "enough cautionary language . . . that reasonable minds could not disagree [the statement was] not misleading." *In re Stac Elec..*, 89 F.3d at 1409. Defendants highlight the warnings that the cartridge lines "are not complete and could incur substantial delays . . . and may not perform as anticipated" and that Talis or its manufacturing partners "may be unable to successfully increase the manufacturing capacity for any of [Talis's] products in a timely or cost-effective manner, or at all." Defs' Ex. B at 20, 22.

The Court concludes that plaintiffs have failed to sufficiently allege that the statements were false or misleading when made, and that absent any such allegations, the challenged statements would be protected by the bespeaks caution doctrine. In the first statement – "To support our anticipated commercial launch of our COVID-19 test, we have invested in automated cartridge manufacturing lines capable of producing one million cartridges per month, which are scheduled to begin to come on-line in the first quarter of 2021 and *we expect will scale to full capacity through 2021*" – plaintiffs allege that only the last italicized portion is false; plaintiffs do not allege that Talis had not invested in automated cartridge manufacturing lines capable of producing one million cartridges per month, or that those lines were not scheduled to begin to come on-line in the first quarter of 2021. Thus, the alleged falsity is about whether Talis reasonably expected the cartridge manufacturing lines to scale to full capacity through 2021.

The FE-1 allegations are conclusory and lack any specific facts about why, at the time of the Registration Statement, it was not reasonable for Talis to expect that the cartridge manufacturing lines would scale to full capacity through 2021. Plaintiffs allege that FE-1 "indicated that it was not possible for Talis to produce 1 million cartridges per month." The CC does not say what timeframe FE-1 was referring to, nor does FE-1 provide a basis for this opinion other than to mention a lack of "contingency planning" and "scheduling buffer."[13] Alleging that CEO Coe was "notorious" for not

[13] Other statements attributed to FE-1, such as "all the engineering wasn't there" and "The combination of manufacturing, design, and supply chain issues was like running without your pants pulled up all the way" are vague and lack any meaningful detail. *See* CC ¶ 211. FE-1 also stated that there was a problem with leaking cartridges that management worked to fix in December 2020, *id.*; without more – such as allegations that the problems with leaking cartridges were widespread and persisted – a statement that leaking cartridges had been an issue and that management began to

having a scheduling buffer supports an inference that Coe was aggressive in setting timelines, rather than an inference that statements about projected timelines were false when made. *See Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1194 (9th Cir. 2021) ("Plaintiffs rely on allegations that two employees told Musk in 2016 that the goal of producing 5,000 cars per week by the end of 2017 was impossible to achieve, but the district court correctly held that Plaintiffs failed to plead any facts showing that Musk ever accepted those employees' views that the goal was impossible. In particular, the district court properly held that Plaintiffs had failed to plead facts showing that Defendants adopted the conservative timeline for production on which these employees' pessimism was based.").

FE-4's allegations also do not demonstrate that statements were false or misleading when made. FE-4's allegations do not relate to manufacturing of the cartridges and thus are irrelevant to the first statement. Regarding the second statement, FE-4 stating that he/she was told in April 2021 by an unidentified person that delays in launching the Talis One were due to it being expensive to manufacture the instruments, which had to be made by hand, and that there was not a manufacturer at full scale does not render false the statement that "We *designed* the Talis One platform *to be* low cost and manufactured at scale." The Registration Statement did not say that the Talis One platform was currently low cost and manufactured at scale, and to the contrary, the Registration Statement contained lengthy disclosures about the manufacturing risks. In addition to the disclosures mentioned *supra* about the instrument manufacturing being done by hand and by a third party manufacturer, the following is a partial excerpt from the disclosures:

> ***We contract with a significant number of third parties for the manufacturing and supply of products, which supply may become limited or interrupted or may not be of satisfactory quality and quantity***.
>
> We do not have any commercial-scale manufacturing facilities. We rely, and expect to continue to rely, on third parties for the manufacture of the Talis One platform and our tests, as well as for commercial supply if any of our products are authorized for marketing. This reliance exposes us to significant risk that we will not have sufficient quantities of our products at an acceptable cost or quality, which could delay, prevent or impair our clinical trials and commercialization efforts. The manufacturing of our Talis One instrument and cartridge involves over 500 raw materials, intermediates and subassemblies. While we do not have any commercial-scale manufacturing facilities, we have invested in the development of multiple automated assembly lines

address those issues in December 2020 does not render false a February 2021 statement about expecting to manufacture to scale to full capacity through 2021.

> for production of the test cartridges. The automated lines are required to meet the near-term volume commercial needs for the Talis One platform if we receive an EUA for our COVID-19 test. However, the lines are not complete and could incur substantial delays, costs, and may not perform as anticipated, and any failure to perform as anticipated could require us to make significant capital expenditures to make adjustments. Any such delays or required expenditures could prevent us from launching our Talis One platform with COVID-19 test if we receive marketing authorization, which would adversely impact our business, financial condition, and results of operations. The effects of any such delays would also be exacerbated if the demand for COVID-19 tests declines prior to our assembly lines becoming fully operational at scale.

Defs' Ex. B at 20. In light of these and other disclosures, plaintiffs fail to show how the statement that "We designed the Talis One platform to be low cost and manufactured at scale" was false or misleading when made.

C. Performance and Reliability CC ¶¶ 158, 160

Plaintiffs challenge three statements about the design and performance of Talis's COVID-19 test: (1) "The test cartridge for COVID-19 diagnosis contains a NAAT [nucleic acid amplification test] designed for optimal sensitivity and specificity to provide highly accurate results." CC ¶ 158; (2) "An important factor in our ability to commercialize our products is collecting data that supports the value proposition of our products, and in particular that our tests are just as accurate and reliable as central lab testing." *Id.*; and (3) "There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue as our product deliveries increase and our product portfolio expands." *Id.* ¶ 160. Plaintiffs claim that these statements are misleading because defendants did not disclose that the Talis One was neither accurate nor reliable due to its flawed design and high invalid rate.

As support, plaintiffs rely on FE-2, FE-4 and FE-5. Opp'n at 14 (citing CC ¶¶ 53, 55-57). FE-2 worked at Talis as a senior scientist at Talis from February 2020 to October 2020, and with the advent of COVID-19, FE-2 shifted focus to working on a COVID-19 test kit as well as the Talis One test platform. CC ¶ 212. FE-4, mentioned earlier, was a territory account manager who worked at Talis from February 2021 until March 2022. FE-5 was an associate director of technical implementation who ran a team of five technical support specialists focused on the development of process and procedures for the Talis One launch. *Id.* ¶ 215. FE-5 worked at Talis from September

2021 to March 2022. The CC alleges,

> 53. According to FE-2, it was known well before the Company submitted its first EUA application that the test had a high invalid rate. FE-2 indicated that this should have been no surprise, as the Talis One was not developed with the biology in mind, and was developed by engineering without much input from the assay department that developed the biological testing.
>
> 54. Specifically, FE-2 described poor communication between the engineering and assay teams, resulting in a lack of pretesting in the Talis One design and design issues such as the size of the cartridges. FE-2 indicated that the chamber sizes in the Talis One cartridges were created without sufficient volume for proper Limits of Detection (the lowest concentration that a test can consistently identify with high probability) because some of the chambers were too small.
>
> 55. FE-2's account of a high invalid rate is corroborated by FE-4, who joined Talis in February 2021. On or around November 12, 2021, FE-4 observed that the Talis One had a high invalid rate when FE-4 turned on the device and it said "invalid, invalid, invalid" 20 or 30 times. The same day, FE-4 told FE-4's supervisor, Alex de los Reyes, that all the tests were invalid; de los Reyes told FE-4 that the analyzer had such a high invalid rate that Talis could not take a chance by attempting to operate the machine in front of potential clients. Because the device did not function reliably, FE-4 was instructed to just run video presentations and not to turn on the machine with potential clients.
>
> 56. FE-5, who joined Talis in September 2021, was told after Talis received its EUA in November 2021 that the invalid rate had been and remained above 10%.
>
> 57. On or around December 6, 2021, during a business trip in California, FE-4 confronted Mai Nguyen (Product Manager) about the Talis One's high invalid rate. Nguyen indicated to FE-4 that two parts inside the test didn't work; one of the non-functional parts was a gasket, and the other was a plastic piece. FE-4 asked how Talis had been able to submit data to the FDA. Nguyen indicated that, based on her interactions with Talis personnel who ran the studies, including Michelle Roeding (Sr. Director Quality and Regulatory Affairs) and Lori Lai (Director of Product Management), they had performed "simulations" and the FDA did not physically inspect testing devices to ensure that they worked.

With regard to the first challenged statement – "The test cartridge for COVID-19 diagnosis contains a NAAT designed for optimal sensitivity and specificity to provide highly accurate results" – defendants argue that plaintiffs are mischaracterizing the statement, which did not discuss "Talis One" generally but the NAAT (assay) specifically, and focused on "design" not performance. Defendants argue that plaintiffs do not allege that the NAAT was deficient in either design or performance. In any event, defendants argue that the FE statements about Talis One experiencing high invalid rates do not state that these issues existed at the time of the IPO.

On the second statement, defendants argue that Talis did not state that its test was "just as accurate and reliable as central lab testing," but rather Talis disclosed that "[a]n important factor in

our ability to commercialize our products is *collecting data that supports the value proposition of our products*, and in particular that our tests are just as accurate and reliable as central lab testing." CC ¶ 158. Defendants note that the disclaimer that immediately follows this statement states, "The data collected from any studies we complete may not be favorable or consistent with our existing data or may not be statistically significant or compelling to the medical community or to third-party payors seeking such data for purposes of determining coverage for our products." Defs' Ex. B at 24. Defendants argue that even accepting plaintiffs' skewed interpretation of this statement, plaintiffs fail to allege that any contemporaneous data contradicted it. Defendants also argue that the third challenged statement – a risk disclosure – was not misleading for the same reasons that the earlier statements are not misleading. Defendants also note that FE-2 left Talis in October 2020, and that FE-4 and FE-5 reference high invalid rates in late 2021, after the FDA had granted Talis the EUA (based upon a July 2021 submission stating that invalid rates were less than 10%).

Plaintiffs contend that the CC plausibly alleges that there were high invalid rates at the time of the IPO because plaintiffs allege that there were high invalid rates prior to the IPO (FE-2) and after the IPO (FE-4 and FE-5), and the design of the Talis One remained constant throughout. Plaintiffs accuse defendants of engaging in "wordplay" with regard to the NAAT versus the Talis One platform as a whole, and they assert that reasonable investors would interpret the first challenged statement as making representations about the Talis One platform, and the second statement conveyed that the Talis One was just as accurate as central lab testing. Plaintiffs argue that because the first two statements are misleading, the risk disclosure was also misleading.

The Court concludes that plaintiffs have not adequately alleged that the challenged statements were false or misleading when made. Even accepting plaintiffs' assertions about how reasonable investors would interpret the challenged statements,[14] none of the FE allegations state that the Talis One platform – or any part of it – had high invalid rates or design issues at the time of the IPO. The Court cannot infer that issues with "high invalid rates" that existed in November and

[14] The Court is skeptical that the second statement, about the need to collect data supporting the "value proposition" of Talis's products, can be interpreted as a statement that the Talis One was, at the time of the IPO, "just as accurate and reliable as central lab testing," particularly given the extensive risk disclosures about the Talis One.

December of 2021 (FE-4 and FE-5) were present in February 2021, or that issues that existed in or prior to October 2020 (FE-2) persisted until February 2021. The FE allegations that plaintiffs rely upon here refer to invalid rates due to the "test" and the "device" or generally to "Talis One," and plaintiffs appear to assert that all of the issues are interrelated and/or have the same cause. However, FE-2's allegations about high invalid rates refer to the too-small chamber sizes of the cartridges, while FE-4 alleges she/he was told the high invalid rates were due to two non-functional parts inside the test – a gasket and a plastic piece. FE-5 does not attribute the high invalid rate to any particular cause. Further, the FE-2 allegations about high invalid rates are conclusory: the CC alleges based on FE-2 that "It was well known before Talis submitted its first EUA application that the test had a high invalid rate." CC ¶ 212(ii). The CC does not state exactly what that means, how that fact was well known, who knew it, or during what time frame (FE-2 left Talis in October 2020). Similarly, the FE-5 allegation that she/he "was told after Talis received its EUA in November 2021 that the invalid rate had been and remained above 10%" is vague. Without additional details showing that high invalid rates sometime in 2020 and again in November and December 2021 mean that there were high invalid rates in February 2021, the Court cannot infer that high invalid rates existed at the time of the IPO such that the challenged statements were false or misleading.

D. Testing and EUA Submission

Plaintiffs challenge as misleading the following lengthy statements in the Registration Statement concerning the testing of the Talis One and the data submitted to the FDA in support of its initial application for an EUA:

> As part of our development of our COVID-19 test we assessed the performance of the Talis One platform using anterior or mid-turbinate nasal specimens to tests conducted in a centralized laboratory using the CDC quantitative reverse transcription polymerase chain reaction (RT-PCR) test. In a preclinical assessment comparing the Talis One platform to an FDA-authorized reference lab test, on 60 matched anterior or mid-turbinate nasal specimens, our COVID-19 test results exactly matched the central lab comparator test results with 100% positive percentage agreement (PPA) and 100% negative percentage agreement (NPA) for the detection of SARS-CoV-2, the virus that causes COVID-19. The specimens in this assessment were residual clinical specimens previously identified with the comparator test. The specimens were blinded to the instrument operator.
>
> [table omitted]

> To further validate our COVID-19 test we assessed its performance using 200 frozen positive specimens and 100 negative specimens, as determined by the same comparator test, as shown in the table below. In this larger assessment, our COVID-19 test demonstrated a 97% PPA and 99 % NPA using residual clinical specimens previously identified with the comparator test. The assessment generated a single false positive result and six false negatives, three of which were also negative when tested with a tie-breaker test. If the results of the tie-breaker test were reflected in the table below, the Talis One platform would demonstrate a 98.5% PPA (194 or 197 positive specimens correctly identified as positive) and 99% NPA (102 of 103 negative specimens correctly identified as negative). The instrument operator was aware of the positive/negative status of the specimens.
>
> [table omitted]
>
> In a subsequent clinical validation study, which study results will be part of our EUA submission materials, comparing our COVID-19 test to a different FDA-authorized RT-PCR COVID-19 test than used in the assessments described above, on matched mid-turbinate nasal specimens, our COVID-19 test demonstrated 97% PPA and 93.9 NPA as shown in the table below . . .
>
> [table omitted]
>
> . . . The high PPA and NPA reflected in the assessments and studies described above is suggestive of clinical sensitivity and specificity in the broader clinical population and is driven by the very low limits of detection possible on the Talis One platform . . .
>
> *Highly accurate*—The Talis One platform incorporates a shelf-stable, single-use test cartridge that is designed to fully integrate a nucleic acid amplification test (NAAT) with sample preparation, including nucleic acid extraction and purification . . . . In a preclinical assessment comparing the Talis One platform to a reference lab test on 60 matched anterior or mid-turbinate nasal specimens, the Talis One test exactly matched the reference lab results with 100% positive percentage agreement (PPA) and 100% negative percentage agreement (NPA) for detection of SARS-CoV-2, the virus that causes COVID-19. The high PPA and NPA is suggestive of clinical sensitivity and specificity in the broader clinical population and is driven by the very low limits of detection possible on the Talis One platform.

CC ¶ 146.

Plaintiffs allege that "having chosen to speak about the purported positive test results, including results submitted to the FDA, the 'sensitivity and specificity' and 'very low limits of detection' of the Talis One, and that the Talis One had been tested against two 'FDA-authorized' comparator tests, the Registration Statement omitted the most important fact: Talis's EUA submission was deficient because Talis had used a comparator assay that lacked sufficient sensitivity to support its EUA submission under FDA standards." *Id.* ¶ 147. Plaintiffs also allege that the statements that the Talis One displayed "high PPA and NPA" that was purportedly "suggestive of clinical sensitivity and specificity in the broader clinical population and is driven by the very low

limits of detection possible in the Talis One platform" were false because the purported high PPA and NPA was actually driven by Talis's choice of a weak comparator assay and the high PPA and NPA merely indicated agreement with a weak comparator assay. *Id.*

Plaintiffs also challenge statements in the Registration Statement that the FDA had requested additional information from Talis regarding its EUA submission, *id*. ¶ 148, as well as risk disclosures stating that Talis may not receive an EUA from the FDA. *Id.* ¶ 150. Plaintiffs allege that these statements were misleading because Talis had chosen a weak comparator assay and thus Talis's EUA submission was doomed from the start, and that this fact was indicated by the FDA requesting additional information. Plaintiffs allege that the FDA had issued guidance regarding the importance of using a "high sensitivity" comparator assay, and thus the fact that the FDA requested additional information "strongly suggest[ed] that the FDA had raised concerns about the comparator assay before the IPO," and thus that the risk disclosures were inadequate because of these issues. *Id*. ¶ 149.

Defendants contend that plaintiffs have not alleged falsity because whether the comparator assay had "sufficient sensitivity" is not a fact but a subjective judgment. "In order to allege falsity, a plaintiff must set forth facts explaining why the difference between two statements is not merely the difference between two permissible judgments, but rather the result of a falsehood." *In re Rigel Pharms., Inc. Sec. Litig*., 697 F.3d 869, 877 (9th Cir. 2012) (internal quotation omitted, affirming district court's dismissal of allegations of falsity that "essentially are disagreements with the statistical methodology adopted by the doctors and scientists who designed and conducted the study, wrote the journal article, and selected the article for publication. The allegations therefore concern two different judgments about the appropriate statistical methodology to be used by Defendants.").

Here, plaintiffs do not allege that the FDA had set forth objective criteria for the sensitivity of a comparator assay and that the comparator used by Talis did not meet that criteria, nor do plaintiffs allege that at the time of the offering the FDA had determined that the comparator assay lacked sufficient sensitivity to support Talis's application and that the FDA had communicated that information to Talis. Instead, plaintiffs allege that Talis "used a comparator assay that lacked sufficient sensitivity to support its EUA submission under FDA standards" and that "Talis had

chosen a weak comparator assay." CC ¶ 147. That allegation does not allege that the statements about the EUA application in the Registration Statement were false or misleading when made. *See Immanuel Lake v. Zogenix, Inc.*, No. 19-CV-01975-RS, 2020 WL 3820424, at *9 (N.D. Cal. Jan. 27, 2020) (dismissing allegations of falsity for 10(b) claim and noting, "Indeed, were plaintiffs' version of falsity the law, a pharmaceutical company could be sued for securities fraud each and every time it received a NDA rejection from the FDA. Potential plaintiffs could merely parrot any deficiency identified by the FDA rejection letter and then claim the company concealed from the market that it failed to include this 'necessary' piece of information in its application."). Further, the FE-2 allegation that "Talis used a weak comparator assay as a benchmark for its EUA submission," CC ¶ 212(i), is conclusory. FE-2's allegation is not supported by additional detail, such as whether FE-2 or anyone else at Talis had raised concerns about using the comparator assay as its benchmark, or whether Talis's management had been provided information showing or suggesting that the comparator assay was weak and should not be used.[15]

Plaintiffs allege that the fact that the FDA had requested "additional information" from Talis about its EUA application "strongly suggest[ed] that the FDA had raised concerns about the comparator assay before the IPO." CC ¶ 147. However, plaintiffs do not allege any facts regarding what this "additional information" was, nor do they allege any facts suggesting that the FDA had communicated its view that the comparator assay that Talis used for its EUA submission was insufficient prior to the IPO. Without more, the allegation that the FDA had requested "additional information" is insufficient to support an inference that the positive statements in the Registration Statement were false or misleading. The cases that plaintiffs rely upon are distinguishable because in those cases, the plaintiffs alleged that the company had received specific, negative, contrary information from the FDA prior to making a public statement about the same topic that omitted the negative FDA information. *See Khoja*, 899 F.3d at 1010 (finding plaintiffs had alleged material misstatements and omissions where defendants touted positive interim results of a study without

[15] Plaintiffs' opposition also asserts that falsity is demonstrated by an article that defendant Ismagilov co-authored in April 2021 that plaintiffs assert "placed Talis's flawed comparator assay squarely in the 'low-sensitivity' category." Opp'n at 6. These allegations are not contained in the CC and the Court does not consider them here.

also disclosing that the FDA had already explicitly warned defendants that the same results had a high degree of uncertainty and therefore were unreliable); *In re Atossa Genetics Inc Sec. Litig.*, 868 F.3d 784, 802 (9th Cir. 2017) (holding plaintiffs stated a claim for misleading omissions where CEO said "FDA clearance risk has been achieved" because that implied "belief that Atossa's conduct mostly complies with FDA rules governing 510(k) clearance" where plaintiffs alleged that prior to statement FDA gave company a warning about test not having 510(k) clearance; this was "an omission concerning knowledge that the Federal Government has taken the opposite view concerning the lawfulness of Atossa's alleged conduct"); *see also Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016) ("Reasonable investors understand that dialogue with the FDA is an integral part of the drug approval process . . . In the absence of plausible allegations showing a conflict between Defendants' statements and the FDA feedback, Plaintiffs' claims here fail as well."). Here, alleging that the FDA had requested "additional information" does not show any conflict with the statements in the Registration Statement.

E. Omissions in Violation of Item 303 and Item 105

Plaintiffs allege that the Registration Statement contained material omissions in violation of Items 303 and 305 of SEC Regulation S-K. CC ¶¶ 162-67. Item 303 required Talis to disclose "any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." 17 C.F.R. § 229.303(3)(a)(ii). Item 305 required Talis to disclose the material factors that made an investment in Talis speculative or risky. Plaintiffs allege that the Registration Statement violated Items 303 and 305 by omitting the risk that the FDA would reject Talis's flawed comparator assay, and omitting the high invalid rates plaguing Talis One. Plaintiffs allege that "Talis knew that its EUA submission was deficient because Talis had used a comparator assay that lacked sufficient sensitivity under FDA standards" and "Talis also knew that the Talis One suffered from a high invalid rate that foreclosed and/or dramatically delayed commercial production . . . ." CC ¶166. Plaintiffs allege that the "boilerplate" and "generic" warnings in the Registration Statement "did not cover the specific, known, material risks posed by the flawed comparator assay

and high invalid rate." *Id.* ¶ 167.

For the reasons set forth above, plaintiffs have not alleged facts showing that Talis "knew" or had reason to believe that its EUA submission was deficient and that the FDA would likely not approve it, or that there were high invalid rates at the time of the IPO.

Accordingly, the Court GRANTS defendants' motion to dismiss the Section 11 claims with leave to amend. Because the Court has found that plaintiffs have not adequately alleged a Section 11 claim, plaintiffs have also failed to state any claims under Section 15.

III. Exchange Act

Defendants Talis, Coe, Kelley, and Moody move to dismiss plaintiffs' Section 10(b) claim against them on the basis that the CC fails to adequately allege any actionable misstatements or omissions and fails to plead scienter. Defendants also argue that a number of the challenged statements are protected by the "safe harbor" provision of the PSLRA, are inactionable opinions and/or corporate optimism. They also move to dismiss plaintiffs' Section 20(a) claim on the grounds that the complaint fails to adequately allege a primary violation under Section 10(b).

Section 10(b) of the Exchange Act makes it 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 [SEC] may prescribe as necessary." 15 U.S.C. § 78j(b). A plaintiff asserting a claim under Section 10(b) or Rule 10b-5 must adequately allege six elements: (1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation. *Kelly v. Electronic Arts, Inc.*, 71 F. Supp. 3d 1061, 1068 (N.D. Cal. 2014) (citing *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008), and *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1051-52 (9th Cir. 2014)).

The PSLRA requires that a Section 10(b) complaint plead with particularity both falsity and scienter. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 990-91 (9th Cir. 2009) (citation omitted). As to falsity, the complaint must state with particularity each statement alleged to have

been misleading, the reason or reasons why the statement is misleading, and all facts on which that belief is formed. 15 U.S.C. § 78u-4(b)(1); *Daou*, 411 F.3d 1006, 1014 (9th Cir. 2005) (citation omitted). "This requirement 'can be satisfied by pointing to inconsistent contemporaneous statements or information (such as internal reports) which were made by or available to the defendants.'" *Rubke v. Capitol Bancorp Ltd.*, 551 F.3d 1156, 1161 (9th Cir. 2009). "Averments of fraud must be accompanied by 'the who, what, when, where, and how' of the misconduct charged." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) (quoting *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997)). As to scienter, the complaint must state with particularity facts giving rise to a strong inference that the defendant made false or misleading statements either intentionally or with deliberate recklessness. 15 U.S.C. § 78u-4(b)(2); *Daou*, 411 F.3d at 1015.

The PSLRA's "safe harbor" provision "is designed to protect companies and their officials from suit when optimistic projections of growth in revenues and earnings are not borne out by events." *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1142 (9th Cir. 2017). The safe harbor applies only to "forward-looking statements," which include:

> (A) a statement containing a projection of revenues, income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items;
>
> (B) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer;
>
> (C) a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission;
>
> (D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C); . . .
>
> [subsections (E) and (F) omitted]

15 U.S.C. § 78u-5(i)(1).

When a statement falls within the statutory definition for "forward-looking," the safe harbor applies if either one of two conditions is present. *Id*. at 1149. First, a forward-looking statement accompanied by sufficient cautionary language is protected. *Id*. at 1141. Cautionary language is sufficient when it identifies "important factors that could cause actual results to differ materially

from those in the forward-looking statement." 15 U.S.C. § 78u-5(c)(1). Second, a forward-looking statement "made without actual knowledge that it is false or misleading" is protected. *Quality Sys.*, 865 F.3d at 1141.

A. "Ordered 5,000 Instruments"

Plaintiffs challenge statements in Talis's post-IPO SEC filings stating that "[w]e have ordered 5,000 instruments from our instrument contract manufacturing partners." CC ¶¶ 207-08. Talis's 2020 10-K included the additional language about the delivery dates that was contained in the Registration Statement; the subsequent SEC filings removed the language about delivery dates.

The parties' arguments about these statements are identical to those advanced regarding the Section 11 claim, and for the same reasons as stated above, the Court finds that plaintiffs have not adequately alleged falsity.

B. Cartridge Manufacturing Capacity

Plaintiffs challenge the following statements about cartridge manufacturing as false (allegedly false statements in bold):

> March 30, 2021, 10-K Annual Report, CC ¶ 185: "We have invested in automated cartridge manufacturing lines capable of producing one million Talis One cartridges per month for the COVID-19 assay, which are scheduled to begin to come on-line in the first quarter of 2021 and **we expect will scale to full capacity through 2021**."
>
> May 13, 2021, Q1 2021 10-Q, CC ¶ 187: "We have invested in automated cartridge manufacturing lines capable of producing one million Talis One cartridges per month. The first of such lines was delivered in the first quarter of 2021, and **we expect will scale to meet demand through 2021**. These manufacturing lines are located at our contract manufacturers' sites and are operated by our contract manufacturing partners."
>
> 1Q21 Earnings Call, May 11, 2021, CC ¶ 189: During the Q&A portion of the call, a JPMorgan analyst asked for clarification of whether Talis still expected to reach a production capacity of one million cartridges per month:
>
> Q: "At the time of the IPO, you had laid out the path to the 70% margin. I know you talked about – seeing you have 1 million cartridges per month capacity now and automation was kind of the key part, is that still on deck for kind of midyear to incorporate the automation on the manufacturing side?"
>
> A (Defendant Moody): "Sure. So we are **on track to bring up our automated lines and we've begun doing so**. We expect to continue to bring those lines up to meet

> demand through the second half [of 2021]. So that's on plan. And long term, we do think that our margin profile is attractive as a razor-razorblade business, where over time, a majority of the margins will be driven by the cartridge consumable."
>
> August 10, 2021, Q2 2021 10-Q**,** CC ¶¶ 194, 196: "We have invested in automated cartridge manufacturing lines capable of producing one million Talis One cartridges per month. The first of such lines was delivered in the first quarter of 2021, and we expect will scale to meet demand through 2021. These manufacturing lines are located at our contract manufacturers' sites and are operated by our contract manufacturing partners." "The ramp up of our [Talis One] manufacturing efforts, which began in the middle of 2020, **is expected to be completed by the end of 2021**."
>
> November 16, 2021, Q3 2021 10-Q CC ¶¶ 200, 202: "We have invested in automated cartridge lines capable of producing one million Talis One cartridges per month. The first of such lines was delivered in the first quarter of 2021, and we expect will scale to meet demand through 2021." "The ramp up of our [Talis One] manufacturing efforts, which began in the middle of 2020, **is expected to be completed by the end of 2021**."

Plaintiffs contend that these statements "were materially misleading for the reasons set forth *supra*" with regard to the Securities Act claims. Opp'n at 21. As such, the Court finds that plaintiffs have failed to allege falsity for the same reasons set forth above. In addition, the Court notes that FE-1 left Talis in March 2021, and thus it is unclear how FE-1 would have knowledge about Talis after he/she left his/her employment; and allegations that FE-1 heard rumors after he left Talis (CC ¶ 211(vi)) fall far short of meeting the PSLRA's heightened pleading requirements and Rule 9(b). Further, FE-4's statement that he/she was told in April 2021 that Talis did not have a manufacturer at full scale (a statement that appears to relate to instrument manufacturing, not cartridge manufacturing) does not, even if applied to cartridges, show the falsity of statements about expecting to scale to full capacity by the end of 2021.

In addition, the challenged statements would appear to be protected by the PSLRA's safe harbor. The PSLRA's safe harbor for forward-looking statements "'is designed to protect companies' when they merely fall short of their 'optimistic projections.'" *Wochos*, 985 F.3d at 1189 (quoting *Quality Sys.*, 865 F.3d at 1142)); *see also In re VeriFone Sec. Litig.*, 11 F.3d 865, 871 (9th Cir. 1993) ("The fact that [a] prediction proves to be wrong in hindsight does not render the statement untrue when made."). The Court finds *Wochos* instructive because there are many similarities between the plaintiffs' claims and theory in that case and the instant case. In *Wochos*, the plaintiffs alleged that "Tesla announced Model 3 production goals for the end of 2017 that it

knew it would not be able to achieve, and it repeatedly reaffirmed that it was on track to reach those targets, even as the end-of-the-year deadline drew closer and as delays grew increasingly significant." *Wochos*, 985 F.3d at 1186. The plaintiffs challenged a statement in Tesla's Form 8-K that "preparations at our production facilities are on track to support the ramp of Model 3 production to 5,000 vehicles per week at some point in 2017," and subsequent statements that Tesla was "on track" to achieve this goal and that "there were no issues" that "would prevent" Tesla from achieving this goal. *Id*. at 1190-92.

The Ninth Circuit held that these statements were protected by the PSLRA's safe harbor. First, the court found that the statements were forward-looking:

> Tesla's goal to produce 5,000 vehicles per week is unquestionably a "forward-looking statement" under § 21E, because it is a "plan[ ]" or "objective[ ] of management for future operations," and this plan or objective "relat[es] to the products" of Tesla. 15 U.S.C. § 78u-5(i)(1)(B). Contrary to what Plaintiffs contend, Tesla's various statements that it was "on track" to achieve this goal and that "there are no issues" that "would prevent" Tesla from achieving the goal are likewise forward-looking statements. Because any announced "objective" for "future operations" necessarily reflects an implicit assertion that the goal is achievable based on current circumstances, an unadorned statement that a company is "on track" to achieve an announced objective, or a simple statement that a company knows of no issues that would make a goal impossible to achieve, are merely alternative ways of declaring or reaffirming the objective itself. The statutory safe harbor would cease to exist if it could be defeated simply by showing that a statement has the sort of features that are inherent in any forward-looking statement.

Id. at 1192. The court emphasized that "it is not enough to plead that a challenged statement rests on subsidiary premises about how various future events will play out over the timeframe defined by the forward-looking statement." *Id*. Instead, "in order to establish that a challenged statement contains non-forward-looking features that avoid th[e] [statutory] definition, a plaintiff must plead sufficient facts to show that the statement goes beyond the articulation of 'plans,' 'objectives,' and 'assumptions' and instead contains an express or implied 'concrete' assertion concerning a specific 'current or past fact[ ].'" *Id*. at 1191 (quoting *Quality Sys*., 865 F.3d at 1142, 1144).

Second, the Ninth Circuit held that the challenged statements were accompanied by meaningful cautionary statements and that the plaintiffs had failed to show that the safe harbor did not apply. *Id.* at 1193. The court noted that the plaintiffs did not directly challenge the adequacy of the cautionary statements, and instead claimed that the relevant Tesla officers knew that it was

impossible to meet the forward-looking projections, thus that the cautionary language was not truly meaningful. *Id*. The court found it unnecessary to decide the legal question of whether such allegations would be sufficient to overcome the safe harbor protections because the court found that the plaintiffs had "failed to plead that Defendants knew their year's end goal was impossible to achieve." *Id*. at 1194 (holding allegations that "two employees told Musk in 2016 that the goal of producing 5,000 cars per week by the end of 2017 was impossible to achieve" insufficient because "Plaintiffs had failed to plead facts showing that Defendants adopted the conservative timeline for production on which these employees' pessimism was based" and "[s]imilarly, Plaintiffs' allegations that '[s]uppliers had informed Tesla that the production timelines were impossible' do not establish that Defendants (who were still in the process of choosing suppliers) shared that gloomy view.").

Here, plaintiffs do not challenge statements of current or past fact, such as alleging that Talis had not invested in automated cartridge manufacturing lines capable of manufacturing 1 million cartridges per month, nor do plaintiffs claim that Moody's May 11, 2021 statement that Talis "had begun" to bring up the automated lines was false because Talis had not in fact begun to bring up the automated lines. Instead, plaintiffs challenge as misleading the various statements that Talis was "on track" and "expected" to scale the automated lines to full capacity by the end of 2021. Thus, plaintiffs challenge forward-looking statements. Because the challenged statements are forward-looking, they are protected by the safe harbor if they are accompanied by meaningful cautionary language. *Id.* at 1193. Here, each of the challenged statements was identified as forward-looking and accompanied by cautionary language warning, for example, that the automated cartridge manufacturing lines "are not complete and could incur substantial delays . . . and may not perform as anticipated." *See* Defs' Ex. D at 29 (March 30, 2021, 10-K Annual Report); Ex. F at 4 (May 11, 2021 earnings call transcript); Ex. G at 29 (May 13, 2021, Q1 2021 10-Q); Ex. I at 31 (August 10, 2021, Q2 2021 10-Q); Ex. M at 32 (November 16, 2021, Q3 2021 10-Q). Plaintiffs have failed to allege facts showing why the cautionary language was not meaningful, and plaintiffs have not alleged facts showing that defendants "knew their year's end goal was impossible to achieve." *Id*. at 1194.

C. "Ready to Go" and "Ship Product in a Timely Manner"; "Terrific Results"; "Great Product"

Plaintiffs challenge the following statements made by Coe, Kelley and Moody regarding Talis's product and manufacturing ability:

> 1Q21 Earnings Call, May 11, 2011: During the Q&A portion of the call, a Bank of America analyst asked, "hypothetically, after approval, how soon can you ship the product out to customers? I'm just trying to get at if there's any change to the product revenues for the rest of the year."
>
> A (Coe): "We feel we'll be in a position to ship product **in a very timely manner following an approval**. We're certainly spending quite an effort on commercial preparedness. And as we've already commented as well, we have a commercial team in place. And we feel very much **ready to go** on our end." CC ¶ 190;
>
> 2Q21 Earnings Call, August 10, 2021: During the Q&A portion of the call, a Bank of America analyst asked,
>
> Q: "But I mean, you missed your first EUA, your products are delayed. Basically, what you've shared with us on the deal model and everything is dramatically pushed out from where it was. I mean what gives you comp – I mean what can you say to give us confidence that the longer-term opportunity is there?"
>
> A (Coe): "What I'll say is the – yes, the time lines are later than we'd anticipated in the IPO model. And on the other hand, **our results really look terrific**. From a company perspective, we're **way ahead on our ability to produce product** relative to almost any company our size historically." CC ¶ 197;
>
> On the same call, an analyst from JPMorgan Chase & Co. asked:
>
> Q: "You talked a little bit about the phased approach rollout here. Can you talk a little bit about [the] sort of customers you're targeting in 4Q with that phased rollout for the COVID test? And then as things sort of ramp in the beginning of next year, can you just talk a little bit about customer mix? Has your plans changed at all regarding who you're targeting here with this phased rollout?
>
> A (Coe): "So thank you for the question. So I'll start with the **phased approach**, which is to say that we're really, first of all, focusing on an exceptional customer experience. So we don't want to push a ton of product out into the market in one fell swoop. And then if **some small thing arises, we want to be able to react and make sure that everything exceeds customers' expectations**. And then we'll ramp up, and we just think that's best for the business in the long term as **customer loyalty** is critical to us." CC ¶ 198.
>
> 3Q21 Earnings Call, November 15, 2021: Defendant Moody stated, "We expect to recognize $2 million of remaining milestone revenue from our amended RADx contract between now and the contract termination date at the end of January 2022. The balance of the third quarter financials were shaped by **investments in launch preparation that are beginning to come to fruition**." CC ¶ 203.
>
> During the same call, an analyst from JPMorgan Chase & Co. asked:

> Q: "I guess on the commercialization strategy, can you just talk a little bit, are you still prioritizing larger hospital placements before urgent care? And how do you kind of feel about end markets such as some of the urgent clinics? And then the phased rollout you were alluding to, is that type of manufacturing process validation you're calling up?"
>
> A (Kelley): "So the commercial team's focus is to provide the best customer experience possible. And as you know, there's a likelihood that if you go to market with a product too quickly, you can do some damage to reputation, and we just don't want to do that. **We think we've got a great product here**." CC ¶ 205.

Plaintiffs allege that the bolded statements were false and misleading because defendants had no basis to make positive statements about Talis's product, results, or readiness to launch. Plaintiffs claim that all of the challenged statements are false or misleading representations of fact, and that in actuality, Talis was not "ready to go," the results were not "terrific," the product was not "great," the "investments in launch preparation" were not beginning to come to fruition, and Talis did not adopt a "phased approach" to launch in case a "small thing arose" but rather because the Talis One was unreliable and could not launch at scale.

With regard to Coe's May 2021 statements, plaintiffs allege that the statements were false because "FE-3 had briefed Coe over several weeks in May 2021 about the serious issues with the manufacturing timelines for the Talis One," CC ¶¶ 90, 213(ii), and "FE-1 recalled a rumor that in or around May 2021, then SVP of R&D Ramesh Ramarkrishnan had provided a new timeline to Coe, who rejected it; Ramarkrishnan resigned within days. FE-1 indicated that Coe's claim that Talis was 'ready to go' into production upon receiving an EUA had no basis." *Id*. ¶ 90. Plaintiffs also allege that FE-5, who joined Talis in September 2021, "corroborated" FE-1's account by confirming that "Talis was not ready to begin manufacturing as soon as the EUA was received" and because "the Talis One continued to generate high invalid rates in late 2021, as FE-4 confirmed." *Id*. Plaintiffs also argue that the fact that Talis announced delays in launching "just three months" after Coe's May 2021 "ready to go" statement is circumstantial evidence of falsity. Plaintiffs also emphasize that FE-4 was told in April 2021 that Talis did not have a manufacturer at full scale and was manufacturing the instruments by hand. *Id.* ¶ 214(iii).

For reasons consistent with the prior discussion, the Court finds that plaintiffs have failed to

allege that Coe's May 2021 statements were false or misleading when made.[16] The FE-3 allegations are vague as to when in May 2021 FE-3 briefed Coe on the manufacturing issues, and more importantly, do not state that Coe "ever accepted those employees' views that the goal was impossible." *Wochos*, 985 F.3d at 1194. FE-1's allegation, based on a rumor, that Coe rejected Ramarkrishnan's new timeline undercuts an assertion that Coe did not believe his own optimistic projections. *See id*. Indeed, rather than plausibly suggesting fraud, a number of the FE allegations instead suggest that Talis's problems were driven by an "aggressive" "company culture," "incompetence at every level," and that senior management disagreed with lower-level employees' opinions about the technical and manufacturing challenges facing the company. *See, e.g.*, CC ¶ 211(ii),(iii) (FE-1 reporting that "Talis management ignored many of the technical challenges with bringing the Talis One to market" and that FE-1 reported supply chain issues to senior director of supply chain Tony Cunningham but "Cunningham ignored and downplayed FE-1's concerns"); ¶ 213 (FE-3 reporting that "Talis's timelines were overly aggressive, driven in part by company culture"). FE-5's allegations are conclusory and relate to some unspecified time after Talis received its EUA in November 2021, not May 2021. The Court has already discussed the FE-4 allegations about high invalid rates, and again, those relate to November and December 2021, not May. Talis announcing delays in August 2021 does not render false Coe's May statements about being able to ship in a timely manner after an EUA approval (which occurred in November 2021). Further, as currently pled, Coe's May 2021 statement that Talis would be able to ship product following an approval is a forward-looking statement that falls within the PSLRA's safe harbor.

Plaintiffs assert that the August and November 2021 statements were false and misleading

[16] Because of the PSLRA's heightened pleading requirements and the applicability of Rule 9(b), the allegations are even more deficient. For the most part, the Court finds that the FE allegations are conclusory, often stated in the form of an opinion without explaining the basis for the opinion, vague or silent as to time period, and often based on vague hearsay or rumors. "[C]ourts in this district reject CW allegations based on hearsay where the CWs fail to 'provide[ ] any context surrounding when, why, or how these individuals provided [the] CW[ ] with information.'" *Kipling v. Flex Ltd.*, No. 18-CV-02706-LHK, 2020 WL 7261314, at *11 (N.D. Cal. Dec. 10, 2020), *aff'd sub nom. Nat'l Elevator Indus. Pension Fund v. Flex Ltd.*, No. 21-15050, 2021 WL 6101391 (9th Cir. Dec. 21, 2021) (quoting *Costabile v. Natus Med. Inc.*, 293 F. Supp. 3d 994, 1010 (N.D. Cal. 2018)).

for the same reasons the May 2021 statements were false, Opp'n at 19; these arguments fail for the reasons just stated, including the conclusory nature of the FE allegations. Further, absent additional specific allegations showing falsity when made, a number of the challenged statements are inactionable vague corporate optimism and opinions. These include "We think we've got a great product," "our results really look terrific," and "we're way ahead on our ability to produce product relative to almost any company our size historically." Similar statements have been held to be non-actionable puffing. *See In re Syntex Corp. Sec. Litig.*, 855 F. Supp. 1086, 1095 (N.D.Cal.1994), *aff'd*, 95 F.3d 922 (9th Cir. 1996) (holding as non-actionable puffing the phrases "'we're doing well and I think we have a great future,' 'business will be good this year . . . we expect the second half of fiscal 1992 to be stronger than the first half, and the latter part of the second half to be stronger than the first . . . ,' 'everything is clicking [for the 1990s] . . . new products are coming in a wave, not in a trickle . . . old products are doing very well' and that 'I am optimistic about Syntex's performance during this decade' "); *see also In re Cutera Sec. Litig.*, 610 F.3d 1103, 1111 (9th Cir. 2010) (holding inactionable challenge to statement in 10-K that "None of our employees is represented by a labor union, and we believe our employee relations is good" when the plaintiffs alleged that in fact many employees "were already out the door" because "[w]hen valuing corporations, however, investors do not rely on vague statements of optimism like 'good,' 'well-regarded,' or other feel good monikers.").

D. Validation of Cartridge Manufacturing Lines

Plaintiffs challenge as false Talis's statement in its August 2021 second quarter 2021 Form 8-K that it had "[c]ompleted installation and [was] in the final stages of validation for the first set of automated production lines." CC ¶ 192. Plaintiffs claim that this statement was false because "[h]ad Talis been in the 'final stages of validation' as of August 2021, Talis would already have scrutinized the performance of the production lines and resulting cartridges." *Id.* ¶ 193. As support, the CC cites a definition for "process validation" from the Global Harmonization Task Force, and the CC alleges that "Process validation is a term used in the medical device industry to indicate that a process has been subject to such scrutiny that the result of the process (a product, a service or other

outcome) can be practically guaranteed." *Id.* ¶ 97.[17] Plaintiffs allege that "[s]tatements that Talis was 'in the final stages of validation' thus indicated that Talis had extensively scrutinized the cartridge production lines and was on the verge of consistent production at scale." *Id*. However, plaintiffs allege that was not the case because in March 2022, CEO Kelley stated, "When we spoke with you back in November [2021], we were beginning to evaluate the performance of cartridges coming off our high-yield lines," "thereby confirming that Talis was not in the 'final stages of validation' in August 2021." *Id*. Plaintiffs also cite FE-5, who "explained that Talis had not validated its production lines, which was significant and one of the major factors in not launching the Talis One." *Id*. & ¶ 215(iii).

Defendants contend that plaintiffs have failed to allege falsity because the March 2022 statement about *evaluating* the performance of *cartridges* in November 2021 does not render false the August 2021 statement about being in the final stages of *validation* for the first set of production *lines*. Defendants argue that plaintiffs do not plead any contemporaneous facts that contradict the August 2021 statement. Defendants assert that plaintiffs are relying on a third-party definition of "validation" which they do not allege Talis ever referenced, and that the Global Harmonization Task Force definition of "process validation" goes beyond anything Talis ever said and is inconsistent with Talis's contemporaneous disclosures about the status of scaling manufacturing. Defendants also argue that FE-5's allegations are conclusory and without a stated basis: defendants argue that FE-5 is not alleged to have personal knowledge of manufacturing, FE-5 does not state which production lines had not been validated or when, nor does FE-5 explain what it means to "validate" a line and whether that differs from evaluating cartridge performance.

The Court concludes that plaintiffs have failed to allege with particularity why the August 2021 statement about being in the "final stages of validation for the first set of automated production lines" was false or misleading. As an initial matter, Talis stated it was in the "final stages" of validating the first set of automated lines, not that it had completed validating the lines. Even

[17] Plaintiffs' opposition cites additional regulatory definitions, not contained in the CC, for "validation" and "process validation" that require objective evidence that a process consistently produces a result or product meets its predetermined specifications. Opp'n at 22 n.18.

accepting the applicability of the definitions of "validation" cited by plaintiffs, it is not necessarily inconsistent to be in the "final stages of validating" the first set of cartridge production lines in August 2021 – a process that presumably includes a number of steps and "scrutiny" and gathering of data – and to be "beginning to evaluate the performance of cartridges coming off our high-yield lines" in November 2021. As defendants note, the CC does not allege any contemporaneous facts showing that the August 2021 statement was false or misleading when made, such as facts showing that in August 2021 Talis had not yet begun the process of validating the first automated lines. The Court also agrees with defendants that the FE-5 allegations are conclusory. The CC does not explain how FE-5, an associate director of technical implementation who worked at Talis from September 2021 to March 2022, knew that Talis "had not validated its production lines" or what exactly that statement means, nor do plaintiffs provide any facts showing that FE-5's information demonstrates that the August 2021 statement was false when made.

Because the Court concludes that plaintiffs have failed to allege with particularity that any of the challenged statements were false or misleading when made, the Court finds it unnecessary to reach the parties' additional arguments about scienter. In addition, because plaintiffs have failed to state a claim under Section 10(b), they have failed to state a claim under Section 20.

CONCLUSION

For the reasons set forth above, the Court concludes that plaintiffs have failed to state a claim under Sections 11 or 10(b). Further, as plaintiffs have failed to allege primary liability, plaintiffs have failed to state a claim under Sections 15 or 20. Plaintiffs are granted leave to amend, and may file the amended complaint by **January 13, 2023.**

IT IS SO ORDERED.

Dated: December 9, 2022

SUSAN ILLSTON
United States District Judge