BLEICHMAR FONTI & AULD LLP
Lesley E. Weaver (Bar No. 191305)
555 12th Street, Suite 1600
Oakland, California 94607
Telephone: (415) 445-4003
Facsimile: (415) 445-4020

Counsel for Co-Lead Plaintiff Martin Dugan and Co-Lead Counsel for the Putative Class

POMERANTZ LLP
Jennifer Pafiti (Bar No. 282790)
1100 Glendon Avenue, 15th Floor
Los Angeles, California 90024
Telephone: (310) 405-7190
Facsimile: (212) 661-8665

Counsel for Co-Lead Plaintiff Leon Yu and Max Wisdom Technology Limited and Co-Lead Counsel for the Putative Class

[Additional counsel on signature page]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE TALIS BIOMEDICAL SECURITIES LITIGATION	Case No. 3:22-cv-00105-SI
	CLASS ACTION
THIS DOCUMENT RELATES TO: ALL ACTIONS	**CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**
	JURY TRIAL DEMANDED

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Court-appointed Co-Lead Plaintiffs Martin Dugan, Leon Yu, and Max Wisdom Technology Limited (together, "Lead Plaintiffs") bring this action on behalf of themselves and persons and entities that (1) purchased or otherwise acquired common stock issued by Talis Biomedical Corporation ("Talis" or the "Company") pursuant and/or traceable to the registration statement and prospectus (collectively, the "Registration Statement") issued in connection with the Company's February 2021 initial public offering ("IPO" or the "Offering") or (2) purchased or otherwise acquired Talis common stock between March 30, 2021 and March 15, 2022, both inclusive (the "Class Period"), and were damaged thereby (the "Class").

The allegations herein are based upon personal knowledge as to Lead Plaintiffs' own acts, and upon information and belief as to all other matters. Lead Plaintiffs' information and belief is based on, among other things, the investigation conducted by and through Lead Counsel, including without limitation: (a) review and analysis of regulatory filings made by Talis with the United States Securities and Exchange Commission ("SEC"); (b) review and analysis of transcripts of Talis's public conference calls and press releases and media reports issued by and disseminated by Talis; (c) review of other publicly available information concerning Talis, including research reports issued by financial analysts; and (d) interviews with former Talis employees. Lead Plaintiffs believe that, after a reasonable opportunity for discovery, substantial additional evidentiary support will be available that further proves the allegations in this Complaint.

I. SUMMARY OF THE ACTION

1. This action brings (i) strict liability and negligence claims under Sections 11 and 15 of the Securities Act of 1933 (the "Securities Act"), and (ii) fraud claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act").

2. These claims arise from Defendants' materially false and misleading statements and omissions about the Talis One, a molecular diagnostic device that Defendants hastily attempted to develop and market for COVID-19 testing. Defendants claimed that the Talis One would enable highly accurate testing at the point of care (*e.g.*, in a doctor's office), in contrast to central laboratory testing that could take days to receive results.

3. As detailed below, this case is not about the risks of a development-stage company or Defendants' failure to predict the future. Rather, at the time of Talis's February 11, 2021 initial public offering (the "IPO"), Talis had no functioning product, no viable path to commercialization, and had already experienced significant regulatory and technical problems that foreclosed or dramatically delayed the Talis One's commercial launch. Specifically, Talis had already botched its crucial U.S. Food and Drug Administration ("FDA") application for Emergency Use Authorization ("EUA"); the Talis One had unresolved design issues and suffered high invalid rates (*i.e.*, tests that do not yield usable results); and Talis did not have the ability to manufacture the Talis One at scale or even a realistic timeline for doing so.

4. These existing, adverse facts were concealed in the Registration Statement, which instead touted positive test results and falsely claimed the Talis One was "highly accurate," that Talis had "ordered 5,000 instruments" for delivery, and that "automated cartridge manufacturing lines capable of producing one million cartridges per month" were expected to "scale to full capacity through 2021." These false and misleading statements—and Defendants' separately actionable omissions of material, known uncertainties and risks in violation of SEC disclosure requirements—painted a materially false picture of Talis's business, operations, and prospects.

5. Talis originally focused on developing the Talis One for sexually transmitted infections (STIs). In 2020, in a rush to capitalize on the COVID-19 pandemic, Talis abandoned its prior efforts and began to develop a COVID-19 test for the Talis One. In January 2021, Talis applied to the FDA for an EUA for the Talis One COVID-19 test—the initial step in commercialization. At the time, the FDA had only authorized the first COVID-19 vaccines on an emergency basis in December 2020. With a U.S. population that was still largely unvaccinated, this environment created economic opportunity for new manufacturers of COVID-19 diagnostic tests. Because several such tests were already on the market, however, investors were keenly focused on a new entrant's ability to quickly procure an EUA from the FDA; the accuracy and reliability of its product; and its ability to manufacture its product at scale.

6. On each point, the Registration Statement for the IPO contained materially false and misleading statements and omissions that concealed the adverse facts existing at the time.

7. First, immediately before the IPO, Talis made an EUA submission to the FDA. Unknown to investors, this submission used a benchmark comparator assay that lacked sufficient sensitivity to support the submission under FDA standards. The comparator assay is a third-party COVID-19 test that was used as a benchmark of the relative performance of the Talis One. Because such analysis is comparative, the comparator assay's sensitivity—its ability to reliably detect the SARS-CoV-2 virus—is key. As a former Talis senior scientist has stated, however, Talis used a weak comparator assay for its submission (FE-2). Indeed, while FDA guidance requires a "high sensitivity" comparator assay, Talis chose an insufficiently sensitive comparator assay: a COVID-19 test that generated "false negative" results with unacceptable frequency. Based on this deceptive benchmark, Talis reported unreliable data to the FDA.

8. Nonetheless, the Registration Statement misleadingly touted granular details of test data and results, claimed that the Talis One displayed "high PPA and NPA," which were "suggestive of clinical sensitivity and specificity," and stated that Talis had used "FDA-authorized" comparator tests. These statements were misleading when made because they omitted the most important fact: Talis had used a comparator assay that was insufficiently sensitive and did not comply with FDA guidance, and as a result, Talis's EUA submission was doomed from inception.

9. The FDA quickly requested additional information from Talis, but Defendants conducted the IPO on February 11, 2021 and raised $254 million before responding and without disclosing any details about the FDA's request. Just days after the IPO, the FDA formally rejected Talis's flawed comparator assay, forcing Talis to withdraw its EUA submission.

10. Second, before the IPO, the Talis One had serious quality and design issues, including high invalid rates. Nonetheless, the Registration Statement misleadingly touted the Talis One as a "highly accurate" product with safety and convenience features, and misleadingly stated that Talis's "diagnostic tests may contain errors or defects or be subject to reliability issues" when such issues had already arisen.

11. Third, before the IPO, Talis's manufacturing efforts were already severely delayed, and Talis had failed to meet its own internal deadlines. Despite significant, existing manufacturing

delays, the Registration Statement misleadingly claimed that the Talis One was designed to be "low-cost and manufactured at scale" and touted Talis's investment in automated cartridge production lines that would purportedly "scale to full capacity" of one million cartridges per month "through 2021." Further, the Registration Statement falsely stated that Talis had "ordered 5,000 instruments" to be delivered by Q1 2021; in reality, Talis had merely ordered "components for up to 5,000 instruments," a materially different fact that Talis revealed over a year later.

12. On February 11, 2021, Talis conducted its IPO, issuing 15,870,000 shares at a price of $16/share and raising $254 million, largely from the Class. Shortly thereafter, in late February 2021, the FDA rejected the insufficiently sensitive comparator assay used in Talis's EUA submission—a fact Talis continued to conceal for over a week. When Talis publicly revealed the FDA's rejection on March 8, 2021 and disclosed that it had withdrawn its EUA submission, the Company's inflated share price began to collapse.

13. As concerns mounted over Talis's inability to secure an EUA and begin timely production, Talis's senior management continued to mislead the market in an attempt to preserve the positive façade that had enabled Talis to conduct the IPO. In May 2021, Talis's CEO, Defendant Brian Coe, falsely assured investors on a public conference call that Talis was ready to begin production of the Talis One "in a very timely manner" once EUA approval was granted, and was "very much ready to go."

14. These positive public statements, according to a former Talis engineer (FE-1), had no basis. Internally, the Company was in complete disarray: internal schedules were unmet and the Talis One suffered from serious and unresolved design and manufacturing issues that continue to foreclose commercial production today. Nonetheless, CEO Coe—while knowing of the Talis One's high invalid rates and manufacturing delays—continued to tout purported progress, claiming in August 2021 that "our results really look terrific." Even by September 2021, a former associate director of technical implementation (FE-5) confirmed that Talis was not ready to begin manufacturing as soon as the EUA was received.

15. Further, in an effort to create the appearance of commercial activity, Talis sales representatives were instructed to engage in aggressive pre-selling of the Talis One before the FDA

granted an EUA. Under enormous pressure, including threats of termination, Talis's sales force ultimately obtained 140 presales. The executives took the sales, put them in a spreadsheet, then told Talis's Board they had substantial presales. Yet the Talis One remained little more than a "dummy box" that sales representatives were instructed not to turn on in meetings at doctors' offices and hospitals, as a former Talis territory account manager (FE-4) confirmed. Indeed, on or around November 12, 2021, the former account manager turned on the device and it said "invalid, invalid, invalid" 20 or 30 times.

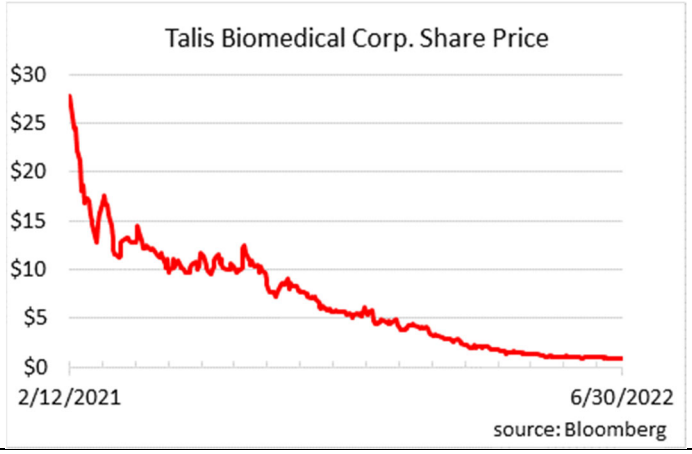
16. As time continued to pass with no functioning product on the market, Talis's share price plummeted. In August 2021, CEO Coe (who had presided over the failed EUA application and IPO) was terminated.

17. Coe's replacement as CEO, Brian Blaser, served for only a week before abruptly resigning in December 2021; the former account manager (FE-4) was told that Blaser quickly departed Talis because there was major fraud.

18. In a March 2022 earnings call, Talis refused to provide any timeline for launching the Talis One and admitted that its "current manufacturing process is not yet sufficient to support commercialization."

19. Finally, in May 2022, Talis disclosed that it still has no timeline for launch and does not expect the Talis One to make any "significant revenue contribution" in 2022.

20. Nearly 17 months after Talis's February 2021 IPO, Talis still has no commercially available product. The following chart shows the price of Talis common stock, which peaked at $27.80 and closed at $0.81 on June 30, 2022, a 95% decline from its IPO price of $16.00/share:



II. JURISDICTION AND VENUE

21. The claims asserted herein arise under and pursuant to Sections 11 and 15 of the Securities Act (15 U.S.C. §§ 77K and 77o) and Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)), and the rules and regulations promulgated thereunder, including Rule 10b-5 (17 C.F.R. §240.10b-5).

22. This Court has jurisdiction over the subject matter of this action pursuant to Section 22 of the Securities Act (15 U.S.C. § 77v) and Section 27 of the Exchange Act (15 U.S.C. § 78aa). In addition, because this is a civil action arising under the laws of the United States, this Court has jurisdiction pursuant to 28 U.S.C. § 1331.

23. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the mails, interstate telephone communications, and the facilities of a national securities exchange.

24. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b). Many of the acts and transactions giving rise to the violations of law complained of herein occurred in this District. In addition, Talis maintained its corporate headquarters and principal executive offices in this District throughout the Class Period.

III. BACKGROUND ALLEGATIONS

25. The allegations in this Complaint are based on Co-Lead Counsel's investigation, which included interviews with former Talis employees who have provided information supporting Lead Plaintiffs' allegations (the "FEs"). The FEs provided information on a confidential basis and are described in Section V.C.a. below by job description, title, responsibility, and period of employment, thereby providing sufficient detail to establish their reliability and personal knowledge. Allegations attributed to a particular FE are referenced by the employee's "FE __" designation or job description.

A. Talis Originally Focuses on Diagnostics for Sexually Transmitted Infections

26. Talis has yet to successfully launch any product of its own or generate any revenue from a product it has developed.

27. Talis was founded in 2010 as SlipChip LLC by Defendants Coe and Ismagilov to develop point-of-care ("POC") diagnostic tests for infectious diseases. (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.)

28. In February of 2018, SlipChip changed its name to Talis Biomedical and established headquarters in Menlo Park, California. At this point, Talis was developing rapid POC diagnostic tests for chlamydia and gonorrhea.

B. Talis Abruptly Pivots to Capitalize on the COVID-19 Pandemic

29. The first cases of SARS-CoV-2, the virus that causes COVID-19, were identified in China in December 2019. By mid-January 2020, the virus was detected in multiple countries, including the United States, which confirmed its first case on January 20, 2020.

30. On February 4, 2020, the United States Secretary of Department of Health and Human Services determined, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the "FD&CA"), that there was a public health emergency with a significant potential to affect national security or the health and security of United States citizens living abroad. The World Health Organization declared the COVID-19 outbreak a pandemic on March 11, 2020, and the United States declared a national emergency shortly thereafter.

31. The rapid spread of COVID-19 created an urgent need for reliable tests. For example, on April 17, 2020, a former American Medical Association President wrote that "[i]t is critically important that we dramatically expand our testing capacity, both diagnostic and antibody testing. Only through that expansion will we have the data and information necessary for public health officials to determine when it is safe to resume a semi-normal way of life."

32. By summer 2020, Talis abandoned its original focus on STI testing and started to develop a molecular diagnostic test for COVID-19. 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.

33. 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," declaring that the Company 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"). The press release proclaimed that the RADx Contract and $100M in new, private financing would allow the Company to "scale manufacturing" for the launch of the Talis One diagnostic platform, which purportedly would provide "rapid and highly accurate detection of COVID-19 at the point-of-care."

34. Talis's press release included an image of the Talis One platform, comprised of a box-shaped analyzer device and a consumable cartridge to contain the sample for testing:

35. In contrast to cumbersome and time-intensive central lab testing, Talis claimed that the Talis One platform was "designed to be operated by untrained personnel and incorporate safety and convenience features, including automated cartridge-based sample preparation for reliable results, closed cartridges to mitigate contamination, room-temperature cartridge storage for convenient storage, and cloud connectivity for easily accessed results and records."

C. Defendants Go All Out in the Build-Up to the IPO, Ignoring Problems with the Talis One EUA Submission, Manufacturing, and Invalid Rates

36. By late 2020, Defendants' plan was to take Talis public and secure additional funding through an IPO. FE-1, a former Talis senior engineer, described the Company moving to rapidly conduct an IPO.[1] Unfortunately, as FE-1 explained, Talis was a few years behind in technical development, and its response was to throw money at the problem.

37. Defendants' haste was largely driven by two factors:

38. First, Talis nearly ran out of cash and was forced to issue a "going concern" warning, meaning that it was probable that Talis would become insolvent within the next year. Talis's first draft registration statement (confidentially filed with the SEC on October 15, 2020) explained that "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."

39. Under FASB ASU No. 2014-15, "[s]ubstantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued)." While Talis temporarily staved off its auditor's "going concern" warning by raising $126 million in private financing in November 2020, the Company still needed more capital.

40. Second, Talis sought to capitalize on a temporary—and rapidly closing—window to get a COVID-19 test to market and quickly achieve sales before demand for testing began to cool. In this regard, timing was crucial to investors and analysts given that FDA had recently authorized the Pfizer and Moderna COVID-19 vaccines in December 2020. Further, several competing COVID-19 molecular diagnostic tests were already on the market by late 2020.

[1] Each FE's role, tenure at the Company, and statements are further described in Section V.C.a.

41. Talis's survival, let alone its value as a public company, was thus wholly dependent on its ability to quickly produce and sell the Talis One. This would enable Talis to create a large installed base for consumable cartridges and additional, non-COVID-19 assays to generate revenues and profits after COVID-19. Further, to succeed as a relatively late entrant in a crowded field, Talis would need to demonstrate an accurate, reliable product that could be manufactured at scale.

42. As detailed below, however, by early 2021, Talis had no functioning product or viable path to commercialization, the Talis One was plagued with unresolved design issues and high invalid rates, and Talis had botched its crucial EUA application with the FDA. These existing, adverse facts were concealed in the Registration Statement.

a. Talis Could Not Manufacture the Talis One at Scale

43. When Talis quickly pivoted from its original focus on STI testing to COVID-19, Talis substantially accelerated its timeline for bringing the Talis One to market. FE-1, a former Talis R&D engineer, explained that, had COVID not happened, the original cartridge for STI testing was slated to go into production in 2022. This timetable is corroborated by a five-year grant from the NIH awarded in June 2018 to fund development of a POC diagnostic system for the "culture-independent identification and determination of antimicrobial susceptibility to bacterial pathogens from whole blood."[2]

44. The Registration Statement touted 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 by "the first quarter of 2021" and touted 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.

45. In reality, Talis did not have a realistic timeline to manufacture the Talis One, and the process was plagued by production problems. FE-2—a senior scientist with a Ph.D. in

[2] *See* https://investors.talisbio.com/news-releases/news-release-details/talis-biomedical-corporation-awarded-56m-nih

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.

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.

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.

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.

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.

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 testing and to prove Talis's manufacturing capability, but Talis produced far fewer instruments in the quarter.

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.

b. Talis One Was Non-Functional Due to Design Issues and High Invalid Rates

52. Beyond Talis's unrealistic timelines and manufacturing delays, the Talis One suffered from serious design issues and a high invalid rate (meaning the tests did not yield usable results). These problems were known within the Company before the IPO.

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'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.

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.

58. Nonetheless, 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." In doing so, the Registration Statement made no mention of the high invalid rates that were already known to the Company.

c. Talis Botches Its Crucial EUA Application

59. Talis was required to obtain Emergency Use Authorization from the FDA before marketing or selling the Talis One COVID-19 test.[3]

60. Talis's ability to quickly procure an EUA was highly material to investors, as this was Talis's fastest path to marketing and selling the Talis One and generating revenue—and time was of the essence, particularly with increasing vaccination rates and multiple competitors' products already on the market. Further, obtaining and maintaining an EUA was required under

[3] Under Section 564 of the FD&CA, 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.

Talis's $25 million RADx Contract, which provided that "[s]uccessful performance under this contract requires [Talis] to obtain and maintain an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA)."

61. The details of Talis's product testing and future EUA submission were also of interest to the SEC. On November 10, 2020, an SEC comment letter directed to Defendant Coe sought clarifications to the draft registration statement Talis had confidentially filed on October 15, 2020. The SEC's comment letter directed Talis to "disclose any material protocols used during the preclinical assessment of your COVID-19 test, including indicating if any portions of the assessments were blinded . . . . Please revise your textual discussion of the 95% CI statistical analysis performed to explain the significance of the ranges you provided and how this data translates into you[r] plan to submit an Emergency Use Authorization to the FDA."

62. Talis applied for an EUA on January 29, 2021, just days before the IPO. By 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.[4]

63. 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, among other things, studies demonstrating their test's Limit of Detection (LoD),[5] inclusivity (analytical sensitivity), cross-reactivity (analytical specificity), and a clinical evaluation.

64. Certain of these studies measure important data points called positive percentage agreement (PPA) and negative percentage agreement (NPA). PPA and NPA are the percentages of specimens that a new test correctly identifies as positive or negative relative to a prior test, known as the comparator assay. For example, if a comparator assay identifies 100 samples as positive and the new test identifies 99 of the 100 as positive, the new test's PPA is 99%. Likewise,

[4] *See* https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2

[5] The LoD, typically measured in units of NAAT Detectable Units per mL, is the lowest number of copies of viral material per milliliter that a test can detect.

if the comparator assay identifies 100 negative samples and the new test identifies 99 of the 100 as negative, the new test's NPA is 99%. These results are shown below:

		Comparator Assay		
		Positive	**Negative**	**Total**
New Test	**Positive**	99	1	100
	Negative	1	99	100
	Total	100	100	200
		New Test PPA = 99%	**New Test NPA = 99%**	

65. Because this testing is comparative in nature, the resulting data is only valid if the benchmark comparator assay is reliable. For example, if 120 of the 200 samples were positive but the comparator assay only identified 100 as positive, a new test with 99% PPA would be accurate only 82.5% of the time (99 of 120). Likewise, if 80 of the samples were negative but the comparator assay identified 100 as negative, a new test with 99% NPA would be accurate only 80.8% of the time (80 of 99). These results are shown below:

	Positive	**Negative**	**Total**
Unsuitable Comparator Assay	100	100	200
New Test (with 99% PPA/NPA)	99 (+1 false negative)	99 (+1 false positive)	200
Reality from Accurate Test	120	80	200
New Test Accuracy	**82.5%** (99 of 120 correct)	**80.8%** (80 of 99 correct)	

66. For this reason, it was critical that Talis's EUA submission use a high quality, sensitive comparator assay that correctly identified the SARS-CoV-2 virus and minimized false negative results. The John Hopkins Center Bloomberg School of Public Health's Center for Health Security has explained that sensitivity "measures the proportion of positive test results out of all

truly positive samples. In other words, a test's sensitivity is its ability to correctly identify those with the disease (the true positives) while minimizing the number of false negative results."[6]

67. Given the importance of the comparator assay, the FDA specified that applicants should use "only" a "high sensitivity" comparator assay. The FDA's Molecular Diagnostic Template for Commercial Manufacturers (July 28, 2020) stated:

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)."

b) "If available, FDA recommends selecting a comparator assay that has established high sensitivity with an internationally recognized standard or the FDA SARS-CoV-2 Reference Panel. Please contact CDRH-EUA-Templates@fda.hhs.gov to discuss options to establish sensitivity."

68. Contrary to the FDA's guidance, Talis used an insufficiently sensitive comparator assay. FE-2—the former Talis senior scientist with a Ph.D. in molecular genetics—described performance issues with the original comparator assay used by Talis and indicated that the Company had chosen a weak comparator assay.

69. The EUA submission resulting from Talis's flawed process and selection of a low sensitivity comparator assay was deceptive because it compared the Talis One's performance to a useless benchmark. However, the Registration Statement extensively touted positive information about the Talis One's purported testing and the EUA submission, claiming that the Talis One had been tested against "FDA-authorized" comparator tests and that the Talis One displayed "high PPA and NPA [that] is suggestive of clinical sensitivity and specificity." The Registration Statement further 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

[6] *See* https://www.centerforhealthsecurity.org/resources/COVID-19/COVID-19-fact-sheets/201207-sensitivity-specificty-factsheet.pdf A related term, specificity, "measures the proportion of negative test results out of all truly negative samples. In other words, a test's specificity is its ability to correctly [identify] those without the disease (the true negatives) while minimizing false positive results." *Id.*

platform," and claimed that the Talis One "demonstrated a limit of detection for SARS-CoV-2 of ≤500 viral particles per milliliter."

70. Before the IPO, the FDA requested additional information from Talis. The Registration Statement cryptically stated that "[d]uring its preliminary review of our EUA submission, the FDA requested that we provide it with additional information on our test prior to initiating its substantive review of the submission, which we expect to promptly provide," without disclosing any detail about the "additional information" the FDA requested.

71. Nowhere did the Registration Statement disclose the critical fact that Talis had used a comparator assay that lacked sufficient sensitivity to support its EUA submission under FDA standards, as the FDA confirmed only days after the IPO.

D. Defendants Raise Over $250 Million in the IPO Using a Materially False and Misleading Registration Statement; Talis's Share Price Temporarily Pops

72. Pursuant to the materially false and misleading Registration Statement, Defendants completed the IPO on February 11, 2021, and 15,870,000 shares of Talis common stock (including 2,070,000 shares sold pursuant to the exercise in full by the underwriters of their option to purchase additional shares) were offered at $16.00 per share. The IPO raised $253.9 million for Talis (before deducting underwriting discounts and commissions and offering expenses).

73. Talis's common stock began trading on the NASDAQ on February 12, 2021. In the first day of trading, the share price popped to $27.80.

E. The FDA Swiftly Rejects the Comparator Assay Used in Talis's EUA Submission

74. Shortly after the IPO, in late February 2021, the FDA concluded that the comparator assay Talis used was not of "sufficient sensitivity to support Talis's EUA application." Rather than promptly disclosing this material event in a Form 8-K, Talis did not reveal the FDA's rejection for over a week.

75. On March 8, 2021, Talis issued a press release titled "Talis Provides Update on Regulatory Pathway for Emergency Use Authorization (EUA) of its Talis One™ COVID-19 Test." The press release revealed that:

> [Talis] has withdrawn its current application pursuing U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA)

> for the Talis One™ COVID-19 test . . . . In late February, the FDA informed the company that it cannot ensure the comparator assay used in the primary study has sufficient sensitivity to support Talis's EUA application.
>
> Talis intends to initiate its previously planned clinical validation study in a point-of-care environment, with plans to submit an EUA application for the Talis One COVID-19 test in CLIA waived settings early in the second quarter of 2021. The planned clinical validation study was designed with a different comparator assay, which Talis believes will address the FDA's concerns.

76. This news drove a 12.3% decline in Talis's share price and left Talis stock trading at $12.85 on March 8, 2021—well below the $16.00/share IPO price, and less than half of its $27.80 peak.

F. As the Delays Continue, the Exchange Act Defendants Double Down, Claiming to Be "Ready to Go" and Touting "Terrific" Results

77. After March 8, 2021, Talis's share price continued to stagnate, reaching $11.20 on March 29, 2021—at the time, its lowest price at any point since the IPO.

78. The Exchange Act Defendants' top priority was restoring the Company's credibility with investors and presenting a viable path to commercial launch, regardless of the current facts on the ground. In this context, the Exchange Act Defendants doubled down on their assurances about Talis's purportedly concrete progress towards manufacturing the Talis One at scale.

a. March 30, 2021: Talis Reports 2020 Earnings

79. The Class Period under the Exchange Act begins on March 30, 2021, when Talis filed its annual report on Form 10-K announcing its full-year 2020 financial results (the "2020 10-K").

80. Talis's 2020 10-K stated that "[w]e have ordered 5,000 instruments from our instrument contract manufacturing partners to be delivered through the third quarter of 2021." Likewise, Talis claimed to 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."

81. These affirmative statements sent a clear, positive message to the market: the failure of the first EUA submission was only a temporary setback, and Talis had taken concrete steps toward production and remained capable of commercializing the Talis One on the same timetable it had communicated before the IPO. The market responded positively, as intended: on March 31, 2021, the day after the 2020 10-K filing, Talis stock rose 12.72%.

82. The truth was very different from the Exchange Act Defendants' positive public statements. In fact: (a) Talis had, at most, ordered the components for 5,000 instruments (not 5,000 instruments), which would then require costly and time-consuming assembly and testing before they could be sold; (b) the Exchange Act Defendants had no basis to claim that cartridge manufacturing lines would "scale to full capacity" of "one million Talis cartridges per month" at any point in 2021; and (c) the Exchange Act Defendants knew that the Talis One suffered from design issues and high invalid rates that foreclosed and/or dramatically delayed commercial production. As detailed below, the Exchange Act Defendants knew these facts at the time.

83. Over the next several months, as investor skepticism mounted, the Exchange Act Defendants continued to saturate the market with false and misleading assurances that created an impression of a materially different state of affairs than actually existed.

b. May 11, 2021: Talis Reports First Quarter 2021 Earnings; "On Track" and "Ready to Go"

84. On May 11, 2021, Talis filed a Form 8-K with the SEC attaching a press release disclosing its results for the first quarter of 2021, and held a related investor earnings call. On May 13, 2021, Talis filed its quarterly report on Form 10-Q announcing results for the first quarter of 2021 (the "1Q21 10-Q").

85. The press release stated that Talis was "[o]n-track to complete a clinical validation study for Talis One COVID-19 assay in a point-of-care environment to support an Emergency Use Authorization application submission to the FDA in the second quarter of 2021."

86. On the manufacturing front, the 1Q21 10-Q stated that Talis had "ordered 5,000 Talis One instruments from our instrument contract manufacturer," and further claimed that automated cartridge manufacturing lines were expected to "scale to meet demand through 2021."

87. During the May 11, 2021 earnings call, a JPMorgan analyst sought clarification on whether Talis still expected to reach a production capacity of one million cartridges per month. Defendant Moody assured the analyst that Talis was "on track" and "on plan":

> [Analyst:] 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 cartridge 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?

88. Defendant Moody responded:

> 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 throughout 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.

89. A Bank of America analyst probed further, asking "hypothetically, after approval, how soon can you ship the product out to the customers? I'm just trying to get at if there's any change to the product revenues for the rest of the year." Defendant 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.

90. These statements were false and misleading when made. Talis did not have a realistic timeline to manufacture its product (FE-2), used overly aggressive timelines with no basis (FE-3), and was significantly behind its internal deadlines by the end of 2020 (FE-1); it was not possible to go from a prototype to full production at volume—a 100-fold increase (FE-1). Talis also had no scheduling buffer to account for issues that might arise (FE-1, FE-2). FE-3 had briefed Coe over several weeks in May 2021 about the serious issues with the manufacturing timelines for the Talis One, and FE-1 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. FE-1 indicated that Coe's claim that Talis was "ready to go" into production upon receiving an EUA had no basis. Corroborating FE-1's account, FE-5—who joined Talis in September

2021—confirmed that despite claims from the Company, Talis was not ready to begin manufacturing as soon as the EUA was received. Further, the Talis One continued to generate high invalid rates even in late 2021, as FE-4 confirmed.

c. August 10, 2021: Talis Reports Second Quarter 2021 Earnings; Defendants First Admit Delays, But Tout "Terrific" Results and Claim That Cartridge Production Lines Are in the "Final Stages of Validation"

91. On August 10, 2021, Talis filed a Form 8-K with the SEC attaching a press release disclosing its results for the second quarter of 2021 (the "2Q21 8-K"), held a related investor earnings call, and filed its quarterly report on Form 10-Q announcing results for the second quarter of 2021 (the "2Q21 10-Q").

92. During Talis's August 10, 2021 earnings call, Defendant Coe stated that "development time lines have been extended by delays in the launching of [Talis's] COVID-19 test and manufacturing scale." As a result, Talis "expect[ed] to see [its] first meaningful revenue ramp in 2022." This was the Exchange Act Defendants' first public admission that the timelines they had previously touted were not achievable—a fact they had known months earlier.

93. Nonetheless, the Exchange Act Defendants sought to blunt this negative information with positive affirmations of progress. Defendant Coe's opening remarks sought to deflect attention from Talis's late EUA submission and extended timeline, asserting that "variability in COVID testing demand makes it difficult to project the precise ramp of our commercial launch." An analyst from Bank of America expressed skepticism, given that Talis had already experienced delays:

> But I mean, you missed your first EUA, your products are delayed. Basically, what you 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?

94. In response, Defendant Coe touted "terrific" results, claiming Talis was "way ahead on our ability to produce product":

> 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.

But Talis did not have "terrific" results and was not "way ahead." Rather, as alleged herein, the Talis One continued to suffer from a high invalid rate that foreclosed and/or dramatically delayed commercial production, as Defendants eventually admitted after Coe was terminated.

95. Another focus area was on Talis's ability to produce cartridges at scale. Chief Operating Officer Liu stated that the cartridge production lines were "in the final stages of validation":

> During the second quarter, we modified and improved the first set of automated lines that were supplied earlier this year. At this time, we have completed installation and are in the final stages of validation. These lines have been used to produce thousands of cartridges. We are making final adjustments and expect to have the cartridges from these lines for commercial launch upon receiving our EUA.

96. Similarly, the 2Q21 8-K claimed that the Company had "[c]ompleted installation and [was] in the final stages of validation for the first set of automated cartridge production lines."

97. Importantly, 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: "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."[7] Statements 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.

98. An analyst from BTIG sought to double-check that Talis would in fact be ready to commercialize the Talis One and produce cartridges upon receipt of the EUA:

> And then I also wanted to ask about maybe a clarification around – you're in the final stages of validating the first set of automated cartridge production lines. I think I heard you guys say that you do think you'll be ready to go, ready to commercialize product upon

[7] Global Harmonization Task Force, Quality Management Systems – Process Validation Guidance (2004), *available at* https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n99-10-2004-qms-process-guidance-04010.pdf

> receipt of the EUA. So I guess, do you have a sense for what your -- how many cartridges you could manufacture? Let's just call it, October, November, December. What that number looks like? And what else needs to be done just to make sure you're ready to go?

99. In response, Chief Operating Officer Liu again emphasized that the cartridge production lines were in the "final steps of validation":

> We are, as mentioned earlier, we have invested in 3 sets of lines. The first one has been installed, and we're in the final steps of validation. We haven't completed them yet, but our objective and our belief is that we will be able to meet this, that we will be able to have those lines ready to go and producing product to meet demand upon receipt of the EUA. So in terms of further ramp-up beyond that, we have invested in additional production lines, and they are essentially built. We haven't installed them yet, but the facilities to receive them exist. And so if demand warrants it, which we'll be monitoring, we'll be moving forward with additional capacity on an ongoing basis.

100. These false and misleading statements concealed the reality that Talis was nowhere near the "final steps" or "final stages of validation" on the cartridge manufacturing lines in August 2021, as Defendants later admitted by revealing that they were only "beginning to evaluate the performance of cartridges" in November 2021. FE-5—a former associate director of technical implementation—confirmed that Talis had not validated its production lines, which was significant and one of the major factors in not launching the Talis One.

d. August 30, 2021: CEO Coe Departs Abruptly

101. On August 30, 2021, Talis announced that Defendant Coe had "stepped down" as its President, CEO, and Director, effective immediately. Talis offered no explanation for Defendant Coe's abrupt departure, and, without a permanent replacement, appointed its Chairman of the Board, Defendant Kimberly J. Popovits, as Interim CEO. 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.

e. November 15, 2021: Talis Reports Third Quarter 2021 Earnings

102. On November 8, 2021, Talis reported that it had finally obtained an EUA for the Talis One COVID-19 test. On November 15, 2021, Talis filed a Form 8-K with the SEC attaching a press release disclosing its results for the third quarter of 2021 (the "3Q21 8-K") and held a

related investor earnings call. On November 16, 2021, Talis filed its quarterly report on Form 10-Q announcing results for the third quarter of 2021 (the "3Q21 10-Q").

103. The 3Q21 8-K stated that Brian Blaser had been appointed as President, CEO, and Director of Talis, effective December 1, 2021.

104. During the November 15, 2021 earnings call, Interim CEO Popovits revealed that Talis would execute a "controlled product rollout" using a "measured approach." 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 begin "in the first quarter of 2022" that would involve "a small number of sites representative of the customers we are targeting . . . ." This delayed timeline and small-scale commercial introduction recognized that the Company was currently unprepared and unable to manufacture the Talis One at scale.

f. December 8, 2021: New CEO Blaser Leaves After Only a Week Due to Major Fraud

105. Blaser became Talis's CEO on December 1, 2021. Only a week later, on December 8, 2021, Talis announced that, Brian Blaser had "stepped down" from his positions as President, CEO, and Director effective immediately. 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.

g. March 15, 2022: 2021 Earnings Call; First Disclosure of High Invalid Rates and External Review of Design and Manufacturing; COO Liu Out

106. The Class Period ends on March 15, 2022, when Talis—in its first financial reporting under its new CEO, Defendant Kelley—reported a barrage of new, negative information.

107. As explained above, in its prior earnings call, Talis had described a "phased" launch of the Talis One to begin in the first quarter of 2022. On March 15, 2022, however, Talis revealed that it "has not started its phased launch of the Talis One™ COVID-19 Test System due to challenges with manufacturing. The company has engaged in a manufacturing review process to determine appropriate next steps and undertaken initiatives to align resources and preserve cash."

108. During the Company's March 15, 2022 conference call, 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." Moreover, Kelley stated that "based on the level of information we have today, we are not providing a timeline for commercial launch."

109. Further, during the same conference call, Kelley disclosed that "the rate of invalid or failed tests remains higher than what we believe is acceptable." This was Defendants' first public recognition—over a year after the IPO—that the Talis One suffered from high invalid rates. Even then, Kelley misleadingly implied that this was a recent development, stating that "we had begun premarketing studies to get feedback from customers. And we actually suspended that because we started to identify that this invalid rates [sic] were high enough that they weren't going to be putting our best foot forward with customers." In reality, the high invalid rates had plagued the device since before the IPO (FE-2) and continued thereafter (FE-4, FE-5).

110. In addition, while Defendants had claimed to be in the "final stages of validation" of Talis's cartridge production in August 2021, that was not the case. On March 15, 2022, Kelley stated: "When we spoke with you back in November, we were beginning to evaluate the performance of cartridges coming off our high-yield lines," thereby conceding that the Company had not extensively scrutinized the performance of the production lines and resulting cartridges in August 2021, as a proper validation required. FE-5 confirmed that Talis had not validated its production lines, which was significant and one of the major factors in not launching the Talis One.

111. Moreover, while Talis had consistently claimed in its prior SEC filings to have "ordered 5,000 Talis One instruments from our instrument contract manufacturer" (as detailed above), Talis's Form 10-K for 2021, filed on March 15, 2022, revealed a materially different truth, stating: "We have ordered components for up to 5,000 instruments from our instrument contract manufacturing partners." In other words, the Company had not ordered "instruments," as it had claimed; it had merely ordered "components" that would require time-consuming and costly assembly and testing.

112. On March 15, 2022, Talis further disclosed that it had engaged external consultants "to assess product design for manufacturing at scale, evaluate current processes and partners, and

to determine appropriate next steps and timing for bringing the Talis One system to market," and that the Company was laying off approximately 25 percent of its workforce. In addition, Talis revealed that Chief Operating Officer Liu was stepping down.

113. The fact that, over a year after the IPO, Talis was admittedly experiencing unacceptable levels of invalid and failed tests, unable to manufacture the Talis One at scale, unwilling to provide a timeline for commercial launch, and had engaged outside consultants to review the product's design and manufacturing confirmed that Talis had never been "ready to go," as Defendant Coe had falsely claimed.

h. May 10, 2022 First Quarter 2022 Earnings Call: No Timetable for Commercial Production

114. Finally, on May 10, 2022, Talis reported earnings for the first quarter of 2022 and held an earnings call regarding its results. During the call, CEO Kelley conceded that the Company does not expect the Talis One to make a "significant revenue contribution" in 2022.

115. Further, Kelley stated that the external review was complete, and that based on its results, Talis would be "implementing modifications around manufacturing processes, quality controls and supply conformance." While Kelley stated that only "minor design modifications" would be needed, more tellingly, he cautioned that Talis might not even be able to begin its "phased" launch in 2022, explaining that "we have a strategic objective this year to do a phased launch. And the first phase of that launch we're hoping to squeeze into 2022 if all goes well."

116. Kelley also tacitly recognized that Talis had missed the boat on generating meaningful revenue and profits from the Talis One COVID-19 test, stating in response to an analyst that "[t]he rationale for us moving forward with COVID at this point in time is not just to get COVID sales. It's to prove our system, right? . . . So even if there's not a huge amount of adoption of our system for COVID, getting the system into the market is going to be huge for us."

117. Unsurprisingly, after nearly 18 months of false promises with no commercially available product, the market has essentially given up on Talis as a viable company. On May 10, 2022, Talis filed a Form S-3 registration statement indicating that its largest shareholder—Baker Bros. Advisors LP and related entities—seeks to sell its entire stake in Talis, comprised of

37,489,210 shares of common stock (including the conversion of preferred shares)—or 66% of Talis's total outstanding voting stock.

118. As of June 30, 2022, Talis common stock traded at $0.81 per share.

IV. SECURITIES ACT ALLEGATIONS

119. In this section of the Complaint, Lead Plaintiffs assert strict liability claims based on Sections 11 and 15 of the Securities Act on behalf of all persons and entities that purchased or otherwise acquired Talis's common stock pursuant and/or traceable to the Registration Statement issued in connection with the Company's February 2021 initial public offering, and were damaged thereby. Lead Plaintiffs expressly disclaim any allegations of fraud or intentional misconduct in connection with these claims, which are non-fraud claims and pleaded separately in this Complaint from Lead Plaintiffs' Exchange Act Claims.

120. For the avoidance of doubt, all the statements and omissions that Lead Plaintiffs allege to be actionable under the Securities Act are included in the section below titled "Securities Act False and Misleading Statements and Omissions."

A. Securities Act Parties

a. Securities Act Plaintiffs

121. Martin Dugan ("Dugan") is an individual residing in Malibu, California.

122. Leon Yu ("Yu") is an individual residing in Beijing, China.

123. Max Wisdom Technology Limited ("Max Wisdom") is a company incorporated in Hong Kong.

124. Lead Plaintiffs purchased or otherwise acquired Talis common stock pursuant and/or traceable to the Registration Statement, as set forth in the Certifications attached hereto as Exhibits A-C. For instance, on February 12, 2021, Leon Yu purchased 2,004 shares of Talis common stock, on February 16, 2021, Max Wisdom purchased 1,628 shares of Talis common stock, and on March 26, 2021, Dugan purchased 2,000 shares of Talis common stock.

125. As a result of material misstatements and omissions made by the Securities Act Defendants (defined below), Lead Plaintiffs purchased or otherwise acquired Talis common stock at artificially inflated prices. When the relevant truth concerning the Securities Act Defendants'

misstatements and omissions of material fact leaked out into the market from March 2021 to March 2022, the price of Talis stock fell, causing Lead Plaintiffs and the Class to suffer losses.

b. Securities Act Defendants

126. Each of the following Defendants is statutorily liable under Sections 11 and/or 15 of the Securities Act for the material misstatements and omissions contained in and incorporated in the Registration Statement.

127. Defendant Talis is a U.S. medical diagnostic company. Talis is incorporated in Delaware with its principal executive offices at 230 Constitution Drive, Menlo Park, California 94025. Talis common stock trades on the NASDAQ under the ticker symbol "TLIS." Talis was the issuer of the IPO.

128. Defendant Brian Coe ("Coe") is one of Talis's co-founders and served as Talis's President and Chief Executive Officer and a member of the Company's Board of Directors from June 2013 until his abrupt departure on August 30, 2021. Coe signed the Registration Statement for the IPO. During his tenure at Talis, Coe had the power and authority to, and in fact did, approve and control the contents of the Registration Statement. Coe also was a member of Talis's Board of Directors at the time of the IPO.

129. Defendant J. Roger Moody, Jr. ("Moody") has served as the Company's CFO since he joined Talis in May 2020. Moody signed the Registration Statement for the IPO. During his tenure at Talis, Moody had the power and authority to, and in fact did, approve and control the contents of the Registration Statement.

130. Defendant Felix Baker ("Baker") has served as a member of Talis's Board of Directors since June 2013. Baker signed the Registration Statement for the IPO.

131. Defendant Raymond Cheong ("Cheong") served as a member of Talis's Board of Directors from June 2020 until June 10, 2022. Cheong signed the Registration Statement for the IPO.

132. Defendant Melissa Gilliam ("Gilliam") has served as a member of Talis's Board of Directors since December 2020. Gilliam signed the Registration Statement for the IPO.

133. Defendant Rustem F. Ismagilov ("Ismagilov") is a co-founder of the Company and has served as a member of Talis's Board of Directors since June 2013. Ismagilov signed the Registration Statement for the IPO.

134. Defendant Kimberly J. Popovits ("Popovits") has served as a member of Talis's Board of Directors since March 2020. Popovits signed the Registration Statement for the IPO.

135. Defendant Matthew L. Posard ("Posard") has served as a member of Talis's Board of Directors since March 2016. Posard signed the Registration Statement for the IPO.

136. Defendant Randal Scott ("Scott") has served as a member of Talis's Board of Directors since February 2016. Scott signed the Registration Statement for the IPO.

137. Coe, Moody, Baker, Cheong, Gilliam, Ismagilov, Popovits, Posard, and Scott are collectively referred to herein as the "Individual Defendants."

138. Talis and the Individual Defendants are collectively referred to herein as the "Securities Act Defendants."

B. Securities Act False and Misleading Statements and Omissions

139. On October 15, 2020, Talis confidentially filed a draft registration statement with the SEC. After exchanging correspondence with the SEC, on January 22, 2021, Talis filed its registration statement on Form S-1 (the "Registration Statement"), including a preliminary prospectus with the same date.

140. On February 8, 2021, Talis filed an Amendment No. 1 to the Registration Statement on Form S-1, including a revised preliminary prospectus with the same date.

141. On February 11, 2021, Talis filed an Amendment No. 2 to the Registration Statement on Form S-1, including a revised preliminary prospectus with the same date. At 4:30 PM on February 11, 2021, Talis's Registration Statement was declared effective.

142. Talis shares began trading on NASDAQ on February 12, 2021.

143. Finally, on February 12, 2021, pursuant to Rule 424(b)(4), Talis filed the final prospectus, dated February 11, 2021 (the "Final Prospectus"). The Final Prospectus and various previously filed exhibits are incorporated into the Registration Statement.

144. The Registration Statement contained materially false and misleading statements and omissions 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, the Registration Statement omitted material information about known uncertainties and specific risks in violation of applicable SEC rules and regulations. These material statements and omissions, and the grounds for falsity as to each, are detailed below.

a. Materially False and Misleading Statements Concerning the Testing of the Talis One and the Data Submitted to the FDA

145. Particularly because the Talis One COVID-19 test was slated to be Talis's first product, the results of pre-clinical and clinical testing, the data provided with Talis's EUA submission to the FDA, and whether it complied with FDA guidance were of critical importance to investors.

146. The Registration Statement touted the results from multiple purported analyses of the Talis One, detailing a preclinical assessment on 60 samples, a larger assessment of 300 samples, and a clinical validation study on 66 samples submitted to the FDA:

> 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.

		Comparator Test		
		Positive	Negative	Total
Talis One	Positive	29	0	29
	Negative	0	31	31
	Total	29	31	60
		Positive percentage agreement (PPA)		100.0%
		Negative percentage agreement (NPA)		100.0%

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 98.5% PPA (194 of 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.

		Comparator Test		
		Positive	Negative	Total
Talis One	Positive	194	1*	195
	Negative	6**	99	105
	Total	200	100	300
		Positive percentage agreement (PPA)		97.0%
		Negative percentage agreement (NPA)		99.0%

* Specimen tested negative by the tie-breaker test.
** Three specimens tested negative and three specimens tested positive by the tie-breaker test.

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 . . .

		Comparator Test		
		Positive	Negative	Total
Talis One	Positive	32	2*	34
	Negative	1	31	32
	Total	33	33	66
		Positive percentage agreement (PPA)		97.0%
		Negative percentage agreement (NPA)		93.9%

*Both specimens tested positive by the tie-breaker test.

> . . . 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.

147. These statements were materially false and misleading when made. First, 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. As detailed above, before the IPO, Talis had chosen a weak comparator assay for its submission, and the FDA had already requested "additional information" from Talis, strongly

suggesting that the FDA had raised concerns about the comparator assay before the IPO. In failing to disclose these existing, material negative facts, the Registration Statement omitted material facts necessary to make the statements not misleading in the context in which they were made. Second, 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 on the Talis One platform" were false because (a) the purported "high PPA and NPA" was "driven by" Talis's choice of a weak comparator assay, not the "very low limits of detection possible on the Talis One platform," and (b) the purported "high PPA and NPA" merely indicated agreement with a weak comparator assay, and therefore were not "suggestive of clinical sensitivity and specificity in the broader clinical population."

148. The Registration Statement also stated:

> During its preliminary review of our EUA submission, the FDA requested that we provide it with additional information on our test prior to initiating its substantive review of the submission, which we expect to promptly provide.
>
> …

149. This statement was materially misleading when made because, having chosen to speak about the EUA submission and the FDA's request for "additional information on our test," 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. As detailed above, before the IPO, Talis had chosen a weak comparator assay for its submission, and the circumstances strongly suggest that the FDA had raised concerns about the comparator assay before the IPO. In failing to disclose these existing, material negative facts, the Registration Statement omitted material facts necessary to make the statements not misleading in the context in which they were made.

150. The Registration Statement also stated:

> 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 EUA by the FDA.
>
> We may not be able to obtain marketing authorization for our Talis One platform or for any test.

> There can be no assurances that the FDA will authorize either of these requests and if we do not receive both authorizations, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

151. These purported risk disclosures were materially misleading when made because they omitted the existing, material negative fact that 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. As detailed above, before the IPO, Talis had chosen a weak comparator assay for its submission, and the FDA had already requested "additional information" from Talis, strongly suggesting that the FDA had raised concerns about the comparator assay before the IPO. By portraying the FDA's rejection of Talis's EUA submission and resulting adverse effects on Talis's business, financial condition, results of operations, and future growth prospects as merely hypothetical risks, rather than known certainties, the Registration Statement omitted material facts necessary to make the statements not misleading in the context in which they were made. Indeed, the FDA's rejection manifested itself just days after the IPO.

b. Materially False and Misleading Statements Concerning Talis's Manufacturing Capability

152. Talis's ability to quickly manufacture the Talis One at scale was of critical importance to investors given increasing vaccination rates and a crowded market for COVID-19 molecular diagnostic tests.

153. The Registration Statement stated:

> 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.
>
> …
>
> *Low cost to manufacture*—We designed the Talis One platform to be low-cost and manufactured at scale.

154. These statements were materially false and misleading when made. First, Talis had no basis to claim that cartridge production "will scale to full capacity" of "one million cartridges per month" in 2021; as detailed above, production at that scale in 2021 was not possible. Second,

having chosen to speak about Talis's purported investment in automated cartridge production lines and their capacity and timetable for operation, as well as the Talis One's ability to be manufactured at scale and with low cost, 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. In failing to disclose these existing, material negative facts, the Registration Statement omitted material facts necessary to make the statements not misleading in the context in which they were made.

155. The Registration Statement also stated:

> 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.

156. 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. Both aspects of the statement were false. In its Form 10-K filed on March 30, 2021, Talis admitted that it had actually "ordered 5,000 instruments from our instrument contract manufacturing partners to be delivered through the third quarter of 2021"—two quarters after the Registration Statement claimed. Further, in Talis's Form 10-K filed on March 15, 2022, Talis admitted that it had ordered "components for up to 5,000 instruments"—not the instruments themselves, as the Registration Statement claimed. For both reasons, the statement in the Registration Statement was false. Moreover, in failing to disclose the existing facts that Talis had only ordered components for up to 5,000 instruments to be delivered through the third quarter of 2021, the Registration Statement omitted material facts necessary to make the statements not misleading in the context in which they were made.

c. Materially False and Misleading Statements Concerning the Talis One's Performance and Reliability

157. At the time of the IPO, Talis had no product on the market. The Talis One COVID-19 test would be Talis's first product offering, and it was critical that the Talis One

COVID-19 test capture market share quickly given intense competition as well as the dwindling need for COVID-19 tests in light of increasing vaccination rates. Thus, the performance, function, and reliability of the Talis One were of critical importance to the Company's business model and to investors.

158. The Registration Statement stated:

> The test cartridge for COVID-19 diagnosis contains a NAAT designed for optimal sensitivity and specificity to provide highly accurate results. The assay on the Talis One cartridge is an isothermal NAAT targeting two physically separated locations in the SARS-CoV-2 genome to increase sensitivity and inclusivity. While natural evolution of the SARS-CoV-2 virus is to be expected, the inclusion of two distinct targets reduces the likelihood that natural mutations in the virus would cause a false negative result when using the Talis One COVID-19 test.
>
> …
>
> 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.
>
> …
>
> In addition, our platform is designed to be operated by untrained personnel and incorporate safety and convenience features, including automated cartridge-based sample preparation for reliable results, closed cartridges to mitigate contamination, room-temperature cartridge storage for convenient storage, and cloud connectivity for easily accessed results and records.

159. These statements were materially false and misleading when made. First, the Talis One did not "provide highly accurate results" and was not "just as accurate and reliable as central lab testing." Rather, as detailed above, the Talis One had a high invalid rate well before the Company submitted its first EUA application, as well as after the IPO, driven by two non-functional parts, a gasket and a plastic piece. Further, the Talis One suffered from design issues, such as the size of the cartridges, which had some chambers that were too small for proper Limits of Detection. Second, having chosen to speak about the accuracy, reliability, safety, and convenience of the Talis One, the Registration Statement omitted important facts about the Talis One's high invalid rates and design problems. In failing to disclose these existing, material

negative facts, the Registration Statement omitted material facts necessary to make the statements not misleading in the context in which they were made.

160. Further, the Registration Statement stated:

> If our products do not perform as expected, including due to errors, defects or reliability issues, our reputation and market acceptance of our products could be harmed, and our operating results, reputation and business will suffer. . . . 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.
>
> …
>
> 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, or those developed in the future, 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 result in longer than expected turnaround times or they may cause our products to malfunction.
>
> …
>
> Unfavorable results from ongoing preclinical and clinical studies could result in delays, modifications or abandonment of ongoing analytical or future clinical studies, or abandonment of a product development program, or may delay, limit or prevent regulatory approvals or clearances or commercialization of our products, any of which may materially adversely affect our business, financial condition and results of operations. Furthermore, results that would be sufficient for regulatory approval may not demonstrate strong performance characteristics, limiting the market demand for the platform, which would adversely affect our business.

161. These purported risk disclosures were materially misleading when made because they omitted the existing, material negative facts about the Talis One's high invalid rates and design problems. As detailed above, the Talis One had a high invalid rate well before the Company submitted its first EUA application, as well as after the IPO, driven by two non-functional parts, a gasket and a plastic piece. Further, the Talis One suffered from design issues, such as the size of the cartridges, which had some chambers that were too small for proper Limits of Detection. By portraying errors, defects, reliability, accuracy, and other performance issues as merely

hypothetical risks, rather than known certainties, the Registration Statement omitted material facts necessary to make the statements not misleading in the context in which they were made.

d. The Registration Statement Omitted Material Information in Violation of Item 105 and Item 303 of SEC Regulation S-K

162. In addition to the materially false and misleading statements detailed above, the Registration Statement contained material omissions in violation of applicable SEC rules and regulations.

163. Specifically, Item 303 of SEC Regulation S-K ("Item 303") required Talis to disclose known trends or uncertainties that have had, or that Talis reasonably expects will have, a material favorable or unfavorable impact on net sales or revenues or income from continuing operations. The failure to disclose a material trend or uncertainty in violation of Item 303 is an omission that is actionable under the Securities Act. As relevant here, Item 303 required Talis to:

> Describe 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. If the registrant knows of events that will cause a material change in the relationship between costs and revenues (such as known future increases in costs of labor or materials or price increases or inventory adjustments), the change in the relationship shall be disclosed.[8]

164. The SEC's May 18, 1989 interpretive release (No. 33-6835) provides a two-step test to determine whether disclosure under Item 303 is required:

> Where a trend, demand, commitment, event or uncertainty is known, management must make two assessments:
>
> (1) Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.
>
> (2) If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management

[8] Certain amendments to Item 303 became effective on February 10, 2021. While the amendments do not apply to the Registration Statement because it did not include financial statements issued after the amendment, the language quoted above is substantially similar in the amended version of Item 303.

> determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur.

165. The 1989 interpretive release emphasizes that "[e]vents that have already occurred or are anticipated often give rise to known uncertainties," and provided the example of a "material government contract that is about to expire":

> Events that have already occurred or are anticipated often give rise to known uncertainties. For example, a registrant may know that a material government contract is about to expire. The registrant may be uncertain as to whether the contract will be renewed, but nevertheless would be able to assess facts relating to whether it will be renewed. More particularly, the registrant may know that a competitor has found a way to provide the same service or product at a price less than that charged by the registrant, or may have been advised by the government that the contract may not be renewed. The registrant also would have factual information relevant to the financial impact of non-renewal upon the registrant. In situations such as these, a registrant would have identified a known uncertainty reasonably likely to have material future effects on its financial condition or results of operations, and disclosure would be required.

166. Before the Offering, Talis knew that its EUA submission was deficient because Talis had used a comparator assay that lacked sufficient sensitivity to support the submission under FDA standards. Thus, the FDA's rejection of the flawed comparator assay was a known uncertainty that was having, and that Talis reasonably expected would have, a material unfavorable impact on the Company's revenues, net sales, and income. Before the Offering, Talis also knew that the Talis One suffered from a high invalid rate that foreclosed and/or dramatically delayed commercial production—another known uncertainty that Talis reasonably expected would have a material unfavorable impact on the Company's revenues, net sales, and income. In violation of Item 303, the Registration Statement omitted these known facts.

167. Further, Item 105 of SEC Regulation S-K ("Item 105") required the Registration Statement to discuss the material factors that make an investment in Talis or the Offering speculative or risky. Talis's Registration Statement failed to disclose the material risks resulting from Talis's use of a comparator assay that lacked sufficient sensitivity to support its EUA submission under FDA standards, and the material risk that the Talis One's known high invalid rate foreclosed and/or dramatically delayed commercial production. While the Registration

Statement provided boilerplate warnings that an EUA might not be granted or Talis's products might suffer from performance or reliability issues, these generic warnings did not cover the specific, known, material risks posed by the flawed comparator assay and high invalid rate. In violation of Item 105, the Registration Statement omitted these specific, known, and material risks.

C. The Individual Defendants Failed to Perform Reasonable Diligence Before the Offering

168. As the issuer, Talis is strictly liable under the Securities Act and has no defenses to liability. The Individual Defendants are also liable because they acted negligently and cannot establish any due diligence defense to liability.

169. The Individual Defendants failed to perform a reasonable investigation. Defendants Coe and Moody were officers of Talis, as its CEO and CFO, and were directly involved with the Talis One prior to the IPO. The remaining Individual Defendants, members of Talis's Board of Directors, are experienced medical diagnostics investors, executives, and scientists. For example, Defendant Baker holds a Ph.D. in immunology, has been active in biotechnology investing since the early 1990s, and serves on numerous corporate boards, while Defendant Cheong holds an M.D. and a Ph.D. in biomedical engineering from Johns Hopkins University. According to Talis's website, Defendant Popovits is the former CEO of Genomic Health; Defendant Posard is the founder of a life sciences and diagnostics consulting firm; Defendant Scott is the founder of a genomic medicine company; and Defendant Gilliam is "a highly accomplished physician and research scientist."[9] Defendant Ismagilov is one of Talis's co-founders and thus intimately familiar with its operations and the status of the Talis One at the time of the IPO. Such individuals are necessarily familiar with the EUA submission process and the design and manufacturing of diagnostic products, and had the Individual Defendants conducted a reasonable investigation, they could not have believed (or had reasonable ground to believe) that the Registration Statement contained no materially false or misleading statements or omissions.

170. The misstated and omitted facts that render the Registration Statement materially false and misleading existed at the time of the IPO and would have been discovered with a

[9] *See* https://talisbio.com/meet-our-team/

reasonable investigation. For example, the FDA's request for "additional information" in connection with Talis's EUA submission strongly suggests that the FDA had raised concerns about the comparator assay before the IPO. The FDA's request should have been carefully reviewed by the Individual Defendants in the exercise of reasonable care.

171. Similarly, in the exercise of reasonable care, the Individual Defendants should have reviewed the results of Talis's internal testing of the Talis One with regard to design problems and invalid rates, and reviewed Talis's timelines for production and whether Talis was meeting its internal deadlines for beta testing. Further, as described below, the RADx Contract (signed by Defendant Coe) required Talis "to provide data and reports (e.g., manufacturing, supply chain, production rates)" to the NIH, and provided that if "a milestone deliverable is delayed," Talis was "responsible for reporting the reason and providing an updated schedule." These data, reports, and schedules existed and would have been reviewed by the Individual Defendants in the exercise of reasonable care.

172. In the exercise of reasonable care, the Individual Defendants also should have evaluated the statement that Talis had ordered 5,000 instruments, including through the review of relevant contracts and other documentation.

173. Reviewing correspondence with the FDA, Talis's internal testing results; production timelines and results; data, reports, and schedules provided to the NIH; and contracts and other documentation supporting any orders of Talis One instruments or components was particularly important because the Talis One was slated to be Talis's first product, and the IPO was occurring at a crucial point when Talis's ability to quickly manufacture the Talis One at scale was of critical importance to investors.

174. A reasonable investigation would have uncovered the existing facts that (a) Talis's EUA submission failed to comply with FDA standards because it did not evaluate the Talis One COVID-19 test against a sufficiently sensitive comparator assay; (b) the Talis One suffered from design problems and high invalid rates identified before the IPO; (c) Talis did not have a realistic timeline for production, could not produce one million cartridges per month, and was already significantly behind its internal deadlines for beta testing; (d) the Talis One's high invalid rates

foreclosed and/or dramatically delayed commercial production; and (e) Talis had not ordered 5,000 instruments to be delivered between the fourth quarter of 2020 and the first quarter of 2021, but instead merely ordered "components for up to 5,000 instruments." In uncovering these facts, a reasonable investigation would also have revealed that the Registration Statement omitted known, material uncertainties and risks in violation of Item 303 and Item 105.

D. Talis's Share Price Collapses by the Time of Suit

175. Talis's common stock was offered in the IPO at $16 per share. By the time this action was filed on January 7, 2022, its price had fallen to $3.31 per share. Even then, its actual value was significantly lower, and after January 7, 2022, as described below, the price of Talis common stock further declined as the truth about Defendants' misstatements and omissions continued to emerge in piecemeal fashion.

V. EXCHANGE ACT ALLEGATIONS

A. Exchange Act Parties

a. Exchange Act Plaintiffs

176. Lead Plaintiffs Dugan, Yu, and Max Wisdom are described above.

177. Lead Plaintiffs purchased or otherwise acquired Talis common stock listed on the NASDAQ during the Class Period, as set forth in the certifications attached as Exhibits A-C, and suffered damages as a result of the violations of the federal securities laws alleged herein.

b. Exchange Act Defendants

178. Defendant Talis is described above.

179. Defendant Coe is described above. In addition to signing the Registration Statement, Coe signed and certified certain Forms 10-K and 10-Q that Talis filed during the Class Period and made false and misleading statements on conference calls with investors and analysts, as alleged specifically herein. During his tenure at Talis, Coe had the power and authority to, and in fact did, approve and control the contents of the Company's SEC filings alleged herein to be false and misleading.

180. Defendant Moody is described above. In addition to signing the Registration Statement, Moody signed and certified certain Forms 10-K and 10-Q that Talis filed during the

Class Period and made false and misleading statements on conference calls with investors and analysts, as alleged specifically herein. During his tenure at Talis, Moody had the power and authority to, and in fact did, approve and control the contents of the Company's SEC filings alleged herein to be false and misleading.

181. Defendant Robert J. Kelley ("Kelley") has served as Talis's CEO and a member of its Board of Directors since December 2021. Kelley joined Talis in September 2020 as Chief Commercial Officer. Kelley signed and certified Talis's report on Form 10-K filed with the SEC on March 15, 2022 and made false and misleading statements on conference calls with investors and analysts, as alleged specifically herein. During his tenure at Talis, Kelley had the power and authority to, and in fact did, approve and control the contents of the Company's SEC filings alleged herein to be false and misleading.

182. Defendants Coe, Moody, and Kelley are collectively referred to herein as the "Officer Defendants." Talis and the Officer Defendants are collectively referred to herein as the "Exchange Act Defendants."

B. False and Misleading Statements and Omissions

183. During the Class Period, the Exchange Act Defendants made 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."

184. As a result of the conduct and knowledge described above and in Section V.C below, the Exchange Act Defendants knew or recklessly disregarded that the following statements were materially false and misleading and/or omitted material facts necessary to make the statements not misleading in the context in which they were made.

a. False and Misleading Statements Made on March 30, 2021 and May 11, 2021

185. 2020 10-K. In Talis's 2020 10-K, filed with the SEC on March 30, 2021, Talis claimed to 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."

186. This statement was materially false and misleading when made because, as detailed above and below, the Exchange Act Defendants had no basis to claim that production lines "will scale to full capacity" of one million cartridges per month at any point in 2021. Rather, as detailed above and below, (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 Exchange Act Defendants knew that the Talis One suffered from design issues and high invalid rates that foreclosed and/or dramatically delayed commercial production. Having chosen to speak positively about Talis's cartridge production capacity, the 2020 10-K omitted these known, material negative facts, which were necessary to make the statements not misleading in the context in which they were made.

187. 1Q21 10-Q. Talis's 1Q21 10-Q, filed on May 11, 2021, stated:

> 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.

188. This statement was materially false and misleading when made because, as detailed above and below, the Exchange Act Defendants had no basis to claim that production lines "will scale to meet demand" and produce one million cartridges per month at any point in 2021. Rather, as detailed above and below, (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 Exchange Act Defendants knew that the Talis One suffered from design issues and high invalid rates that foreclosed and/or dramatically delayed commercial production. Having chosen to speak positively about Talis's cartridge production capacity, the 1Q21 10-Q omitted these known, material negative facts, which were necessary to make the statements not misleading in the context in which they were made.

189. 1Q21 Earnings Call. Also on May 11, 2021, Talis held its first quarter 2021 earnings call. During the Q&A portion of the call, a JPMorgan analyst asked for clarification on whether Talis still expected to reach a production capacity of one million cartridges per month:

> 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 cartridge 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?

Defendant Moody responded:

> 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 throughout 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.

190. During the same earnings call, a Bank of America analyst asked, "hypothetically, after approval, how soon can you ship the product out to the customers? I'm just trying to get at if there's any change to the product revenues for the rest of the year." Defendant 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.

191. The statements in ¶¶189-190 above were materially false and misleading when made because Talis was neither "on track" nor "ready to go" to begin production "in a very timely manner following an approval." Rather, as detailed above and below, (a) Talis did not have a realistic timeline for production; (b) Talis was already significantly behind its internal deadlines for beta testing; (c) the Exchange Act Defendants knew that the Talis One suffered from design issues and high invalid rates that foreclosed and/or dramatically delayed commercial production; (d) Coe was briefed over several weeks in May 2021 about the serious issues with the manufacturing timelines for the Talis One; and (e) Coe's claims that Talis was "ready to go" into production and able "to ship product in a very timely manner" upon receiving an EUA had no basis, as Talis was not ready to begin manufacturing as soon as the EUA was received. Having

chosen to speak positively about Talis's purported readiness to begin production, Defendants Coe and Moody omitted these known, material negative facts, which were necessary to make the statements not misleading in the context in which they were made.

b. False and Misleading Statements Made on August 10, 2021

192. 2Q21 8-K. On August 10, 2021, Talis announced its second quarter 2021 earnings on Forms 8-K and 10-Q filed with the SEC. In the 2Q21 8-K, Talis claimed that the Company had "[c]ompleted installation and [was] in the final stages of validation for the first set of automated cartridge production lines."

193. This statement was materially false and misleading when made because Talis was not in the "final stages of validation" on the cartridge manufacturing lines. As detailed above, "validation" is a technical term indicating that a process has been scrutinized and the result is practically guaranteed. Had 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. However, that was not the case. On March 15, 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. FE-5 confirmed that Talis had not validated its production lines, which was significant and one of the major factors in not launching the Talis One.

194. 2Q21 10-Q. Talis's 2Q21 10-Q, filed on August 10, 2021, stated:

> 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.

195. This statement was materially false and misleading when made because, as detailed above and below, the Exchange Act Defendants had no basis to claim that production lines "will scale to meet demand" and produce one million cartridges per month at any point in 2021. Rather, as detailed above and below, (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 Exchange Act Defendants knew that the Talis One suffered

from design issues and high invalid rates that foreclosed and/or dramatically delayed commercial production. Having chosen to speak positively about Talis's cartridge production capacity, the 2Q21 10-Q omitted these known, material negative facts, which were necessary to make the statements not misleading in the context in which they were made.

196. In addition, Talis claimed in its 2Q21 10-Q that "[t]he 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."

197. 2Q21 Earnings Call. During Talis's 2Q21 earnings call held on August 10, 2021, an analyst from Bank of America asked:

> But I mean, you missed your first EUA, your products are delayed. Basically, what you 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?

Defendant Coe responded:

> 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.

198. Similarly, an analyst from JPMorgan Chase & Co. asked:

> You talked a little bit about the phased approach rollout here. Can you talk a little bit about sort of the 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?

Defendant Coe responded:

> 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.

199. The statements in ¶¶196-198 above were materially false and misleading when made because, as detailed above and below, the Exchange Act Defendants had no basis to claim that Talis could complete its manufacturing "ramp up" in 2021, that the Company's "results really look terrific," that Talis was "way ahead on our ability to produce product," or that Talis was adopting a "phased approach" so that "if some small thing arises, [Talis could] react and make sure that everything exceeds customers' expectations" in order to achieve an "exceptional customer experience" and maintain "customer loyalty." Rather, as detailed above and below, (a) Talis did not have a realistic timeline for production; (b) Talis was already significantly behind its internal deadlines for beta testing; (c) the Exchange Act Defendants knew that the Talis One suffered from design issues and high invalid rates that foreclosed and/or dramatically delayed commercial production; (d) Coe was briefed over several weeks in May 2021 about the serious issues with the manufacturing timelines for the Talis One; and (e) Coe's claim that Talis was "ready to go" into production upon receiving an EUA had no basis, as Talis was not ready to begin manufacturing as soon as the EUA was received. Having chosen to speak positively about Talis's purported readiness to begin production, results, and the reasons for a "phased approach," the Exchange Act Defendants omitted these known, material negative facts, which were necessary to make the statements not misleading in the context in which they were made.

c. False and Misleading Statements Made on November 15 and 16, 2021

200. 3Q21 10-Q. Talis's 3Q21 10-Q, filed on November 16, 2021, stated:

> 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.

201. This statement was materially false and misleading when made because, as detailed above and below, the Exchange Act Defendants had no basis to claim that production lines "will scale to meet demand" and produce one million cartridges per month at any point in 2021. Rather, as detailed above and below, (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 Exchange Act Defendants knew that the Talis One suffered

from design issues and high invalid rates that foreclosed and/or dramatically delayed commercial production. Having chosen to speak positively about Talis's cartridge production capacity, the 3Q21 10-Q omitted these known, material negative facts, which were necessary to make the statements not misleading in the context in which they were made.

202. Talis further claimed in its 3Q21 10-Q that "[t]he 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."

203. 3Q21 Earnings Call. On 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 2021 financials were shaped by investments in launch preparation that are beginning to come to fruition.

204. The statements in ¶¶202-203 above were materially false and misleading when made because, as detailed above and below, the Exchange Act Defendants had no basis to claim that Talis could complete its manufacturing "ramp up" by "the end of 2021," or that Talis's purported "investments in launch preparation" were "beginning to come to fruition." Rather, as detailed above and below, (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 Exchange Act Defendants knew that the Talis One suffered from design issues and high invalid rates that foreclosed and/or dramatically delayed commercial production. Having chosen to speak positively about Talis's manufacturing progress, the Exchange Act Defendants omitted these known, material negative facts, which were necessary to make the statements not misleading in the context in which they were made.

205. During the November 15, 2021 call, an analyst from JPMorgan Chase & Co. asked:

> 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?

Defendant Kelley responded:

> 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.

206. The statement in ¶205 above was materially false and misleading when made because, as detailed above and below, Defendant Kelley had no basis to claim that Talis had "a great product" or had delayed the launch of the Talis One to avoid "damage to reputation" from "go[ing] to market with a product too quickly." Rather, as detailed above and below, (a) Talis did not have a realistic timeline for production; (b) Talis was already significantly behind its internal deadlines for beta testing; and (c) the Exchange Act Defendants knew that the Talis One suffered from design issues and high invalid rates that foreclosed and/or dramatically delayed commercial production. Having chosen to speak positively about Talis's manufacturing progress and the reasons for a "phased rollout," Defendant Kelley omitted these known, material negative facts, which were necessary to make the statements not misleading in the context in which they were made.

d. False and Misleading Statements That Talis Had Ordered "5,000 Instruments"

207. In Talis's 2020 10-K, Talis touted its order of Talis One instruments, stating, "[w]e have ordered 5,000 instruments from our instrument contract manufacturing partners to be delivered through the third quarter of 2021." In Talis's 1Q21 10-Q, 2Q21 10-Q, and 3Q21 10-Q, Talis reiterated this claim, but removed language pertaining to the delivery dates, stating that Talis had "ordered 5,000 Talis One instruments from our instrument contract manufacturer."

208. These statements were materially false and misleading when made because Talis did not order "5,000 instruments." Rather, as Talis admitted in its Form 10-K filed on March 15, 2022, Talis had merely ordered "components for up to 5,000 instruments"—not the instruments themselves, which would require time-consuming and costly assembly and testing. Further, in failing to disclose the known, material fact that Talis had only ordered components for up to 5,000

instruments, the Exchange Act Defendants omitted material facts necessary to make the statements not misleading in the context in which they were made.

C. Additional Allegations of Scienter

209. The Exchange Act Defendants each acted with scienter in that each knew or recklessly disregarded the true facts in making the materially false and misleading statements identified herein. Set forth below is a summary of the key allegations that support scienter.

a. Former Employee Allegations

210. Several former Talis employees provided information on a confidential basis supporting the strong inference that the Exchange Act Defendants acted with scienter in making the alleged material false and misleading statements and omissions. The former employees' accounts corroborate one another and the additional facts alleged herein.

211. FE-1 worked at Talis from August 2016 to March 2021, first as a senior mechanical R&D engineer, and then as the new product introduction manager, and was based in the Company's Menlo Park, CA office. FE-1 initially reported to Thomas "Trey" Cauley III, Talis's VP of Engineering, and then moved to manufacturing operations, reporting to James Harland. FE-1 has worked as an engineer over the last two decades, focusing on the medical field for the last decade. FE-1 worked to make the cartridge for the Talis One, as designed, more manufacturable. According to FE-1, based on personal knowledge:

(i) Accelerated timetable: Had COVID not happened, the original cartridge for STI testing was slated to go into production in 2022. Defendants sought to accelerate Talis's plans and quickly conduct an IPO in light of the pandemic, but Talis was a few years behind in technical development, and its response was to throw money at the problem.

(ii) Failure to recognize technical challenges: Talis management ignored many of the technical challenges with bringing the Talis One to market, as all the engineering wasn't there, the Talis One was a concept model, and going from prototype to full production at volume—a 100-fold increase—was not possible. The combination of manufacturing, design, and supply chain issues was like running without your pants pulled up all the way.

(iii) Design and supply issues ignored: 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 2020, after being known for a year. Management knew about the leaking cartridges because Talis had conducted a user study and the feedback was given to all of management. Starting around August 2020, FE-1 spoke directly about supply issues to Tony Cunningham (the senior director of supply chain starting in July 2020), 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.

(iv) Missed internal targets: Cunningham posted a weekly schedule of production that indicated a Q4 2020 goal of producing 1,000 instruments for beta testing and to prove Talis's manufacturing capability, but Talis produced far fewer instruments in the quarter.

(v) Large-scale manufacturing not possible: FE-1 was responsible for sourcing component vendors for Talis's cartridge manufacturing. 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. CEO Coe was notorious for not having any scheduling buffer, which failed to recognize that in the engineering and operations world, things happen.

(vi) Talis was not "ready to go": Coe's May 2021 claim that Talis was "ready to go" into production upon receiving an EUA had no basis. Coe was also unwilling to consider adjusted timelines; it was rumored 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.

212. FE-2 holds a Ph.D. in molecular genetics and worked at Talis as a senior scientist from February 2020 to October 2020. FE-2 was hired to work on infectious disease diagnostics and assay development, and with the advent of COVID-19, FE-2 shifted focus to the virus. Based in Talis's Menlo Park, CA location, FE-2 reported to Hedia Maamar, the VP of R&D Assay, who in turn reported to SVP Ramesh Ramakrishnan. FE-2 worked on developing a test kit as well as the Talis One test platform. According to FE-2, based on personal knowledge:

(i) Flawed comparator assay: The Talis One suffered from performance issues, especially when it came to the original comparator assay used by the Company. Talis used a weak

comparator assay as a benchmark for its EUA submission to the FDA.

(ii) High invalid rate known: It was known well before Talis submitted its first EUA application that the test had a high invalid rate. 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.

(iii) Design issues: Poor communication between the engineering and assay teams resulted in a lack of pretesting in the Talis One design and design issues such as the size of the cartridges. The chamber sizes in the Talis One's cartridges were created without sufficient volume for proper Limits of Detection because some of the chambers were too small.

(iv) Lack of SOPs and processes: Talis had a lack of communication, proper documentation, and standard operating procedures; Talis did not apply the processes or vetting necessary to conduct the IVD (In Vitro Diagnostics) process properly.

(v) No realistic timeline and limited resources: Talis did not have a realistic timeline to manufacture its product, let alone bring it to market. Indeed, 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. Within the Company, there was an amalgamation of incompetency at every level – marketing, alignment with R&D, and even creating a plan or timeline.

213. FE-3 worked at Talis from November 2016 to June 2021 as associate director, Consumables Engineering, based in Menlo Park. FE-3 initially reported to Cauley (VP of Engineering); in turn, Cauley reported to VP of Operations Martin Goldberg, who left the company in January 2020, and then to SVP Ramakrishnan. FE-3 was hired to work on projects related to the design of consumables (*e.g.*, cartridges) for testing. By the time FE-3 left, FE-3 was working on multiple items related to consumables design and the transfer of consumable designs to manufacturing. According to FE-3, based on personal knowledge:

(i) Overly aggressive timelines that had no basis: Talis's timelines were overly aggressive, driven in part by company culture. 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.

(ii) CEO Coe knew of issues: Then-CEO Coe knew there were serious issues with the manufacturing timelines for the Talis One, as FE-3 had briefed Coe on the topic over several weeks in May 2021.

214. FE-4 was a territory account manager at Talis and oversaw the western region from February 1, 2021 to March 15, 2022, when FE-4 was laid off in the Company's reduction in force. FE-4 was based in San Diego and reported to National Sales Director Alex de los Reyes, who reported to Vice President, Sales & Commercial Strategy Anthony Green; Green reported to Rob Kelley, then-Chief Commercial Officer. FE-4 was recruited to Talis from a large medical device company after a 20-year diagnostic testing equipment sales career, and was one of the first members of Talis's salesforce. According to FE-4, based on personal knowledge:

(i) Focus on generating "sales" and pre-selling even before FDA approval: From the beginning, FE-4 was told that Talis needed to generate sales to show shareholders. While FE-4's past employers had refrained from telling employees what products were in the works to ensure that they didn't start promoting them preemptively, Talis wanted its salesforce to sell a product that was in its earliest stages, even before the Talis One had received FDA approval. FE-4 was concerned about this practice, since other firms prohibited marketing of products that were still in development, and violations could result in large penalties and fines from the FDA.

(ii) Aggressive sales tactics led to presales reported to the Board: Contacts with potential customers were logged and tracked in Salesforce CRM (customer relationship management) software. Sales representatives were paid per contract; FE-4 recalled that one representative was forced to obtain at least three signed contracts by the end of the quarter or face termination. As a result of these tactics, Talis's salesforce ultimately obtained 140 presales. The executives took the sales, put them in a spreadsheet, then told Talis's Board they had substantial presales.

(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.

(iv) No functioning product: In FE-4's view, to say Talis had a working test was not the truth. 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. 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. On or around November 12, 2021, 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.

(v) High invalid rate: 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.

(vi) CEO Blaser's abrupt departure: After leaving Talis in March 2022, FE-4 learned from a contact at another company that Brian Blaser, who served as CEO for only a week, left Talis because there was major fraud.

(vii) Defendants misled investors: FE-4 sat in on shareholder meetings and noticed investors were becoming skeptical about the launch timeline. According to FE-4, Talis offered reassurances that misleadingly implied the product was launch-ready and awaiting the green light from regulators.

215. FE-5 was an associate director of technical implementation at Talis from September 2021 to March 2022, when FE-5 was laid off in the Company's reduction in force. FE-5 was based in Dallas and ran a team of five technical support specialists focused on the development of process and procedures for the Talis One launch. FE-5 reported to Emily Korkofigas, senior director of

customer success, who reported to Kelley (Chief Commercial Officer, and later CEO). According to FE-5, based on personal knowledge:

(i) Not ready to begin production upon receipt of EUA: When FE-5 was hired in September 2021, Talis did not have a target launch date for the Talis One COVID-19 test because the Company had not yet received its EUA from the FDA. The submission had been sent in late July 2021, and despite claims from the company, Talis was not ready to begin manufacturing as soon as the EUA was received.

(ii) High invalid rate known: FE-5 confirmed that it was already known inside Talis that the invalid rate was high; after Talis received its EUA in November 2021, FE-5 was told that the invalid rate had been and remained above 10%.

(iii) No validation of production lines: FE-5 explained that Talis had not validated its production lines, which was significant and one of the major factors in not launching the Talis One.

b. The Talis One Was the Company's Core Operation and Only Product

216. The Talis One played a crucial role and constituted the core operation of the Company. Indeed, the Talis One COVID-19 test is Talis's only significant product. For example, the Registration Statement indicated that "[s]ubstantially all of our revenue will initially be dependent upon" sales of the "Talis One platform with our COVID-19 test in the United States," and that "[a]s a result, our future success will depend in large part on our ability to effectively launch the Talis One platform with our COVID-19 test and subsequently introduce enhanced or new tests for the Talis One platform."

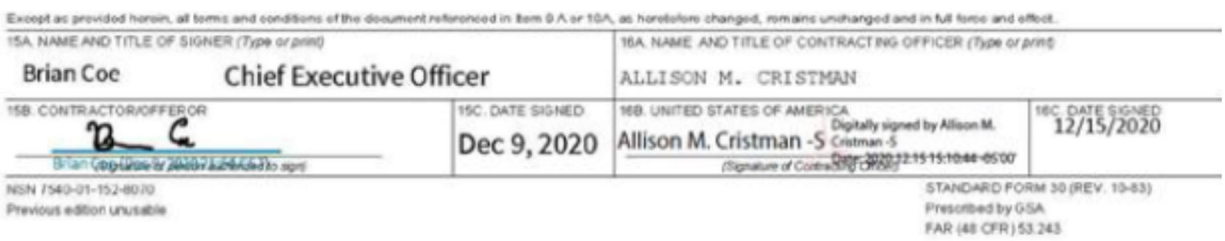
217. The Talis One's reliability and timetable for production and launch were thus crucial for the Company, as they determined whether and when it would begin generating meaningful revenue. That was particularly important given the finite amount of cash raised in the IPO, which was rapidly being consumed by research and development expenses. For example, Talis spent $60.2 million in research and development expenses for the first quarter of 2021 alone. Moreover, the ability to commercialize the Talis One COVID-19 test also affected Talis's whole pipeline of other planned tests for the Talis One platform, underscoring its central importance to the Company.

218. Given these facts, it would be absurd to suggest that the Exchange Act Defendants were without knowledge of the manufacturing delays, high invalid rates, and other technical problems with the Talis One that existed at the time of their false and misleading statements.

c. The Officer Defendants Had Continuous Access to Information Showing That Talis Was Far from "Ready to Go"

219. In addition to the information set forth above—including as to how a user study apprised all of management of leaking cartridges in 2020 (FE-1), how FE-1 spoke directly about supply issues to Tony Cunningham (who reported to CFO Moody) starting around August 2020, how CEO Coe knew there were issues with the Talis One because FE-3 had briefed Coe over several weeks in May 2021 about the serious issues with the manufacturing timelines for the Talis One, and how FE-3 mentioned concerns about the overly aggressive timelines to a scientific advisor on Talis's Board—the detailed reporting and advance purchase requirements in two material contracts and FDA correspondence further confirm that the Officer Defendants were aware of the true state of affairs with regard to the Talis One, and underscore the Exchange Act Defendants' knowledge or recklessness.

220. First, the RADx Contract—Talis's largest government contract—contained detailed requirements, including that Talis report the "reason" for any delays. In its November 10, 2020 comment letter, the SEC required Talis to publicly file the RADx Contract as an exhibit to the Registration Statement.[10] The RADx Contract was signed by Defendant Coe, who was necessarily familiar with its terms and requirements:


Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Brian Coe Chief Executive Officer		ALLISON M. CRISTMAN	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
[signature]	Dec 9, 2020	Allison M. Cristman -S Digitally signed by Allison M. Cristman -S	12/15/2020
		(Signature of Contracting Officer)	

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221. The RADx Contract required Talis to make specific reports to NIH and report the "reason" for any delays in milestone deliverables. For example, Talis was "required to provide

[10] *See* Exhibit 10.14 to Registration Statement, *available at* https://www.sec.gov/Archives/edgar/data/0001584751/000119312521014914/d25171dex1014.htm

data and reports (e.g., manufacturing, supply chain, production rates), which NIH will use to evaluate completion or achievement of milestones, progress toward deliverables, and compliance with the requirements of the contract"; if "a milestone deliverable is delayed," Talis was "responsible for reporting the reason and providing an updated schedule." Talis also committed that it would "complete verification and validation of its IVD platform, seek Emergency Use Authorization from the FDA for its COVID-19 assay, manufacture at least 3,300 instruments for sale, and design and construct three automated manufacturing lines, which combined have a total capacity of approximately 1 million cartridges per month."

222. The detailed reporting requirements above—and the fact that millions of dollars of revenue were riding on whether Talis met the RADx Contract's milestones—strongly indicate that the Officer Defendants had full access to current information about Talis's manufacturing, supply chain, and production rates, as well as any delays, the reasons for them, and the impact on Talis's schedule, yet knew or recklessly disregarded the true facts at the time of their false and misleading statements.

223. Second, Talis's principal contract for cartridge manufacturing was a May 2020 supply agreement with thinXXS, a wholly-owned subsidiary of IDEX Corporation, for the purchase of certain materials, including single-use cartridges for use with the Talis One platform and components and subassemblies of such single-use cartridges (the "thinXXS Contract"). Talis has reported that the thinXXS Contract required Talis "to submit an annual forecast of expected purchase volumes with portions of such annual forecast constituting a binding commitment based on certain percentages set forth in the thinXXS Agreement. We are also required to submit non-binding rolling forecasts to thinXXS." Thus, under the thinXXS Contract, Talis was required to commit in advance each year to purchasing a specified volume of cartridges—a major financial commitment that, on information and belief, would have required approval by CFO Moody and other members of senior management—and to provide periodic rolling forecasts.

224. These advance purchase and forecasting requirements for Talis One cartridges, a material expenditure for the Company, further confirm that the Officer Defendants knew or recklessly disregarded the true facts concerning Talis's cartridge production lines, and in particular

had no basis to claim that cartridge production would reach "full capacity" or "scale to meet demand" of "one million Talis One cartridges per month" in 2021.

225. Finally, in its November 5, 2021 letter approving Talis's second EUA application, the FDA specifically required that Talis "must have a process in place to track invalid rates of your product and report to DMD/OHT7-OIR/OPEQ/CDRH) [sic] the invalid rates 30 days, 90 days and 6 months after product launch. The report must include the total number of tests performed, all initially invalid results and results of all repeat testing." This explicit requirement to "track" and "report" invalid rates further confirms that the Officer Defendants knew or recklessly disregarded the Talis One's high invalid rates.

d. The Officer Defendants Spoke Repeatedly About the Talis One's Production Status and Other Issues, Which Wall Street Analysts Continuously Scrutinized

226. The statements of the Officer Defendants indicated their knowledge and access to the internal facts that the actionably false and misleading statements above misstated or concealed. For example, CFO Moody stated that Talis was "on track" and "on plan" to "bring up our automated lines," which necessarily indicated that Moody knew or had access to information on the actual status and production level of Talis's cartridge production lines, as well as Talis's cartridge purchase commitments and the annual and rolling forecasts provided under the thinXXS Contract, detailed above.

227. Similarly, CEO Coe's statements that Talis would "be in a position to ship product in a very timely manner following an approval," felt "very much ready to go on our end," saw "results" that "really look terrific," and was "way ahead on our ability to produce product relative to almost any company our size historically" all indicate that Coe knew or had access to information on Talis's actual manufacturing progress, results, and any delays or other issues. Indeed, as explained above, Coe signed Talis's RADx Contract—which required detailed reporting to the NIH, including the "reason" for any delays—and was thus familiar with its requirements and able to access the reports that Talis provided. Similarly, COO Liu—who reported to Coe—confirmed that he was monitoring cartridge demand, stating on an earnings call

that "if demand warrants it, which we'll be monitoring, we'll be moving forward with additional capacity on an ongoing basis."

228. CEO Kelley's statements similarly confirm that he knew or had access to information contradicting the Exchange Act Defendants' public statements. For example, in the November 15, 2021 earnings call, Defendant Kelley stated that "[o]ver the past several months, the commercial team [which Kelley led at the time] has been busy assessing and generating demand in this extremely dynamic COVID market while simultaneously performing a handful of premarketing studies at select prospective customer sites," thereby indicating his knowledge or access to information about customer demand and the results of the "premarketing studies." Kelley later indicated that those same studies revealed issues with the Talis One's invalid rates. Further, in earnings calls on March 15, 2022 and May 10, 2022, Kelley spoke in detail about Talis's "strategic plan" to evaluate design, process, and manufacturing issues with the Talis One and the "modifications around manufacturing processes, quality controls and supply conformance" that resulted.

229. The Officer Defendants addressed these issues in detail because Wall Street analysts were laser-focused on Talis's ability to bring the Talis One to market and produce at scale, repeatedly citing this as the major driver in their valuations of the Company, as illustrated below.

e. Officer Terminations Support Scienter

230. Further supporting scienter, CEO Coe, CEO Blaser, and COO Liu were all terminated or resigned as the Talis One's regulatory, design, and manufacturing issues began to be exposed. There is a strong inference that the termination of Coe was connected to his fraudulent statements about Talis's purported readiness to begin production of the Talis One, which were false when made. Indeed, Coe's August 30, 2021 termination occurred shortly after the August 10, 2021 earnings call where Coe admitted for the first time that "development time lines have been extended by delays."

231. There is a similarly strong inference arising from the fact that Coe's replacement as CEO, Blaser, resigned almost immediately, serving for only a week. As noted above, FE-4 was told that Blaser left because there was major fraud at Talis.

232. Finally, Talis announced the departure of COO Liu—the executive largely responsible for the failed efforts to manufacture the Talis One—on March 15, 2022. The fact that Liu's departure was announced on the same day that Talis finally admitted the Talis One was not ready for commercial production, and revealed that external consultants were reviewing the product's design and manufacturing process, likewise supports a strong inference of scienter.

f. Corporate Scienter

233. Talis possessed scienter for two independent reasons. First, the Officer Defendants who acted with scienter were senior executives with binding authority over the Company and acted within the scope of their apparent authority. The scienter of the Officer Defendants is imputed to the Company.

234. Second, certain allegations herein establish Talis's corporate scienter based on (i) the state of mind of employees (other than the Officer Defendants) whose intent can be imputed to the Company, and/or on (ii) the knowledge of employees who approved the statements alleged herein despite knowing the statements' false and misleading nature. It can be strongly inferred that senior executives at Talis possessed scienter such that their intent can be imputed to the Company. Given the significance of the Talis One to Talis, the importance of Defendants' purported ability to bring the Talis One to market, and the necessary involvement of numerous Talis departments and personnel—including scientists, engineers, and sales personnel who observed the Talis One's design problems, high invalid rate, manufacturing delays, and other issues—additional executives unknown at this time and sufficiently senior to impute their scienter to Talis also knew of the misstatements alleged herein.

235. As-yet-unidentified Talis senior executives also approved the false statements despite knowing of their false and misleading nature. As alleged above, Talis had extensive reporting requirements under the RADx Contract and thinXXS Contract and was required by the FDA to track the Talis One's invalid rates, and the appearance of a viable path to commercialization was highly significant to Talis's share price. From this, it can be strongly inferred that senior executives at Talis approved the false and misleading statements concerning

the Talis One, while knowing of its high invalid rate, inability to be manufactured at scale, and the other issues detailed above.

D. Loss Causation

236. The Exchange Act Defendants' fraudulent conduct directly and proximately caused Lead Plaintiffs and the Class to suffer substantial losses as a result of purchasing or otherwise acquiring Talis common stock at artificially inflated prices during the Class Period.

237. The Exchange Act Defendants, through their materially false and misleading statements and omissions set forth above, concealed the truth that the Talis One was far from ready for commercial production, with significant and known design problems, an unacceptably high invalid rate, and a flawed and unreliable manufacturing process. By concealing these facts, the Exchange Act Defendants also concealed the numerous risks associated with their false and misleading statements and omissions, including without limitation the risks that the known problems with the Talis One would significantly delay its commercial launch and the Company's pipeline of additional diagnostic tests, thereby foreclosing Talis's ability to generate meaningful revenues and profits, and the risk that the Company would be further disrupted by the termination or departure of the senior executives responsible for the Talis One's failure.

238. Beginning in August 2021, the concealed risks began to materialize through a series of negative events and disclosures that revealed, on a piecemeal basis, the false and misleading nature of Defendants' Class Period statements and omissions. Despite these partially corrective events and disclosures, Talis's stock price remained artificially inflated and was prevented from declining to its true value by the Exchange Act Defendants continuing to make materially false and misleading statements that had the effect of, at least temporarily, concealing the fraud. As the relevant truth leaked out into the market from August 2021 to March 2022, the Class suffered losses, which were foreseeable and caused by the materialization of the risks that the Exchange Act Defendants' fraudulent conduct concealed from investors, as set forth below.

a. August 10, 2021

239. On August 10, 2021, after the market closed, Talis revealed that its "development time lines have been extended by delays in the launching of [Talis's] COVID-19 test and

manufacturing scale." As a result, Talis "expect[s] to see [its] first meaningful revenue ramp in 2022." This was the Company's first public acknowledgement of manufacturing delays with the Talis One. Talis also revealed that it had finally submitted a new EUA application to the FDA in late July 2022, later than the second-quarter estimate Talis had previously provided.

240. On this news, the Company's stock price fell $0.58, or 6%, to close at $8.39 per share on August 11, 2021, on unusually heavy trading volume.

241. Analysts were disappointed. For example, on August 11, 2021, Bank of America wrote: "Overall, we are disappointed with the company's 2Q update, as the execution missteps, pipeline delays, increasingly competitive end market, and uncertainty over demand for C19 testing make it difficult for us to forecast TLIS's top-line." The report added that "we see some potential for the Talis One platform if the company can deliver, but time is of the essence."

b. August 30, 2021

242. On August 30, 2021, after the market closed, Talis announced that Defendant Coe had "stepped down" as its President, CEO, and Director, effective immediately. Talis offered no explanation for Defendant Coe's departure; on information and belief, Coe was terminated.

243. On this news, the Company's stock price fell $1.00, or 11%, to close at $8.06 per share on August 31, 2021, on unusually heavy trading volume.

244. In an August 30, 2021 report, Bank of America cited the "unexpected CEO transition," which was "surprising given that TLIS went public in Feb. '21 and held an earnings call on 8/10," and "creates more uncertainty." Likewise, on August 31, 2021, BTIG wrote that the "move caught us by surprise."

c. November 15, 2021

245. On November 15, 2021, after the market closed, Talis filed a press release on Form 8-K announcing Q3 2021 financial results and that it would execute a "controlled product rollout" using a "measured approach." In the Company's November 15, 2021 conference call with investors, Defendant Kelley reiterated that Talis had "decided to take a phased approach for rolling out the Talis One System," with a "limited rollout" to begin "in the first quarter of 2022" that would involve "a small number of sites representative of the customers we are targeting . . . ."

246. On this news, the Company's stock price fell $1.04, or 17.93%, to close at $4.76 per share on November 16, 2021, on unusually heavy trading volume.

247. Analysts were surprised and concerned about the announcement of yet another delay in commercialization. On November 15, 2021, both Bank of America and JPMorgan reduced their price targets from $7.00 to $6.00 per share, with Bank of America citing the "slower than expected commercial rollout." Similarly, JPMorgan wrote that "3Q21 brought more uncertainty for TLIS, as the excitement of the EUA was more than offset by the measured 'phased' approach to the rollout," and that "[m]ultiple push-outs of the entire portfolio due to delays in the COVID standalone launch . . . create further uncertainty to the platform's revenue ramp (particularly, Women's Health launch set for 2H23 launch) at a time when competition has intensified in the POC setting, leaving more risk to numbers."

d. December 8, 2021

248. On December 8, 2021, Talis announced that Brian Blaser had "stepped down" from his positions as President, CEO, and Director only a week after his December 1 appointment. While Talis publicly claimed that Blaser's departure was due to "personal matters," in truth, as detailed above, Blaser left because there was major fraud at the Company.

249. On this news, the Company's stock price fell $0.55 per share, or more than 11%, to close at $4.28 per share on December 8, 2021.

e. March 15, 2022

250. On March 15, 2022, after the market closed, Talis reported financial results for 2021 and revealed that "Talis has not started its phased launch of the Talis One™ COVID-19 Test System due to challenges with manufacturing. The company has engaged in a manufacturing review process to determine appropriate next steps and undertaken initiatives to align resources and preserve cash." Talis further disclosed that it had engaged external consultants "to assess product design for manufacturing at scale" and "evaluate current processes"; that the Company was laying off approximately 25 percent of its workforce; and that COO Liu was stepping down. Moreover, while Talis had repeatedly claimed in its SEC filings to have "ordered 5,000 Talis One instruments from our instrument contract manufacturer" (as detailed above), Talis's Form 10-K

for 2021, filed on March 15, 2022, stated that Talis had "ordered components for up to 5,000 instruments from our instrument contract manufacturing partners"—a material shift from the Company's consistent earlier claims to have ordered 5,000 "instruments."

251. During the Company's March 15, 2022 conference call with investors, 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." Moreover, Kelley stated that "based on the level of information we have today, we are not providing a timeline for commercial launch." Kelley also revealed that "the rate of invalid or failed tests remains higher than what we believe is acceptable," conceding that the invalid rates were "above 10%," while adding that "I wouldn't say it's significantly above 10%."

252. On this news, the Company's stock price fell $0.39, or 23.08%, to close at $1.30 per share on March 16, 2022, on unusually heavy trading volume.

253. Analysts were disappointed yet again. On March 15, 2022, Bank of America cited the "disappointing product yield and consistency of manufacturing processes [that] have surfaced." JPMorgan recounted that "the company announced it has delayed the phased launch of its instrument and COVID assay *again* due to challenges to manufacture at scale" (emphasis in original), withdrew its price target and concluded: "With no timelines in place for commercialization, we see little visibility in the business's trajectory in the near-term, and longer-term we remain uncertain of the platform's ramp (particularly, Women's Health) at a time when competition has intensified in the POC setting."

E. Presumption of Reliance and Fraud-on-the-Market Doctrine

254. The Class is entitled to a presumption of reliance on Defendants' material misrepresentations and omissions pursuant to the fraud-on-the-market doctrine. At all relevant times, the market for Talis's common stock was efficient for the following reasons, among others:

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

b) The average daily trading volume of Talis's common stock was significant and amounted to approximately 213,000 shares during the Class Period;

c) As a regulated issuer, Talis filed public reports with the SEC and the NASDAQ;

d) Talis was eligible to file simplified SEC filings;

e) Talis regularly communicated with the public through established market communication channels, including through the regular dissemination of news releases through major newswire services, communications with the financial press, and other wide-ranging public disclosures; and

f) Numerous securities analysts followed Talis and wrote reports that were published, distributed, and entered the public domain.

255. Accordingly, the market for Talis common stock promptly digested current information regarding the Company from all publicly available sources and reflected such information in the price of Talis common stock. Under these circumstances, all purchasers of Talis common stock during the Class Period suffered similar injury through their purchases at artificially inflated prices. A presumption of reliance therefore applies.

256. In addition, or in the alternative, the Class is entitled to a presumption of reliance pursuant to *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), and its progeny, because the claims asserted herein are predicated in part upon omissions of material fact that Defendants had a duty to disclose.

VI. CLASS ACTION ALLEGATIONS

257. Lead Plaintiffs bring this action as a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure, on behalf of the following proposed Class:

- As to claims under the Securities Act, 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 were damaged thereby; and

- As to claims under the Exchange Act, all persons and entities who purchased or otherwise acquired Talis common stock between March 30, 2021 and March 15, 2022, both inclusive, and were damaged thereby.

258. Excluded from the Class are: (i) Defendants and any affiliates or subsidiaries thereof; (ii) present and former officers and directors of Talis and their immediate family members (as defined in Item 404 of SEC Regulation S-K, 17 C.F.R. § 229.404, Instructions (1)(a)(iii) & (1)(b)(ii)); (iii) Defendants' liability insurance carriers, and any affiliates or subsidiaries thereof; (iv) any entity in which any Defendant had or has had a controlling interest; (v) Talis's employee

retirement and benefit plan(s); and (vi) the legal representatives, heirs, estates, agents, successors, or assigns of any person or entity described in the preceding categories.

259. The Class is so numerous that joinder of all members is impracticable. Lead Plaintiffs believe that the Class members number at least in the thousands. Talis sold 15,870,000 shares of common stock in the IPO and, as of June 30, 2022, had over 26 million shares of common stock outstanding. Throughout the Class Period, Talis common stock had an average daily volume on the NASDAQ of approximately 213,000 shares. Talis common stock traded actively in the United States during the Class Period.

260. Lead Plaintiffs' claims are typical of the claims of Class members. All Class members are similarly situated in that they sustained damages by acquiring Talis common stock at prices artificially inflated by the wrongful conduct complained of herein.

261. Lead Plaintiffs will fairly and adequately protect the interests of the Class. Lead Plaintiffs have retained counsel competent and experienced in class and securities litigation. Lead Plaintiffs have no interest that conflicts with those of the Class.

262. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. The questions of law and fact common to the Class include, but are not limited to, the following:

a) Whether Defendants' conduct violated the federal securities laws, as alleged herein;

b) Whether the Registration Statement contained any untrue statements of material fact or omitted to state any material facts required to be stated therein or necessary to make the statements therein not misleading;

c) Whether Defendants made any untrue statements of material fact or omitted to state any material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

d) Whether Defendants acted with scienter as to Lead Plaintiffs' claims for relief under Section 10(b) of the Exchange Act;

e) Whether the Officer Defendants were controlling persons under Section 15 of the Securities Act and Section 20(a) of the Exchange Act;

f) Whether any of the Individual Defendants can sustain their burden of establishing an affirmative defense under applicable provisions of the Securities Act;

g) Whether and to what extent the prices of Talis common stock were artificially inflated or maintained during the Class Period due to the misstatements and omissions complained of herein;

h) Whether, with respect to Lead Plaintiffs' claims under the Exchange Act, reliance may be presumed under the fraud-on-the-market presumption;

i) Whether and to what extent Class members have sustained damages as a result of the conduct complained of herein and, if so, the proper measure of damages.

263. A class action is superior to other available methods for the fair and efficient adjudication of this controversy because joinder of all Class members is impracticable.

264. There will be no difficulty in the management of this action as a class action. Class members may be identified from records maintained by the Company or its transfer agent(s), or by other means, and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

VII. INAPPLICABILITY OF STATUTORY SAFE HARBOR OR BESPEAKS CAUTION DOCTRINE

265. The protections applicable to forward-looking statements under certain circumstances do not apply to any of the false or misleading statements alleged herein. The statements complained of herein concerned then-present or historical facts or conditions that existed at the time the statements were made. Further, the PSLRA safe harbor expressly excludes forward-looking statements "made in connection with an initial public offering," 15 U.S.C. § 77z-2(b)(2)(D), such as the IPO.

266. To the extent any of the false or misleading statements alleged herein can be construed as forward-looking, (a) they were not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements, and the generalized risk disclosures Talis or other Defendants made were not sufficient to shield Defendants from liability, and (b) the person who made each such statement knew that the statement was untrue or misleading when made, or each such statement was approved by an executive officer of Talis who knew that the statement was untrue or misleading when made.

VIII. CLAIMS FOR RELIEF

COUNT I
For Violation of Section 11 of the Securities Act Against the Securities Act Defendants

267. Lead Plaintiffs repeat and reallege each and every allegation above relating to the Securities Act claims as if fully set forth herein.

268. This Count does not sound in fraud. Any allegations of fraud or fraudulent conduct and/or motive are specifically excluded, except that any challenged statements of opinion or belief made in the Registration Statement are alleged to have been materially misstated statements of opinion or belief when made and at the time of the IPO. For purposes of asserting this and their other claims under the Securities Act, Lead Plaintiffs do not allege that the Securities Act Defendants acted with intentional, reckless, or otherwise fraudulent intent.

269. The Registration Statement, at the time when it became effective, was inaccurate and misleading, contained untrue statements of material facts, omitted to state material facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

270. The Securities Act Defendants were responsible for the content and dissemination of the Registration Statement.

271. Talis is the issuer and registrant for the IPO. As issuer, Talis is strictly liable for any material misstatements and omissions in the Registration Statement.

272. The other Securities Act Defendants acted negligently in that none of them made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and not misleading, and that the Registration Statement did not omit any material facts required to be stated therein or necessary to make the statements made therein not misleading.

273. Lead Plaintiffs and the Class acquired Talis common stock pursuant and/or traceable to the Registration Statement.

274. When they acquired Talis common stock pursuant and/or traceable to the Registration Statement, Lead Plaintiffs and others similarly situated did not know, nor in the

exercise of reasonable care could they have known, of the untruths and omissions contained (and/or incorporated by reference) in the Registration Statement.

275. Lead Plaintiffs and the Class have sustained damages. The value of Talis common stock has declined substantially subsequent to and due to the Securities Act Defendants' violations.

COUNT II
For Violation of Section 15 of the Securities Act
Against the Individual Defendants

276. Lead Plaintiffs repeat and reallege each and every allegation above relating to the Securities Act claims as if fully set forth herein.

277. This Count does not sound in fraud. Any allegations of fraud or fraudulent conduct and/or motive are specifically excluded, except that any challenged statements of opinion or belief made in the Registration Statement are alleged to have been materially misstated statements of opinion or belief when made and at the time of the Offering. For purposes of asserting this and their other claims under the Securities Act, Lead Plaintiffs do not allege that the Securities Act Defendants acted with intentional, reckless, or otherwise fraudulent intent.

278. During their tenures as officers and/or directors of Talis, including at the time of the Offering and when the Registration Statement became effective, the Individual Defendants acted as controlling persons of Talis within the meaning of § 15 of the Securities Act.

279. By virtue of their positions of control and authority and their direct participation in and/or awareness of Talis's operations and finances, the Individual Defendants had the power to, and did, direct or cause the direction of the management, policies, and actions of Talis and its employees, and caused Talis to issue, offer, and sell common stock pursuant to the defective Registration Statement.

280. The Individual Defendants had the power to, and did, control the decision-making of Talis, including the content and issuance of the statements contained (and/or incorporated by reference) in the Registration Statement; they were provided with or had unlimited access to copies of the Registration Statement (and/or documents incorporated by reference) alleged herein to contain actionable statements or omissions prior to and/or shortly after such statements were issued, and had the power to prevent the issuance of the statements or omissions or to cause them

to be corrected; and they signed the Registration Statement and were directly involved in or responsible for providing false or misleading information contained in the Registration Statement (and/or documents incorporated by reference therein) and/or certifying and approving that information.

281. The Individual Defendants acted negligently in that none of them exercised reasonable care to ensure, or had reasonable grounds to believe, that the Registration Statement was true and not misleading as to all material facts and did not omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading.

282. Lead Plaintiffs and others similarly situated suffered damages in connection with the purchase or acquisition of Talis common stock pursuant and/or traceable to the Registration Statement.

283. By reason of such conduct, the Individual Defendants are liable pursuant to § 15 of the Securities Act.

COUNT III
For Violation of Section 10(b) of the Exchange Act
Against the Exchange Act Defendants

284. Lead Plaintiffs incorporate ¶¶1-283 by reference as if fully set forth herein.

285. During the Class Period, the Exchange Act Defendants made, disseminated, or approved the false and misleading statements specified above, which they knew or recklessly disregarded were false and misleading in that the statements contained material misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

286. The Exchange Act Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 thereunder in that they:

a) Employed devices, schemes, and artifices to defraud;

b) Made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or

c) Engaged in acts, practices and a course of business that operated as a fraud or deceit upon Lead Plaintiffs and others similarly situated in connection with their purchases of Talis common stock during the Class Period.

287. Lead Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Talis common stock. Lead Plaintiffs and the Class would not have purchased Talis common stock at the prices they paid, or at all, if they had been aware that the market prices of those securities were artificially inflated by the Exchange Act Defendants' false and misleading statements and omissions.

288. As a direct and proximate result of the Exchange Act Defendants' wrongful conduct, Lead Plaintiffs and the Class suffered damages in connection with their purchases of Talis common stock during the Class Period.

COUNT IV
For Violation of Section 20(a) of the Exchange Act
Against the Officer Defendants

289. Lead Plaintiffs incorporate ¶¶1-288 by reference as if fully set forth herein.

290. During the Class Period, the Officer Defendants acted as controlling persons of Talis within the meaning of § 20(a) of the Exchange Act. By virtue of their positions and their power to control Talis's public statements, the Officer Defendants had the power and ability to control the actions of Talis and its employees. The Officer Defendants controlled Talis and its other officers and employees. By reason of such conduct, the Officer Defendants are liable pursuant to § 20(a) of the Exchange Act.

IX. JURY DEMAND

291. Lead Plaintiffs, on behalf of themselves and the Class, hereby demand a trial by jury.

X. PRAYER FOR RELIEF

292. WHEREFORE, Lead Plaintiffs, on behalf of themselves and the other members of the Class, pray for relief as follows:

a) Declaring this action to be a proper class action pursuant to Rule 23 of the Federal Rules of Civil Procedure;

b) Awarding Lead Plaintiffs and the Class damages, including interest;

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

d) Granting such other and further relief as the Court may deem just and proper.

Dated: July 1, 2022

By: */s/ Joseph A. Fonti*

BLEICHMAR FONTI & AULD LLP
Joseph A. Fonti (*pro hac vice*)
jfonti@bfalaw.com
Evan A. Kubota (*pro hac vice*)
ekubota@bfalaw.com
7 Times Square, 27th Floor
New York, New York 10036
Tel: (212) 789-1340
Fax: (212) 205-3960

– and –

Lesley E. Weaver (Bar No. 191305)
lweaver@bfalaw.com
555 12th Street, Suite 1600
Oakland, California 94607
Tel.: (415) 445-4003
Fax: (415) 445-4020

Counsel for Co-Lead Plaintiff Martin Dugan and Co-Lead Counsel for the Putative Class

THE SCHALL LAW FIRM
Brian Schall (Bar No. 290685)
2049 Century Park East, Suite 2460
Los Angeles, California 90067
Telephone: (424) 303-1964
brian@schallfirm.com

Additional Counsel for Co-Lead Plaintiff Martin Dugan

POMERANTZ LLP
Jennifer Pafiti (Bar No. 282790)
1100 Glendon Avenue, 15th Floor
Los Angeles, California 90024
Telephone: (310) 405-7190
Facsimile: (212) 661-8665
jpafiti@pomlaw.com

Jeremy A. Lieberman (*pro hac vice* application forthcoming)
Jonathan D. Park (*pro hac vice*)
600 Third Avenue, 20th Floor

New York, New York 10016
Telephone: (212) 661-1100
Facsimile: (212) 661-8665
jalieberman@pomlaw.com
jpark@pomlaw.com

Counsel for Co-Lead Plaintiff Leon Yu and Max Wisdom Technology Limited and Co-Lead Counsel for the Putative Class

CERTIFICATE OF SERVICE

I hereby certify that on July 1, 2022, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record via transmission of Notices of Electronic Filing generated by CM/ECF.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on July 1, 2022.

/s/ Joseph A. Fonti
Joseph A. Fonti

Exhibit A

CERTIFICATION

I, Martin Dugan, hereby certify as follows:

1. I have reviewed the Consolidated Class Action Complaint for Violations of the Federal Securities Laws against Talis Biomedical Corporation ("Talis Biomedical") and others (the "Complaint") and authorized its filing.

2. I did not purchase or sell securities of Talis Biomedical that are the subject of the Complaint at the direction of counsel or in order to participate in any private action under the federal securities laws.

3. I am willing to serve as lead plaintiff on behalf of the Class in this matter, including providing testimony at deposition and trial, if necessary. I fully understand the duties and responsibilities of the lead plaintiff under the Private Securities Litigation Reform Act, including the selection and retention of counsel and overseeing the prosecution of the action for the benefit of the Class.

4. My transactions in Talis Biomedical common stock that is the subject of the Complaint from the time of the February 11, 2021 IPO through the end of the Class Period specified in the Complaint (March 15, 2022) are reflected in Schedule A, attached hereto.

5. Other than in the instant action, I have not sought to serve as lead plaintiff in a class action filed under the federal securities laws in the last three years.

6. Beyond my *pro rata* share of any recovery, I will not accept payment for serving as lead plaintiff on behalf of the Class, except the reimbursement of such reasonable costs and expenses including lost wages as ordered or approved by the Court.

I declare under penalty of perjury, under the laws of the United States, that the foregoing is true and correct this day of 6/28/2022, 2022.

DocuSigned by:
Martin Dugan
2FC1738043F143D...

Martin Dugan

SCHEDULE A
TRANSACTIONS IN
TALIS BIOMEDICAL CORPORATION

Transaction Type	Trade Date	Shares	Price Per Share	Cost/Proceeds
Purchase	03/26/2021	1,000.00	12.47	($12,470.00)
Purchase	03/26/2021	1,000.00	12.38	($12,382.70)
Purchase	04/21/2021	1,000.00	12.42	($12,416.50)
Purchase	04/21/2021	1,000.00	12.40	($12,399.00)
Purchase	04/21/2021	1,000.00	12.22	($12,220.00)
Purchase	05/07/2021	1,000.00	11.55	($11,550.00)
Purchase	05/10/2021	1,000.00	11.17	($11,165.00)
Purchase	05/24/2021	1,000.00	10.76	($10,760.00)
Purchase	05/25/2021	1,000.00	10.24	($10,240.00)
Purchase	05/26/2021	1,000.00	10.20	($10,200.00)
Purchase	06/01/2021	1,000.00	9.70	($9,700.76)
Purchase	06/07/2021	1,000.00	10.62	($10,620.00)
Purchase	06/07/2021	1,000.00	10.77	($10,770.00)
Purchase	06/08/2021	1,000.00	10.55	($10,550.00)
Purchase	06/08/2021	1,000.00	10.00	($10,000.00)
Purchase	06/16/2021	1,000.00	10.70	($10,700.00)
Purchase	06/16/2021	1,000.00	10.45	($10,450.00)
Purchase	06/16/2021	1,000.00	10.25	($10,250.00)
Purchase	06/16/2021	1,000.00	10.75	($10,749.80)
Sale	08/05/2021	-1,000.00	9.90	$9,900.00
Sale	09/13/2021	-1,000.00	7.68	$7,680.00
Sale	09/17/2021	-500.00	7.68	$3,840.00
Sale	09/20/2021	-1,000.00	7.27	$7,270.00
Sale	12/06/2021	-1,000.00	4.74	$4,740.90
Purchase	12/17/2021	3,000.00	4.44	($13,320.00)
Purchase	12/17/2021	1,000.00	4.40	($4,400.00)
Purchase	12/17/2021	1,000.00	4.23	($4,230.00)
Purchase	12/17/2021	1,000.00	4.37	($4,370.00)
Purchase	12/17/2021	500.00	4.36	($2,180.00)
Sale	12/27/2021	-1,000.00	4.22	$4,220.00
Sale	12/27/2021	-1,000.00	4.24	$4,242.00
Sale	12/27/2021	-1,000.00	4.23	$4,230.00
Sale	12/27/2021	-1,000.00	4.23	$4,230.00
Purchase	02/22/2022	3,000.00	2.01	($6,030.00)
Purchase	03/04/2022	1,000.00	1.75	($1,750.00)

Exhibit B

CERTIFICATION

I, Leon Yu, hereby certify as follows:

1. I have reviewed the Consolidated Class Action Complaint for Violations of the Federal Securities Laws against Talis Biomedical Corporation ("Talis Biomedical") and others and authorized its filing.

2. I did not purchase or sell securities of Talis Biomedical at the direction of counsel in order to participate in any private action under the federal securities laws.

3. I am willing to serve as lead plaintiff on behalf of the Class in this matter, including providing testimony at deposition and trial, if necessary. I fully understand the duties and responsibilities of the lead plaintiff under the Private Securities Litigation Reform Act, including the selection and retention of counsel and overseeing the prosecution of the action for the benefit of the Class.

4. My transactions in Talis Biomedical common stock issued pursuant and/or traceable to the Registration Statement and purchased or acquired through the end of the Class Period on March 15, 2022 are reflected in Schedule A, attached hereto.

5. Other than in the instant action, I have not sought to serve as lead plaintiff in a class action filed under the federal securities laws in the last three years.

6. Beyond my pro rata share of any recovery, I will not accept payment for serving as lead plaintiff on behalf of the Class, except the reimbursement of such reasonable costs and expenses including lost wages as ordered or approved by the Court.

I declare under penalty of perjury, under the laws of the United States, that the foregoing is true and correct this 30th day of June, 2022.

DocuSigned by:
Leon Yu
897A5256FD8B47F...

Leon Yu

Talis Biomedical Corporation (TLIS) **Yu, Leon**

List of Purchases and Sales

Transaction Type	Date	Number of Shares/Unit	Price Per Share/Unit
Purchase	2/12/2021	500	$31.1900
Purchase	2/12/2021	500	$29.0100
Purchase	2/12/2021	504	$27.5100
Purchase	2/12/2021	500	$26.1100
Purchase	2/16/2021*	3	$27.8000
Purchase	2/16/2021*	97	$28.3900
Purchase	2/16/2021*	96	$28.6000
Purchase	2/16/2021*	104	$28.3900
Purchase	2/16/2021	200	$27.2300
Purchase	2/16/2021	200	$27.2300
Purchase	2/16/2021	500	$25.1100
Purchase	2/16/2021	500	$24.1500
Purchase	2/16/2021	300	$26.0100
Purchase	2/17/2021*	97	$26.0000
Purchase	2/17/2021*	3	$26.0000
Purchase	2/17/2021*	107	$26.2000
Purchase	2/17/2021	3	$24.4000
Purchase	2/18/2021	15	$23.2400
Purchase	2/19/2021	115	$22.5900
Purchase	2/19/2021	130	$22.3600
Purchase	2/19/2021	15	$23.3500
Purchase	2/19/2021	84	$23.8200
Purchase	2/19/2021	1	$23.7000
Purchase	2/19/2021	130	$23.8100
Purchase	2/26/2021	300	$16.6500
Purchase	3/3/2021	500	$15.5900
Purchase	3/22/2021	250	$14.8900
Purchase	4/20/2021	250	$12.4800
Purchase	4/22/2021	1,000	$12.1600
Sale	2/12/2021	(4)	$32.4900
Sale	4/22/2021	(96)	$12.4400

*Premarket Purchase

Exhibit C

CERTIFICATION

I, Leon Yu, on behalf of Max Wisdom Technology Limited ("Max Wisdom"), as President, with authority to bind Max Wisdom and enter into litigation on its behalf, hereby certify as follows:

1. I have reviewed the Consolidated Class Action Complaint for Violations of the Federal Securities Laws against Talis Biomedical Corporation ("Talis Biomedical") and others and authorized its filing on behalf of Max Wisdom.

2. Max Wisdom did not purchase or sell securities of Talis Biomedical at the direction of counsel in order to participate in any private action under the federal securities laws.

3. Max Wisdom is willing to serve as lead plaintiff on behalf of the Class in this matter, including providing testimony at deposition and trial, if necessary. Max Wisdom fully understands the duties and responsibilities of the lead plaintiff under the Private Securities Litigation Reform Act, including the selection and retention of counsel and overseeing the prosecution of the action for the benefit of the Class.

4. Max Wisdom's transactions in Talis Biomedical common stock issued pursuant and/or traceable to the Registration Statement and purchased or acquired through the end of the Class Period on March 15, 2022 are reflected in Schedule A, attached hereto.

5. Other than in the instant action, Max Wisdom has not sought to serve as lead plaintiff in a class action filed under the federal securities laws in the last three years.

6. Beyond its pro rata share of any recovery, Max Wisdom will not accept payment for serving as lead plaintiff on behalf of the Class, except the reimbursement of such reasonable costs and expenses including lost wages as ordered or approved by the Court. \

I declare under penalty of perjury, under the laws of the United States, that the foregoing is true and correct this 30th day of June, 2022.

DocuSigned by:
Leon Yu
897A5250FD8B47F...

Leon Yu
President
Max Wisdom Technology Limited

Talis Biomedical Corporation (TLIS) **Max Wisdom Technology Limited**

List of Purchases and Sales

Transaction Type	Date	Number of Shares/Unit	Price Per Share/Unit
Purchase	2/16/2021*	150	$27.9800
Purchase	2/16/2021*	150	$28.2400
Purchase	2/16/2021*	150	$28.2300
Purchase	2/16/2021*	128	$28.2900
Purchase	2/16/2021*	130	$28.2900
Purchase	2/16/2021*	120	$28.2900
Purchase	2/16/2021*	150	$28.2900
Purchase	2/16/2021*	150	$28.2800
Purchase	2/16/2021*	150	$27.9700
Purchase	2/16/2021*	150	$28.1900
Purchase	2/16/2021*	200	$28.1000
Purchase	2/16/2021	100	$27.2300
Purchase	2/16/2021	100	$27.2400
Purchase	2/16/2021	122	$27.4000
Purchase	2/16/2021	550	$26.0100
Purchase	2/16/2021	500	$25.1100
Purchase	2/16/2021	500	$24.1500
Purchase	2/16/2021	100	$24.9400
Purchase	2/18/2021	150	$24.4700
Purchase	2/18/2021	100	$24.2000
Purchase	2/22/2021	100	$22.5900
Purchase	2/26/2021	150	$16.6600
Purchase	3/3/2021	500	$15.5900
Purchase	3/22/2021	500	$14.8400
Purchase	9/24/2021	500	$7.1400
Sale	2/26/2021	(100)	$17.6900

*Premarket Purchase