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

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

19 I. SUMMARY OF THE ACTION

20 1. This action brings (i) strict liability and negligence claims under Sections 11 and 15
21 of the Securities Act of 1933 (the “Securities Act”), and (ii) fraud claims under Sections 10(b) and
22 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

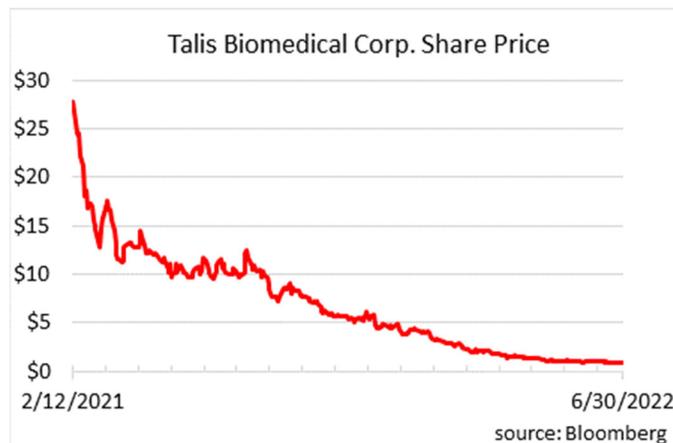
8 16. As time continued to pass with no functioning product on the market, Talis’s share
 9 price plummeted. In August 2021, CEO Coe (who had presided over the failed EUA application
 10 and IPO) was terminated.

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

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

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

19 20. Nearly 17 months after Talis’s February 2021 IPO, Talis still has no commercially
 20 available product. The following chart shows the price of Talis common stock, which peaked at
 21 \$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.

1 27. Talis was founded in 2010 as SlipChip LLC by Defendants Coe and Ismagilov to
2 develop point-of-care (“POC”) diagnostic tests for infectious diseases. (POC testing refers to
3 medical diagnostic testing that takes place at or near the time and place of patient care, rather than
4 in a central laboratory.)

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

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

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

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

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

23 32. By summer 2020, Talis abandoned its original focus on STI testing and started to
24 develop a molecular diagnostic test for COVID-19. There are two basic types of COVID-19
25 diagnostic tests. Antigen tests (like those widely available at drugstores) detect specific viral
26 proteins (antigens), but provide only a simple “yes” or “no” and sacrifice accuracy for speed. By
27 contrast, molecular diagnostic tests amplify genetic material to detect viral nucleic acid (viral
28 RNA), offering greater accuracy but generally lower speed than antigen tests.

1 33. On July 31, 2020, Talis issued a press release titled “Talis Awarded NIH RADx
2 Contract to Launch Talis One™ System for Point-of-Care COVID-19 Testing and Further
3 Strengthens Financial Position and Leadership Team,” declaring that the Company had been
4 awarded a \$25 million National Institutes of Health (“NIH”) contract through the NIH’s Rapid
5 Acceleration of Diagnostics (“RADx”) initiative (the “RADx Contract”). The press release
6 proclaimed that the RADx Contract and \$100M in new, private financing would allow the
7 Company to “scale manufacturing” for the launch of the Talis One diagnostic platform, which
8 purportedly would provide “rapid and highly accurate detection of COVID-19 at the point-of-
9 care.”

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



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21 35. In contrast to cumbersome and time-intensive central lab testing, Talis claimed that
22 the Talis One platform was “designed to be operated by untrained personnel and incorporate safety
23 and convenience features, including automated cartridge-based sample preparation for reliable
24 results, closed cartridges to mitigate contamination, room-temperature cartridge storage for
25 convenient storage, and cloud connectivity for easily accessed results and records.”
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1 **C. Defendants Go All Out in the Build-Up to the IPO, Ignoring Problems with the**
2 **Talis One EUA Submission, Manufacturing, and Invalid Rates**

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

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

8 38. First, Talis nearly ran out of cash and was forced to issue a "going concern"
9 warning, meaning that it was probable that Talis would become insolvent within the next year.
10 Talis's first draft registration statement (confidentially filed with the SEC on October 15, 2020)
11 explained that "Our recurring losses from operations and negative cash flows raise substantial
12 doubt about our ability to continue as a going concern. As a result, our independent registered
13 public accounting firm on our financial statements as of and for the year ended December 31, 2019
14 included an explanatory paragraph indicating that there is substantial doubt about our ability to
15 continue as a going concern."

16 39. Under FASB ASU No. 2014-15, "[s]ubstantial doubt about an entity's ability to
17 continue as a going concern exists when relevant conditions and events, considered in the
18 aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they
19 become due within one year after the date that the financial statements are issued (or available to
20 be issued)." While Talis temporarily staved off its auditor's "going concern" warning by raising
21 \$126 million in private financing in November 2020, the Company still needed more capital.

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

27
28 ¹ Each FE's role, tenure at the Company, and statements are further described in Section V.C.a.

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

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

11 **a. Talis Could Not Manufacture the Talis One at Scale**

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

19 44. The Registration Statement touted that concrete steps toward production of the
20 Talis One had been taken and were scheduled in 2021. For example, it stated that Talis had
21 “ordered 5,000 instruments” to be delivered by “the first quarter of 2021” and touted that
22 “automated cartridge manufacturing lines capable of producing one million cartridges per month”
23 were “scheduled to begin to come on-line in the first quarter of 2021” and expected to “scale to
24 full capacity through 2021,” a year earlier than the original STI project.

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

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

1 molecular genetics—confirmed that Talis did not have a realistic timeline to manufacture its
2 product, let alone bring it to market. Indeed, FE-2 explained that for much of the period when
3 FE-2 worked at Talis (February to October 2020), Talis only had one person and a supporting
4 technician working on the COVID-19 test, but was aggressively applying for grants. FE-2
5 described an amalgamation of incompetency at every level within the Company – marketing,
6 alignment with R&D, and even creating a plan or timeline.

7 46. Similarly, FE-3—an engineer who worked at Talis for over four years before the
8 IPO—stated that Talis’s timelines were overly aggressive, citing company culture as one of the
9 drivers. When FE-3 mentioned concerns about the overly aggressive timelines to a scientific
10 advisor on Talis’s Board, the advisor responded that the aggressive timelines were “inspirational.”
11 FE-3 was infuriated and thought the timelines had no basis.

12 47. In the view of FE-1, a senior mechanical R&D engineer, Talis management ignored
13 many of the technical challenges with bringing the Talis One to market. FE-1 explained that all
14 the engineering wasn’t there, and the Talis One was a concept model. FE-1 further explained that
15 to go from prototype to full production at volume—a 100-fold increase—was not possible at the
16 time of the IPO.

17 48. Overall, FE-1 said that the combination of manufacturing, design, and supply chain
18 issues was like running without your pants pulled up all the way. In the second quarter of 2020,
19 FE-1 raised flags, especially about an issue with leaking cartridges that only began to be fixed in
20 December of 2020, after being known for a year. Management knew about the leaking cartridges,
21 FE-1 stated, because Talis had conducted a user study and the feedback was given to all of
22 management.

23 49. FE-1 also highlighted Tony Cunningham, the senior director of supply chain
24 starting in July 2020. Starting around August 2020, FE-1 spoke directly about supply issues to
25 Cunningham, who reported to CFO Roger Moody, but Cunningham ignored and downplayed
26 FE-1’s concerns. FE-1 also explained that Talis’s executive team knew what was being purchased
27 and they knew the testing results.

1 50. Talis was also significantly behind its internal deadlines shortly before the February
2 2021 IPO. FE-1 explained that Cunningham posted a weekly schedule of production that indicated
3 a Q4 2020 goal of producing 1,000 instruments for beta testing and to prove Talis’s manufacturing
4 capability, but Talis produced far fewer instruments in the quarter.

5 51. FE-1—who was responsible for sourcing component vendors for Talis’s cartridge
6 manufacturing—indicated that it was not possible for Talis to produce 1 million cartridges per
7 month. There was no contingency planning due to the company’s fatal flaw of not building in a
8 scheduling buffer to account for issues that might arise. FE-1 recalled that CEO Coe was notorious
9 for not having any scheduling buffer, which failed to recognize that in the engineering and
10 operations world, things happen.

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

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

15 53. According to FE-2, it was known well before the Company submitted its first EUA
16 application that the test had a high invalid rate. FE-2 indicated that this should have been no
17 surprise, as the Talis One was not developed with the biology in mind, and was developed by
18 engineering without much input from the assay department that developed the biological testing.

19 54. Specifically, FE-2 described poor communication between the engineering and
20 assay teams, resulting in a lack of pretesting in the Talis One design and design issues such as the
21 size of the cartridges. FE-2 indicated that the chamber sizes in the Talis One’s cartridges were
22 created without sufficient volume for proper Limits of Detection (the lowest concentration that a
23 test can consistently identify with high probability) because some of the chambers were too small.

24 55. FE-2’s account of a high invalid rate is corroborated by FE-4, who joined Talis in
25 February 2021. On or around November 12, 2021, FE-4 observed that the Talis One had a high
26 invalid rate when FE-4 turned on the device and it said “invalid, invalid, invalid” 20 or 30 times.
27 The same day, FE-4 told FE-4’s supervisor, Alex de los Reyes, that all the tests were invalid;
28 de los Reyes told FE-4 that the analyzer had such a high invalid rate that Talis could not take a

1 chance by attempting to operate the machine in front of potential clients. Because the device did
2 not function reliably, FE-4 was instructed to just run video presentations and not to turn on the
3 machine with potential clients.

4 56. FE-5, who joined Talis in September 2021, was told after Talis received its EUA
5 in November 2021 that the invalid rate had been and remained above 10%.

6 57. On or around December 6, 2021, during a business trip in California, FE-4
7 confronted Mai Nguyen (Product Manager) about the Talis One’s high invalid rate. Nguyen
8 indicated to FE-4 that two parts inside the test didn’t work; one of the non-functional parts was a
9 gasket, and the other was a plastic piece. FE-4 asked how Talis had been able to submit data to
10 the FDA. Nguyen indicated that, based on her interactions with Talis personnel who ran the
11 studies, including Michelle Roeding (Sr. Director Quality and Regulatory Affairs) and Lori Lai
12 (Director of Product Management), they had performed “simulations” and the FDA did not
13 physically inspect testing devices to ensure that they worked.

14 58. Nonetheless, the Registration Statement touted the Talis One as a “highly accurate”
15 product with safety and convenience features, while advising that Talis’s “diagnostic tests may
16 contain errors or defects or be subject to reliability issues.” In doing so, the Registration Statement
17 made no mention of the high invalid rates that were already known to the Company.

18 **c. Talis Botches Its Crucial EUA Application**

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

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

25 ³ Under Section 564 of the FD&CA, the FDA “may authorize unapproved medical products or
26 unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or
27 prevent serious or life-threatening disease.” This provides medical device manufacturers with an
28 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.

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

4 61. The details of Talis’s product testing and future EUA submission were also of
5 interest to the SEC. On November 10, 2020, an SEC comment letter directed to Defendant Coe
6 sought clarifications to the draft registration statement Talis had confidentially filed on October
7 15, 2020. The SEC’s comment letter directed Talis to “disclose any material protocols used during
8 the preclinical assessment of your COVID-19 test, including indicating if any portions of the
9 assessments were blinded Please revise your textual discussion of the 95% CI statistical
10 analysis performed to explain the significance of the ranges you provided and how this data
11 translates into you[r] plan to submit an Emergency Use Authorization to the FDA.”

12 62. Talis applied for an EUA on January 29, 2021, just days before the IPO. By that
13 time, the EUA process was well-established; the FDA had granted EUAs to other COVID-19
14 molecular diagnostic tests as early as April 2020, and authorized dozens of such tests by the end
15 of the year.⁴

16 63. The FDA’s Molecular Diagnostic Template for Commercial Manufacturers
17 (July 28, 2020) provided specific guidance to companies like Talis seeking EUAs. Applicants
18 were required to submit, among other things, studies demonstrating their test’s Limit of Detection
19 (LoD),⁵ inclusivity (analytical sensitivity), cross-reactivity (analytical specificity), and a clinical
20 evaluation.

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

26 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](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-
27 authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)

28 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.

1 if the comparator assay identifies 100 negative samples and the new test identifies 99 of the 100
2 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% | |

9 65. Because this testing is comparative in nature, the resulting data is only valid if the
10 benchmark comparator assay is reliable. For example, if 120 of the 200 samples were positive but
11 the comparator assay only identified 100 as positive, a new test with 99% PPA would be accurate
12 only 82.5% of the time (99 of 120). Likewise, if 80 of the samples were negative but the
13 comparator assay identified 100 as negative, a new test with 99% NPA would be accurate only
14 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) | |

23 66. For this reason, it was critical that Talis's EUA submission use a high quality,
24 sensitive comparator assay that correctly identified the SARS-CoV-2 virus and minimized false
25 negative results. The John Hopkins Center Bloomberg School of Public Health's Center for Health
26 Security has explained that sensitivity "measures the proportion of positive test results out of all
27
28

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

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

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

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

17 69. The EUA submission resulting from Talis’s flawed process and selection of a low
18 sensitivity comparator assay was deceptive because it compared the Talis One’s performance to a
19 useless benchmark. However, the Registration Statement extensively touted positive information
20 about the Talis One’s purported testing and the EUA submission, claiming that the Talis One had
21 been tested against “FDA-authorized” comparator tests and that the Talis One displayed “high
22 PPA and NPA [that] is suggestive of clinical sensitivity and specificity.” The Registration
23 Statement further stated that the “Talis One test results exactly matched the central lab results with
24 100% positive percentage agreement (PPA) and 100% negative percentage agreement (NPA) for
25 detection of COVID-19,” touted “the very low limits of detection possible on the Talis One

26 ⁶ See [https://www.centerforhealthsecurity.org/resources/COVID-19/COVID-19-fact-
27 sheets/201207-sensitivity-specificity-factsheet.pdf](https://www.centerforhealthsecurity.org/resources/COVID-19/COVID-19-fact-sheets/201207-sensitivity-specificity-factsheet.pdf) A related term, specificity, “measures the
28 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.*

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

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

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

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

13 72. Pursuant to the materially false and misleading Registration Statement, Defendants
14 completed the IPO on February 11, 2021, and 15,870,000 shares of Talis common stock (including
15 2,070,000 shares sold pursuant to the exercise in full by the underwriters of their option to purchase
16 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).

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

19 **E. The FDA Swiftly Rejects the Comparator Assay Used in Talis’s EUA Submission**

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

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

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

1 for the Talis One™ COVID-19 test In late February, the FDA
2 informed the company that it cannot ensure the comparator assay
3 used in the primary study has sufficient sensitivity to support Talis’s
4 EUA application.

5 Talis intends to initiate its previously planned clinical validation
6 study in a point-of-care environment, with plans to submit an EUA
7 application for the Talis One COVID-19 test in CLIA waived
8 settings early in the second quarter of 2021. The planned clinical
9 validation study was designed with a different comparator assay,
10 which Talis believes will address the FDA’s concerns.

11 76. This news drove a 12.3% decline in Talis’s share price and left Talis stock trading
12 at \$12.85 on March 8, 2021—well below the \$16.00/share IPO price, and less than half of its
13 \$27.80 peak.

14 **F. As the Delays Continue, the Exchange Act Defendants Double Down, Claiming to
15 Be “Ready to Go” and Touting “Terrific” Results**

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

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

23 **a. March 30, 2021: Talis Reports 2020 Earnings**

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

27 80. Talis’s 2020 10-K stated that “[w]e have ordered 5,000 instruments from our
28 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.”

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

6 82. The truth was very different from the Exchange Act Defendants' positive public
7 statements. In fact: (a) Talis had, at most, ordered the components for 5,000 instruments (not
8 5,000 instruments), which would then require costly and time-consuming assembly and testing
9 before they could be sold; (b) the Exchange Act Defendants had no basis to claim that cartridge
10 manufacturing lines would "scale to full capacity" of "one million Talis cartridges per month" at
11 any point in 2021; and (c) the Exchange Act Defendants knew that the Talis One suffered from
12 design issues and high invalid rates that foreclosed and/or dramatically delayed commercial
13 production. As detailed below, the Exchange Act Defendants knew these facts at the time.

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

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

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

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

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

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

4 [Analyst:] At the time of the IPO, you had laid out the path to the
5 70% margin. I know you talked about -- seeing you have 1 million
6 cartridge per month capacity now and automation was kind of the
7 key part, is that still on deck for kind of midyear to incorporate the
8 automation on the manufacturing side?

9 88. Defendant Moody responded:

10 Sure. So we are on track to bring up our automated lines, and we’ve
11 begun doing so. We expect to continue to bring those lines up to
12 meet demand throughout the second half [of 2021]. So that’s on
13 plan. And long term, we do think that our margin profile is attractive
14 as a razor-razorblade business, where over time, a majority of the
15 margins will be driven by the cartridge consumable.

16 89. A Bank of America analyst probed further, asking “hypothetically, after approval,
17 how soon can you ship the product out to the customers? I’m just trying to get at if there’s any
18 change to the product revenues for the rest of the year.” Defendant Coe responded:

19 We feel we’ll be in a position to ship product in a very timely
20 manner following an approval. We’re certainly spending quite an
21 effort on commercial preparedness. And as we’ve already
22 commented as well, we have a commercial team in place. And we
23 feel very much ready to go on our end.

24 90. These statements were false and misleading when made. Talis did not have a
25 realistic timeline to manufacture its product (FE-2), used overly aggressive timelines with no basis
26 (FE-3), and was significantly behind its internal deadlines by the end of 2020 (FE-1); it was not
27 possible to go from a prototype to full production at volume—a 100-fold increase (FE-1). Talis
28 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

1 2021—confirmed that despite claims from the Company, Talis was not ready to begin
 2 manufacturing as soon as the EUA was received. Further, the Talis One continued to generate
 3 high invalid rates even in late 2021, as FE-4 confirmed.

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

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

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

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

22 But I mean, you missed your first EUA, your products are delayed.
 23 Basically, what you shared with us on the deal model and everything
 24 is dramatically pushed out from where it was. I mean what gives
 25 you comp -- I mean what can you say to give us confidence that the
 26 longer-term opportunity is there?

27 94. In response, Defendant Coe touted “terrific” results, claiming Talis was “way ahead
 28 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

1 on our ability to produce product relative to almost any company
2 our size historically.

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

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

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

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

18 97. Importantly, in the medical device industry, “validation” is a technical term that
19 indicates an extensive degree of scrutiny such that a successful result is practically assured:
20 “Process validation is a term used in the medical device industry to indicate that a process has been
21 subject to such scrutiny that the result of the process (a product, a service or other outcome) can
22 be practically guaranteed.”⁷ Statements that Talis was “in the final stages of validation” thus
23 indicated that Talis had extensively scrutinized the cartridge production lines and was on the verge
24 of consistent production at scale.

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

27 And then I also wanted to ask about maybe a clarification around –
28 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>

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

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

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

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

24 **d. August 30, 2021: CEO Coe Departs Abruptly**

25 101. On August 30, 2021, Talis announced that Defendant Coe had "stepped down" as
 26 its President, CEO, and Director, effective immediately. Talis offered no explanation for
 27 Defendant Coe's abrupt departure, and, without a permanent replacement, appointed its Chairman
 28 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

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

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

5 104. During the November 15, 2021 earnings call, Interim CEO Popovits revealed that
6 Talis would execute a “controlled product rollout” using a “measured approach.” Chief
7 Commercial Officer Rob Kelley reiterated that Talis had “decided to take a phased approach for
8 rolling out the Talis One System,” with a “limited rollout” to begin “in the first quarter of 2022”
9 that would involve “a small number of sites representative of the customers we are targeting . . .
10 .” This delayed timeline and small-scale commercial introduction recognized that the Company
11 was currently unprepared and unable to manufacture the Talis One at scale.

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

14 105. Blaser became Talis’s CEO on December 1, 2021. Only a week later, on December
15 8, 2021, Talis announced that, Brian Blaser had “stepped down” from his positions as President,
16 CEO, and Director effective immediately. While Talis publicly claimed that Blaser’s departure
17 was due to “personal matters,” FE-4 later learned from a contact at another company that Blaser
18 left Talis because there was major fraud.

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

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

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

28 108. 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

1 commercialization,” and that “our current process is not yet optimized to produce a minimum
2 monthly yield [of instruments] to support a commercial launch.” Moreover, Kelley stated that
3 “based on the level of information we have today, we are not providing a timeline for commercial
4 launch.”

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

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

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

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

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

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

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

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

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

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

25 117. Unsurprisingly, after nearly 18 months of false promises with no commercially
26 available product, the market has essentially given up on Talis as a viable company. On May 10,
27 2022, Talis filed a Form S-3 registration statement indicating that its largest shareholder—Baker
28 Bros. Advisors LP and related entities—seeks to sell its entire stake in Talis, comprised of

1 37,489,210 shares of common stock (including the conversion of preferred shares)—or 66% of
2 Talis’s total outstanding voting stock.

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

4 **IV. SECURITIES ACT ALLEGATIONS**

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

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

15 **A. Securities Act Parties**

16 **a. Securities Act Plaintiffs**

17 121. Martin Dugan (“Dugan”) is an individual residing in Malibu, California.

18 122. Leon Yu (“Yu”) is an individual residing in Beijing, China.

19 123. Max Wisdom Technology Limited (“Max Wisdom”) is a company incorporated in
20 Hong Kong.

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

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

1 misstatements and omissions of material fact leaked out into the market from March 2021 to March
2 2022, the price of Talis stock fell, causing Lead Plaintiffs and the Class to suffer losses.

3 **b. Securities Act Defendants**

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

7 127. Defendant Talis is a U.S. medical diagnostic company. Talis is incorporated in
8 Delaware with its principal executive offices at 230 Constitution Drive, Menlo Park, California
9 94025. Talis common stock trades on the NASDAQ under the ticker symbol “TLIS.” Talis was
10 the issuer of the IPO.

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

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

21 130. Defendant Felix Baker (“Baker”) has served as a member of Talis’s Board of
22 Directors since June 2013. Baker signed the Registration Statement for the IPO.

23 131. Defendant Raymond Cheong (“Cheong”) served as a member of Talis’s Board of
24 Directors from June 2020 until June 10, 2022. Cheong signed the Registration Statement for the
25 IPO.

26 132. Defendant Melissa Gilliam (“Gilliam”) has served as a member of Talis’s Board of
27 Directors since December 2020. Gilliam signed the Registration Statement for the IPO.

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

4 134. Defendant Kimberly J. Popovits (“Popovits”) has served as a member of Talis’s
5 Board of Directors since March 2020. Popovits signed the Registration Statement for the IPO.

6 135. Defendant Matthew L. Posard (“Posard”) has served as a member of Talis’s Board
7 of Directors since March 2016. Posard signed the Registration Statement for the IPO.

8 136. Defendant Randal Scott (“Scott”) has served as a member of Talis’s Board of
9 Directors since February 2016. Scott signed the Registration Statement for the IPO.

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

12 138. Talis and the Individual Defendants are collectively referred to herein as the
13 “Securities Act Defendants.”

14 **B. Securities Act False and Misleading Statements and Omissions**

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

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

21 141. On February 11, 2021, Talis filed an Amendment No. 2 to the Registration
22 Statement on Form S-1, including a revised preliminary prospectus with the same date. At
23 4:30 PM on February 11, 2021, Talis’s Registration Statement was declared effective.

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

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

1 144. The Registration Statement contained materially false and misleading statements
2 and omissions concerning the testing performed on the Talis One and the data submitted to the
3 FDA; Talis's ability to manufacture the Talis One at commercial scale, including a false claim that
4 Talis had ordered 5,000 instruments before the IPO; and the performance, reliability, safety, and
5 convenience of the Talis One. In addition, the Registration Statement omitted material information
6 about known uncertainties and specific risks in violation of applicable SEC rules and regulations.
7 These material statements and omissions, and the grounds for falsity as to each, are detailed below.

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

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

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

17 As part of our development of our COVID-19 test we assessed the
18 performance of the Talis One platform using anterior or mid-
19 turbinate nasal specimens to tests conducted in a centralized
20 laboratory using the CDC quantitative reverse transcription
21 polymerase chain reaction (RT-PCR) test. In a preclinical
22 assessment comparing the Talis One platform to an FDA-authorized
23 reference lab test, on 60 matched anterior or mid-turbinate nasal
24 specimens, our COVID-19 test results exactly matched the central
25 lab comparator test results with 100% positive percentage
26 agreement (PPA) and 100% negative percentage agreement (NPA)
27 for the detection of SARS-CoV-2, the virus that causes COVID-19.
28 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

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

11 148. The Registration Statement also stated:

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

16 ...

17 149. This statement was materially misleading when made because, having chosen to
18 speak about the EUA submission and the FDA’s request for “additional information on our test,”
19 the Registration Statement omitted the most important fact: Talis’s EUA submission was deficient
20 because Talis had used a comparator assay that lacked sufficient sensitivity to support its EUA
21 submission under FDA standards. As detailed above, before the IPO, Talis had chosen a weak
22 comparator assay for its submission, and the circumstances strongly suggest that the FDA had
23 raised concerns about the comparator assay before the IPO. In failing to disclose these existing,
24 material negative facts, the Registration Statement omitted material facts necessary to make the
25 statements not misleading in the context in which they were made.

26 150. The Registration Statement also stated:

27 There can be no assurance that the COVID-19 test we are
28 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.

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

5 151. These purported risk disclosures were materially misleading when made because
6 they omitted the existing, material negative fact that Talis’s EUA submission was deficient
7 because Talis had used a comparator assay that lacked sufficient sensitivity to support its EUA
8 submission under FDA standards. As detailed above, before the IPO, Talis had chosen a weak
9 comparator assay for its submission, and the FDA had already requested “additional information”
10 from Talis, strongly suggesting that the FDA had raised concerns about the comparator assay
11 before the IPO. By portraying the FDA’s rejection of Talis’s EUA submission and resulting
12 adverse effects on Talis’s business, financial condition, results of operations, and future growth
13 prospects as merely hypothetical risks, rather than known certainties, the Registration Statement
14 omitted material facts necessary to make the statements not misleading in the context in which
15 they were made. Indeed, the FDA’s rejection manifested itself just days after the IPO.

16 **b. Materially False and Misleading Statements Concerning Talis’s**
17 **Manufacturing Capability**

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

21 153. The Registration Statement stated:

22 To support our anticipated commercial launch of our COVID-19
23 test, we have invested in automated cartridge manufacturing lines
24 capable of producing one million cartridges per month, which are
25 scheduled to begin to come on-line in the first quarter of 2021 and
26 we expect will scale to full capacity through 2021.

27 ...

28 *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,

1 having chosen to speak about Talis’s purported investment in automated cartridge production lines
2 and their capacity and timetable for operation, as well as the Talis One’s ability to be manufactured
3 at scale and with low cost, the Registration Statement omitted the facts that (a) Talis did not have
4 a realistic timeline for production and could not produce one million cartridges per month; (b)
5 Talis was already significantly behind its internal deadlines for beta testing; and (c) the Talis One
6 suffered from design issues and high invalid rates that foreclosed and/or dramatically delayed
7 commercial production. In failing to disclose these existing, material negative facts, the
8 Registration Statement omitted material facts necessary to make the statements not misleading in
9 the context in which they were made.

10 155. The Registration Statement also stated:

11 We have ordered 5,000 instruments from our instrument contract
12 manufacturing partners to be delivered beginning in the fourth
13 quarter of 2020 through the first quarter of 2021.

14 156. This statement was materially false and misleading when made because it indicated
15 that (a) Talis had ordered 5,000 instruments, and (b) the 5,000 instruments would be delivered
16 between the fourth quarter of 2020 and the first quarter of 2021. Both aspects of the statement
17 were false. In its Form 10-K filed on March 30, 2021, Talis admitted that it had actually “ordered
18 5,000 instruments from our instrument contract manufacturing partners to be delivered through
19 the third quarter of 2021”—two quarters after the Registration Statement claimed. Further, in
20 Talis’s Form 10-K filed on March 15, 2022, Talis admitted that it had ordered “components for up
21 to 5,000 instruments”—not the instruments themselves, as the Registration Statement claimed.
22 For both reasons, the statement in the Registration Statement was false. Moreover, in failing to
23 disclose the existing facts that Talis had only ordered components for up to 5,000 instruments to
24 be delivered through the third quarter of 2021, the Registration Statement omitted material facts
25 necessary to make the statements not misleading in the context in which they were made.

26 **c. Materially False and Misleading Statements Concerning the Talis One’s
27 Performance and Reliability**

28 157. 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

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

5 158. The Registration Statement stated:

6 The test cartridge for COVID-19 diagnosis contains a NAAT
7 designed for optimal sensitivity and specificity to provide highly
8 accurate results. The assay on the Talis One cartridge is an
9 isothermal NAAT targeting two physically separated locations in
10 the SARS-CoV-2 genome to increase sensitivity and inclusivity.
11 While natural evolution of the SARS-CoV-2 virus is to be expected,
12 the inclusion of two distinct targets reduces the likelihood that
13 natural mutations in the virus would cause a false negative result
14 when using the Talis One COVID-19 test.

11 ...

12 An important factor in our ability to commercialize our products is
13 collecting data that supports the value proposition of our products,
14 and in particular that our tests are just as accurate and reliable as
15 central lab testing.

15 ...

16 In addition, our platform is designed to be operated by untrained
17 personnel and incorporate safety and convenience features,
18 including automated cartridge-based sample preparation for reliable
19 results, closed cartridges to mitigate contamination, room-
20 temperature cartridge storage for convenient storage, and cloud
21 connectivity for easily accessed results and records.

22 159. These statements were materially false and misleading when made. First, the
23 Talis One did not "provide highly accurate results" and was not "just as accurate and reliable as
24 central lab testing." Rather, as detailed above, the Talis One had a high invalid rate well before
25 the Company submitted its first EUA application, as well as after the IPO, driven by two non-
26 functional parts, a gasket and a plastic piece. Further, the Talis One suffered from design issues,
27 such as the size of the cartridges, which had some chambers that were too small for proper Limits
28 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

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

3 160. Further, the Registration Statement stated:

4 If our products do not perform as expected, including due to errors,
5 defects or reliability issues, our reputation and market acceptance of
6 our products could be harmed, and our operating results, reputation
7 and business will suffer. . . . There is no guarantee that the accuracy
8 and reproducibility we have demonstrated to date will continue as
9 our product deliveries increase and our product portfolio expands.

10 ...

11 Our diagnostic tests may contain errors or defects or be subject to
12 reliability issues, and while we have made efforts to test them
13 extensively, we cannot assure that our current diagnostic tests, or
14 those developed in the future, will not have performance problems.
15 An operational, technological or other failure in one of these
16 complex processes or fluctuations in external variables may result
17 in sensitivity or specificity rates that are lower than we anticipate or
18 result in longer than expected turnaround times or they may cause
19 our products to malfunction.

20 ...

21 Unfavorable results from ongoing preclinical and clinical studies
22 could result in delays, modifications or abandonment of ongoing
23 analytical or future clinical studies, or abandonment of a product
24 development program, or may delay, limit or prevent regulatory
25 approvals or clearances or commercialization of our products, any
26 of which may materially adversely affect our business, financial
27 condition and results of operations. Furthermore, results that would
28 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

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

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

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

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

13 Describe any known trends or uncertainties that have had or that the
14 registrant reasonably expects will have a material favorable or
15 unfavorable impact on net sales or revenues or income from
16 continuing operations. If the registrant knows of events that will
17 cause a material change in the relationship between costs and
18 revenues (such as known future increases in costs of labor or
19 materials or price increases or inventory adjustments), the change in
20 the relationship shall be disclosed.⁸

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

23 Where a trend, demand, commitment, event or uncertainty is known,
24 management must make two assessments:

25 (1) Is the known trend, demand, commitment, event or uncertainty
26 likely to come to fruition? If management determines that it is not
27 reasonably likely to occur, no disclosure is required.

28 (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.

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

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

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

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

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

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

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

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

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

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

28 ⁹ See <https://talisbio.com/meet-our-team/>

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

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

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

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

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

1 foreclosed and/or dramatically delayed commercial production; and (e) Talis had not ordered
2 5,000 instruments to be delivered between the fourth quarter of 2020 and the first quarter of 2021,
3 but instead merely ordered “components for up to 5,000 instruments.” In uncovering these facts,
4 a reasonable investigation would also have revealed that the Registration Statement omitted
5 known, material uncertainties and risks in violation of Item 303 and Item 105.

6 **D. Talis’s Share Price Collapses by the Time of Suit**

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

12 **V. EXCHANGE ACT ALLEGATIONS**

13 **A. Exchange Act Parties**

14 **a. Exchange Act Plaintiffs**

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

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

19 **b. Exchange Act Defendants**

20 178. Defendant Talis is described above.

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

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

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

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

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

15 **B. False and Misleading Statements and Omissions**

16 183. During the Class Period, the Exchange Act Defendants made false and misleading
17 statements regarding the progress, production levels, and validation of the Talis One cartridge
18 manufacturing lines; Talis's ability to ship the Talis One promptly following FDA approval; the
19 quality of results; the reasons for Talis adopting a "phased approach" to launching the Talis One;
20 and Talis's purported order of 5,000 Talis One "instruments."

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

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

26 185. 2020 10-K. In Talis's 2020 10-K, filed with the SEC on March 30, 2021, Talis
27 claimed to have "invested in automated cartridge manufacturing lines capable of producing one
28

1 million Talis One cartridges per month for the COVID-19 assay, which are scheduled to begin to
2 come on-line in the first quarter of 2021 and we expect will scale to full capacity through 2021.”

3 186. This statement was materially false and misleading when made because, as detailed
4 above and below, the Exchange Act Defendants had no basis to claim that production lines “will
5 scale to full capacity” of one million cartridges per month at any point in 2021. Rather, as detailed
6 above and below, (a) Talis did not have a realistic timeline for production and could not produce
7 one million cartridges per month; (b) Talis was already significantly behind its internal deadlines
8 for beta testing; and (c) the Exchange Act Defendants knew that the Talis One suffered from design
9 issues and high invalid rates that foreclosed and/or dramatically delayed commercial production.
10 Having chosen to speak positively about Talis’s cartridge production capacity, the 2020 10-K
11 omitted these known, material negative facts, which were necessary to make the statements not
12 misleading in the context in which they were made.

13 187. 1Q21 10-Q. Talis’s 1Q21 10-Q, filed on May 11, 2021, stated:

14 We have invested in automated cartridge manufacturing lines
15 capable of producing one million Talis One cartridges per month.
16 The first of such lines was delivered in the first quarter of 2021, and
we expect will scale to meet demand through 2021.

17 188. This statement was materially false and misleading when made because, as detailed
18 above and below, the Exchange Act Defendants had no basis to claim that production lines “will
19 scale to meet demand” and produce one million cartridges per month at any point in 2021. Rather,
20 as detailed above and below, (a) Talis did not have a realistic timeline for production and could
21 not produce one million cartridges per month; (b) Talis was already significantly behind its internal
22 deadlines for beta testing; and (c) the Exchange Act Defendants knew that the Talis One suffered
23 from design issues and high invalid rates that foreclosed and/or dramatically delayed commercial
24 production. Having chosen to speak positively about Talis’s cartridge production capacity, the
25 1Q21 10-Q omitted these known, material negative facts, which were necessary to make the
26 statements not misleading in the context in which they were made.

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

4 At the time of the IPO, you had laid out the path to the 70% margin.
 5 I know you talked about -- seeing you have 1 million cartridge per
 6 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?

7 Defendant Moody responded:

8 Sure. So we are on track to bring up our automated lines, and we've
 9 begun doing so. We expect to continue to bring those lines up to
 10 meet demand throughout the second half [of 2021]. So that's on
 11 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.

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

15 We feel we'll be in a position to ship product in a very timely
 16 manner following an approval. We're certainly spending quite an
 17 effort on commercial preparedness. And as we've already
 18 commented as well, we have a commercial team in place. And we
 feel very much ready to go on our end.

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

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

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

5 192. 2Q21 8-K. On August 10, 2021, Talis announced its second quarter 2021 earnings
6 on Forms 8-K and 10-Q filed with the SEC. In the 2Q21 8-K, Talis claimed that the Company
7 had “[c]ompleted installation and [was] in the final stages of validation for the first set of
8 automated cartridge production lines.”

9 193. This statement was materially false and misleading when made because Talis was
10 not in the “final stages of validation” on the cartridge manufacturing lines. As detailed above,
11 “validation” is a technical term indicating that a process has been scrutinized and the result is
12 practically guaranteed. Had Talis been in the “final stages of validation” as of August 2021, Talis
13 would already have scrutinized the performance of the production lines and resulting cartridges.
14 However, that was not the case. On March 15, 2022, CEO Kelley stated: “When we spoke with
15 you back in November [2021], we were beginning to evaluate the performance of cartridges
16 coming off our high-yield lines,” thereby confirming that Talis was not in the “final stages of
17 validation” in August 2021. FE-5 confirmed that Talis had not validated its production lines,
18 which was significant and one of the major factors in not launching the Talis One.

19 194. 2Q21 10-Q. Talis’s 2Q21 10-Q, filed on August 10, 2021, stated:

20 We have invested in automated cartridge manufacturing lines
21 capable of producing one million Talis One cartridges per month.
22 The first of such lines was delivered in the first quarter of 2021, and
we expect will scale to meet demand through 2021.

23 195. This statement was materially false and misleading when made because, as detailed
24 above and below, the Exchange Act Defendants had no basis to claim that production lines “will
25 scale to meet demand” and produce one million cartridges per month at any point in 2021. Rather,
26 as detailed above and below, (a) Talis did not have a realistic timeline for production and could
27 not produce one million cartridges per month; (b) Talis was already significantly behind its internal
28 deadlines for beta testing; and (c) the Exchange Act Defendants knew that the Talis One suffered

1 from design issues and high invalid rates that foreclosed and/or dramatically delayed commercial
2 production. Having chosen to speak positively about Talis's cartridge production capacity, the
3 2Q21 10-Q omitted these known, material negative facts, which were necessary to make the
4 statements not misleading in the context in which they were made.

5 196. In addition, Talis claimed in its 2Q21 10-Q that "[t]he ramp up of our [Talis One]
6 manufacturing efforts, which began in the middle of 2020, is expected to be completed by the end
7 of 2021."

8 197. 2Q21 Earnings Call. During Talis's 2Q21 earnings call held on August 10, 2021,
9 an analyst from Bank of America asked:

10 But I mean, you missed your first EUA, your products are delayed.
11 Basically, what you shared with us on the deal model and everything
12 is dramatically pushed out from where it was. I mean what gives
13 you comp -- I mean what can you say to give us confidence that the
14 longer-term opportunity is there?

15 Defendant Coe responded:

16 What I'll say is the -- yes, the time lines are later than we'd
17 anticipated in the IPO model. And on the other hand, our results
18 really look terrific. From a company perspective, we're way ahead
19 on our ability to produce product relative to almost any company
20 our size historically.

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

22 You talked a little bit about the phased approach rollout here. Can
23 you talk a little bit about sort of the customers you're targeting in
24 4Q with that phased rollout for the COVID test? And then as things
25 sort of ramp in the beginning of next year, can you just talk a little
26 bit about customer mix? Has your plans changed at all regarding
27 who you're targeting here with this phased rollout?

28 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.

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

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

19 200. 3Q21 10-Q. Talis’s 3Q21 10-Q, filed on November 16, 2021, stated:

20 We have invested in automated cartridge manufacturing lines
21 capable of producing one million Talis One cartridges per month.
22 The first of such lines was delivered in the first quarter of 2021, and
23 we expect will scale to meet demand through 2021.

24 201. This statement was materially false and misleading when made because, as detailed
25 above and below, the Exchange Act Defendants had no basis to claim that production lines “will
26 scale to meet demand” and produce one million cartridges per month at any point in 2021. Rather,
27 as detailed above and below, (a) Talis did not have a realistic timeline for production and could
28 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

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

5 202. Talis further claimed in its 3Q21 10-Q that “[t]he ramp up of our [Talis One]
6 manufacturing efforts, which began in the middle of 2020, is expected to be completed by the end
7 of 2021.”

8 203. 3Q21 Earnings Call. On November 15, 2021, Defendant Moody stated:

9 We expect to recognize \$2 million of remaining milestone revenue
10 from our amended RADx contract between now and the contract
11 termination date at the end of January 2022. The balance of the third
12 quarter 2021 financials were shaped by investments in launch
13 preparation that are beginning to come to fruition.

14 204. The statements in ¶¶202-203 above were materially false and misleading when
15 made because, as detailed above and below, the Exchange Act Defendants had no basis to claim
16 that Talis could complete its manufacturing “ramp up” by “the end of 2021,” or that Talis’s
17 purported “investments in launch preparation” were “beginning to come to fruition.” Rather, as
18 detailed above and below, (a) Talis did not have a realistic timeline for production and could not
19 produce one million cartridges per month; (b) Talis was already significantly behind its internal
20 deadlines for beta testing; and (c) the Exchange Act Defendants knew that the Talis One suffered
21 from design issues and high invalid rates that foreclosed and/or dramatically delayed commercial
22 production. Having chosen to speak positively about Talis’s manufacturing progress, the
23 Exchange Act Defendants omitted these known, material negative facts, which were necessary to
24 make the statements not misleading in the context in which they were made.

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

26 I guess on the commercialization strategy, can you just talk a little
27 bit, are you still prioritizing larger hospital placements before urgent
28 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?

1 Defendant Kelley responded:

2 So the commercial team's focus is to provide the best customer
3 experience possible. And as you know, there's a likelihood that if
4 you go to market with a product too quickly, you can do some
5 damage to reputation, and we just don't want to do that. We think
6 we've got a great product here.

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

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

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

25 208. These statements were materially false and misleading when made because Talis
26 did not order "5,000 instruments." Rather, as Talis admitted in its Form 10-K filed on March 15,
27 2022, Talis had merely ordered "components for up to 5,000 instruments"—not the instruments
28 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

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

3 **C. Additional Allegations of Scienter**

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

7 **a. Former Employee Allegations**

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

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

- 19 (i) Accelerated timetable: Had COVID not happened, the
20 original cartridge for STI testing was slated to go into
21 production in 2022. Defendants sought to accelerate Talis's
22 plans and quickly conduct an IPO in light of the pandemic,
23 but Talis was a few years behind in technical development,
24 and its response was to throw money at the problem.
- 25 (ii) Failure to recognize technical challenges: Talis
26 management ignored many of the technical challenges with
27 bringing the Talis One to market, as all the engineering
28 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

1 leaking cartridges that only began to be fixed in December
 2 2020, after being known for a year. Management knew
 3 about the leaking cartridges because Talis had conducted a
 4 user study and the feedback was given to all of management.
 5 Starting around August 2020, FE-1 spoke directly about
 6 supply issues to Tony Cunningham (the senior director of
 7 supply chain starting in July 2020), who reported to CFO
 8 Roger Moody, but Cunningham ignored and downplayed
 9 FE-1's concerns. FE-1 also explained that Talis's executive
 10 team knew what was being purchased and they knew the
 11 testing results.

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

17 (v) Large-scale manufacturing not possible: FE-1 was
 18 responsible for sourcing component vendors for Talis's
 19 cartridge manufacturing. FE-1 indicated that it was not
 20 possible for Talis to produce 1 million cartridges per month.
 21 There was no contingency planning because of the
 22 company's fatal flaw of not building in a scheduling buffer
 23 to account for issues that might arise. CEO Coe was
 24 notorious for not having any scheduling buffer, which failed
 25 to recognize that in the engineering and operations world,
 26 things happen.

27 (vi) Talis was not "ready to go": Coe's May 2021 claim that
 28 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.

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

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

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

- 3 (ii) High invalid rate known: It was known well before Talis
4 submitted its first EUA application that the test had a high
5 invalid rate. This should have been no surprise, as the Talis
6 One was not developed with the biology in mind, and was
7 developed by engineering without much input from the assay
8 department that developed the biological testing.
- 9 (iii) Design issues: Poor communication between the
10 engineering and assay teams resulted in a lack of pretesting
11 in the Talis One design and design issues such as the size of
12 the cartridges. The chamber sizes in the Talis One's
13 cartridges were created without sufficient volume for proper
14 Limits of Detection because some of the chambers were too
15 small.
- 16 (iv) Lack of SOPs and processes: Talis had a lack of
17 communication, proper documentation, and standard
18 operating procedures; Talis did not apply the processes or
19 vetting necessary to conduct the IVD (In Vitro Diagnostics)
20 process properly.
- 21 (v) No realistic timeline and limited resources: Talis did not
22 have a realistic timeline to manufacture its product, let alone
23 bring it to market. Indeed, for much of the period when FE-2
24 worked at Talis (February to October 2020), Talis only had
25 one person and a supporting technician working on the
26 COVID-19 test, but was aggressively applying for grants.
27 Within the Company, there was an amalgamation of
28 incompetency at every level – marketing, alignment with
R&D, and even creating a plan or timeline.

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

- 26 (i) Overly aggressive timelines that had no basis: Talis's
27 timelines were overly aggressive, driven in part by company
28 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

1 “inspirational.” FE-3 was infuriated and thought the
2 timelines had no basis.

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

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

- 14 (i) Focus on generating “sales” and pre-selling even before
15 FDA approval: From the beginning, FE-4 was told that Talis
16 needed to generate sales to show shareholders. While FE-4’s
17 past employers had refrained from telling employees what
18 products were in the works to ensure that they didn’t start
19 promoting them preemptively, Talis wanted its salesforce to
20 sell a product that was in its earliest stages, even before the
21 Talis One had received FDA approval. FE-4 was concerned
22 about this practice, since other firms prohibited marketing of
23 products that were still in development, and violations could
24 result in large penalties and fines from the FDA.
- 25 (ii) Aggressive sales tactics led to presales reported to the Board:
26 Contacts with potential customers were logged and tracked
27 in Salesforce CRM (customer relationship management)
28 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

1 machines, which had to be made by hand, and that Talis did
2 not have a manufacturer at full scale.

3 (iv) No functioning product: In FE-4's view, to say Talis had a
4 working test was not the truth. The Talis One was little more
5 than a "dummy box" that sales representatives were
6 instructed not to turn on in meetings at doctors' offices and
7 hospitals. Because the device did not function reliably, FE-4
8 was instructed to just run video presentations and not to turn
9 on the machine with potential clients. On or around
10 November 12, 2021, FE-4 turned on the device and it said
11 "invalid, invalid, invalid" 20 or 30 times. The same day,
12 FE-4 told FE-4's supervisor, Alex de los Reyes, that all the
13 tests were invalid; de los Reyes told FE-4 that the analyzer
14 had such a high invalid rate that Talis could not take a chance
15 by attempting to operate the machine in front of potential
16 clients.

17 (v) High invalid rate: On or around December 6, 2021, during
18 a business trip in California, FE-4 confronted Mai Nguyen
19 (Product Manager) about the Talis One's high invalid rate.
20 Nguyen indicated to FE-4 that two parts inside the test didn't
21 work; one of the non-functional parts was a gasket, and the
22 other was a plastic piece. FE-4 asked how Talis had been
23 able to submit data to the FDA. Nguyen indicated that,
24 based on her interactions with Talis personnel who ran the
25 studies, including Michelle Roeding (Sr. Director Quality
26 and Regulatory Affairs) and Lori Lai (Director of Product
27 Management), they had performed "simulations" and the
28 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

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

- 3 (i) Not ready to begin production upon receipt of EUA: When
4 FE-5 was hired in September 2021, Talis did not have a
5 target launch date for the Talis One COVID-19 test because
6 the Company had not yet received its EUA from the FDA.
7 The submission had been sent in late July 2021, and despite
8 claims from the company, Talis was not ready to begin
9 manufacturing as soon as the EUA was received.
- 10 (ii) High invalid rate known: FE-5 confirmed that it was already
11 known inside Talis that the invalid rate was high; after Talis
12 received its EUA in November 2021, FE-5 was told that the
13 invalid rate had been and remained above 10%.
- 14 (iii) No validation of production lines: FE-5 explained that Talis
15 had not validated its production lines, which was significant
16 and one of the major factors in not launching the Talis One.

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

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

25 217. The Talis One's reliability and timetable for production and launch were thus
26 crucial for the Company, as they determined whether and when it would begin generating
27 meaningful revenue. That was particularly important given the finite amount of cash raised in the
28 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.

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

4 **c. The Officer Defendants Had Continuous Access to Information Showing
 5 That Talis Was Far from “Ready to Go”**

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

16 220. First, the RADx Contract—Talis’s largest government contract—contained
 17 detailed requirements, including that Talis report the “reason” for any delays. In its November 10,
 18 2020 comment letter, the SEC required Talis to publicly file the RADx Contract as an exhibit to
 19 the Registration Statement.¹⁰ The RADx Contract was signed by Defendant Coe, who was
 20 necessarily familiar with its terms and requirements:

21

22

23

24

| | | | |
|---|--|--|---------------------------------------|
| <small>Except as provided herein, all terms and conditions of the document referenced in Item 9.A or 10.A, as heretofore changed, remains unchanged and in full force and effect.</small> | | | |
| 15A. NAME AND TITLE OF SIGNER (Type or print) Brian Coe Chief Executive Officer | | 15A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) ALLISON M. CRISTMAN | |
| 15B. CONTRACTOR/OFFEROR  <small>Brian Coe (User ID: 2020111511044-0500)</small> | 15C. DATE SIGNED Dec 9, 2020 | 15B. UNITED STATES OF AMERICA Digitally signed by Allison M. Cristman - S Cristman - S Date: 2020.12.15 15:10:44 -0500 <small>(Signature of Contracting Officer)</small> | 15C. DATE SIGNED 12/15/2020 |
| <small>NSN 7540-01-152-8070 Previous edition unusable</small> | | <small>STANDARD FORM 30 (REV. 10-63) Prescribed by GSA FAR (48 CFR) 53.243</small> | |

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

27 ¹⁰ See Exhibit 10.14 to Registration Statement, available at
 28 <https://www.sec.gov/Archives/edgar/data/0001584751/000119312521014914/d25171dex1014.htm>

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

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

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

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

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

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

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

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

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

1 that “if demand warrants it, which we’ll be monitoring, we’ll be moving forward with additional
2 capacity on an ongoing basis.”

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

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

18 **e. Officer Terminations Support Scierter**

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

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

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

6 **f. Corporate Scienter**

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

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

22 235. As-yet-unidentified Talis senior executives also approved the false statements
23 despite knowing of their false and misleading nature. As alleged above, Talis had extensive
24 reporting requirements under the RADx Contract and thinXXS Contract and was required by the
25 FDA to track the Talis One’s invalid rates, and the appearance of a viable path to
26 commercialization was highly significant to Talis’s share price. From this, it can be strongly
27 inferred that senior executives at Talis approved the false and misleading statements concerning
28

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

3 **D. Loss Causation**

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

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

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

26 **a. August 10, 2021**

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

1 manufacturing scale.” As a result, Talis “expect[s] to see [its] first meaningful revenue ramp in
2 2022.” This was the Company’s first public acknowledgement of manufacturing delays with the
3 Talis One. Talis also revealed that it had finally submitted a new EUA application to the FDA in
4 late July 2022, later than the second-quarter estimate Talis had previously provided.

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

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

12 **b. August 30, 2021**

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

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

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

22 **c. November 15, 2021**

23 245. On November 15, 2021, after the market closed, Talis filed a press release on Form
24 8-K announcing Q3 2021 financial results and that it would execute a “controlled product rollout”
25 using a “measured approach.” In the Company’s November 15, 2021 conference call with
26 investors, Defendant Kelley reiterated that Talis had “decided to take a phased approach for rolling
27 out the Talis One System,” with a “limited rollout” to begin “in the first quarter of 2022” that
28 would involve “a small number of sites representative of the customers we are targeting”

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

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

12 **d. December 8, 2021**

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

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

19 **e. March 15, 2022**

20 250. On March 15, 2022, after the market closed, Talis reported financial results for
21 2021 and revealed that “Talis has not started its phased launch of the Talis One™ COVID-19 Test
22 System due to challenges with manufacturing. The company has engaged in a manufacturing
23 review process to determine appropriate next steps and undertaken initiatives to align resources
24 and preserve cash.” Talis further disclosed that it had engaged external consultants “to assess
25 product design for manufacturing at scale” and “evaluate current processes”; that the Company
26 was laying off approximately 25 percent of its workforce; and that COO Liu was stepping down.
27 Moreover, while Talis had repeatedly claimed in its SEC filings to have “ordered 5,000 Talis One
28 instruments from our instrument contract manufacturer” (as detailed above), Talis’s Form 10-K

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

4 251. During the Company’s March 15, 2022 conference call with investors, CEO Kelley
5 admitted that “the yield and consistency of our current manufacturing process is not yet sufficient
6 to support commercialization,” and that “our current process is not yet optimized to produce a
7 minimum monthly yield [of instruments] to support a commercial launch.” Moreover, Kelley
8 stated that “based on the level of information we have today, we are not providing a timeline for
9 commercial launch.” Kelley also revealed that “the rate of invalid or failed tests remains higher
10 than what we believe is acceptable,” conceding that the invalid rates were “above 10%,” while
11 adding that “I wouldn’t say it’s significantly above 10%.”

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

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

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

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

- 26 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;
- 27 b) The average daily trading volume of Talis’s common stock was significant and
28 amounted to approximately 213,000 shares during the Class Period;

- 1 c) As a regulated issuer, Talis filed public reports with the SEC and the NASDAQ;
 2 d) Talis was eligible to file simplified SEC filings;
 3 e) Talis regularly communicated with the public through established market
 4 communication channels, including through the regular dissemination of news
 5 releases through major newswire services, communications with the financial
 6 press, and other wide-ranging public disclosures; and
 7 f) Numerous securities analysts followed Talis and wrote reports that were published,
 8 distributed, and entered the public domain.

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

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

18 VI. CLASS ACTION ALLEGATIONS

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

- 21 • As to claims under the Securities Act, all persons and entities that purchased or
 22 otherwise acquired common stock issued by Talis pursuant and/or traceable to the
 23 Registration Statement issued in connection with the Company's February 2021
 24 initial public offering, and were damaged thereby; and
- 25 • As to claims under the Exchange Act, all persons and entities who purchased or
 26 otherwise acquired Talis common stock between March 30, 2021 and March 15,
 27 2022, both inclusive, and were damaged thereby.

28 258. 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

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

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

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

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

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

- 18 a) Whether Defendants' conduct violated the federal securities laws, as alleged herein;
- 19 b) Whether the Registration Statement contained any untrue statements of material
20 fact or omitted to state any material facts required to be stated therein or necessary
21 to make the statements therein not misleading;
- 22 c) Whether Defendants made any untrue statements of material fact or omitted to state
23 any material facts necessary to make the statements made, in light of the
24 circumstances under which they were made, not misleading;
- 25 d) Whether Defendants acted with scienter as to Lead Plaintiffs' claims for relief
26 under Section 10(b) of the Exchange Act;
- 27 e) Whether the Officer Defendants were controlling persons under Section 15 of the
28 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;

- 1 h) Whether, with respect to Lead Plaintiffs' claims under the Exchange Act, reliance
- 2 may be presumed under the fraud-on-the-market presumption;
- 3 i) Whether and to what extent Class members have sustained damages as a result of
- 4 the conduct complained of herein and, if so, the proper measure of damages.

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

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

11 **VII. INAPPLICABILITY OF STATUTORY SAFE HARBOR**
12 **OR BESPEAKS CAUTION DOCTRINE**

13 265. The protections applicable to forward-looking statements under certain
14 circumstances do not apply to any of the false or misleading statements alleged herein. The
15 statements complained of herein concerned then-present or historical facts or conditions that
16 existed at the time the statements were made. Further, the PSLRA safe harbor expressly excludes
17 forward-looking statements "made in connection with an initial public offering," 15 U.S.C. § 77z-
18 2(b)(2)(D), such as the IPO.

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

1 **VIII. CLAIMS FOR RELIEF**

2 **COUNT I**

3 **For Violation of Section 11 of the Securities Act**
4 **Against the Securities Act Defendants**

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

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

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

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

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

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

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

28 274. 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

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

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

5 **COUNT II**
6 **For Violation of Section 15 of the Securities Act**
7 **Against the Individual Defendants**

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

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

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

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

24 280. The Individual Defendants had the power to, and did, control the decision-making
25 of Talis, including the content and issuance of the statements contained (and/or incorporated by
26 reference) in the Registration Statement; they were provided with or had unlimited access to copies
27 of the Registration Statement (and/or documents incorporated by reference) alleged herein to
28 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

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

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

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

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

14 **COUNT III**
15 **For Violation of Section 10(b) of the Exchange Act**
16 **Against the Exchange Act Defendants**

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

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

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

- 25 a) Employed devices, schemes, and artifices to defraud;
- 26 b) Made untrue statements of material fact or omitted to state material facts necessary
27 in order to make the statements made, in light of the circumstances under which
28 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.

1 Dated: July 1, 2022

2 By: /s/ Joseph A. Fonti
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21 *Putative Class*

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

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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.

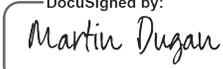
3. I am willing to serve as lead plaintiff on behalf of the Class in this matter, including providing testimony at deposition and trial, if necessary. I fully understand the duties and responsibilities of the lead plaintiff under the Private Securities Litigation Reform Act, including the selection and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

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:

897A5256FB8B47F...
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:

897A5256FD8B47F...

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