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[Additional counsel on signature page]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

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

TABLE OF CONTENTS

Court-appointed Co-Lead Plaintiffs Martin Dugan, Leon Yu, and Max Wisdom Technology Limited (together, "Lead Plaintiffs") bring this action on behalf of themselves and persons and entities that purchased or otherwise acquired common stock issued by Talis Biomedical Corporation ("Talis" or the "Company") pursuant and/or traceable to the registration statement and prospectus (collectively, the "Registration Statement") issued in connection with the Company's February 11, 2021 initial public offering and were damaged thereby (the "Class").

The allegations herein are based upon personal knowledge as to Lead Plaintiffs' own acts, and upon information and belief as to all other matters. Lead Plaintiffs' information and belief is based on, among other things, the investigation conducted by and through Lead Counsel, including without limitation: (a) review and analysis of regulatory filings made by Talis with the United States Securities and Exchange Commission ("SEC"); (b) review and analysis of transcripts of Talis's public conference calls and press releases and media reports issued by and disseminated by Talis; (c) review of other publicly available information concerning Talis, including research reports issued by financial analysts; and (d) interviews with former Talis employees. Lead Plaintiffs believe that, after a reasonable opportunity for discovery, substantial additional evidentiary support will be available that further proves the allegations in this Amended Complaint.[1]

I. SUMMARY OF THE ACTION

1. This action solely brings strict liability and negligence claims under the Securities Act of 1933 (the "Securities Act") based on the Registration Statement for Talis's February 11, 2021 initial public offering (the "IPO").

2. This Amended Complaint does not allege fraud and only asserts non-fraud Securities Act claims governed by Rule 8 of the Federal Rules of Civil Procedure. These claims are not subject to Rule 9(b) or the PSLRA's heightened pleading requirements and do not require allegations of any intentional or deliberately reckless misstatements. In addition, Lead Plaintiffs have removed any challenged statements that the Court indicated may be forward-looking or

[1] Throughout this Amended Complaint, emphasis is added unless otherwise noted.

subject to the bespeaks caution doctrine (ECF 101 at 19). This Amended Complaint's detailed allegations of material falsity are supported by the personal observations of eight former Talis employees, Talis's own statements and admissions, and U.S. Food and Drug Administration ("FDA") regulations and industry standards, among other sources.

3. In Talis's February 2021 IPO, Defendants raised $254 million—largely from the Class. Talis's value as a public company hinged on its ability to timely launch its sole product after a decade of development: a molecular diagnostic device called Talis One, comprised of a box-shaped analyzer instrument and single-use cartridges for COVID-19 testing. The Talis One instruments alone were slated to sell for over $15,000 each. Talis One's timely commercial launch was highly material to investors, particularly given the rapidly closing window to launch a new COVID-19 test in early 2021 due to increasing vaccination rates and competing tests that were already on the market.

4. The Registration Statement for the IPO claimed that Talis sought "to transform diagnostic testing" and touted Talis One as "a compact, easy-to-use instrument, that utilizes single use test cartridges and software, including a central cloud database, which are designed to work together to provide levels of testing accuracy equivalent to a central laboratory." Unlike slow central lab tests, however, Talis One was "designed to provide actionable information to clinicians in approximately 25 minutes" at the point-of-care (*e.g.*, in a doctor's office). In other words, Talis One promised to deliver rapid, accurate, and reliable results directly in a doctor's office, making it superior to "existing point-of-care diagnostic testing technologies for infectious diseases."

5. Crucially, the Registration Statement gave reasonable investors the firm impression that Talis One was an existing, fully functioning, and reliable product that had been "ordered" and was presently being "manufactured" at scale for delivery to Talis starting before the IPO. It further claimed that Talis One was "reliable," "highly accurate," and designed "to provide central lab levels of accuracy at the point-of-care."

6. This was false. In truth, at the time of the IPO, Talis One was merely an unreliable prototype that generated unusable results up to 20% of the time—far from an accurate, reliable device that could be manufactured and sold. And at the time of the IPO, Talis had not ordered

instruments from its third-party manufacturer, which had not started to produce Talis One instruments, much less deliver them to Talis, and had not even been paid. With no working product and no instruments in hand at the time of the IPO, Talis was a fundamentally different—and far less valuable—business than investors were led to believe. The stark difference between the false impression the Registration Statement created and the state of affairs that actually existed at the time of Talis's IPO is actionable under controlling law. *See, e.g.*, *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008); *Miller v. Thane Int'l, Inc.*, 519 F.3d 879, 886 (9th Cir. 2007); *Cutler v. Kirchner*, 696 Fed. App'x 809, 814 (9th Cir. 2017).

7. The Registration Statement contains two categories of actionable misstatements.

8. First, the Registration Statement claimed that (1) Talis's "products are manufactured by several third parties, including a single contract manufacturer that provisions the parts and assembles our instrument," and (2) Talis had "ordered 5,000 instruments from our instrument contract manufacturing partners to be delivered" from "the fourth quarter of 2020 through the first quarter of 2021"—that is, between October 2020 and March 31, 2021.

9. These statements were false when made. At the time of the IPO, Talis had not "ordered 5,000 instruments," Talis One was not being "manufactured" by Talis's "contract manufacturer," and no instruments had been delivered to Talis. Specifically, Talis had not "ordered" any instruments, but merely had a capacity agreement with its third-party manufacturer (¶¶83-85). This meant that at best, Talis's manufacturer had only reserved capacity to produce instruments in the future, even as basic issues—such as where the instruments would be assembled—were unresolved, as Talis's Vice President of Human Resources and Chief Human Resources Officer at the time of the IPO (FE-6) confirmed (¶84). At the time of the IPO, the manufacturer had not started to produce Talis One instruments, and none of the 5,000 instruments had been delivered to Talis (¶¶86-118).

10. The statements were also materially misleading under controlling law because they gave reasonable investors the impression of a state of affairs that differed in a material way from the one that actually existed at the time of Talis's IPO. Far from having a finished, working product that was presently being "manufactured" for delivery to Talis, at the time of the IPO:

- Talis One was merely an unreliable prototype that generated unusable results up to 20% of the time (¶¶89-96 & 103-05);
- Talis only had five to ten Talis One prototypes (¶¶93, 110);
- Talis had not validated Talis One's production process and design, which was required under FDA regulations and industry standards before any devices could be sold (¶¶97-102); and
- Talis had not ordered instruments, or even paid its third-party manufacturer for components (much less their assembly into thousands of finished devices) (¶¶83-85 & 106-08).

11. Having chosen to tout that Talis's products "are manufactured" and that Talis had "ordered 5,000 instruments" for delivery over a six-month period that was already 75% complete, Defendants were obligated to disclose these existing facts, but nothing in the Registration Statement did so. As a result, the statements were materially misleading when made.

12. Second, the Registration Statement touted Talis One as "reliable," "highly accurate," and designed "to provide central lab levels of accuracy at the point-of-care."

13. These statements were false and misleading when made because Talis One was unreliable and inaccurate: at the time of the IPO, as two former Talis senior executives (FE-6 and FE-8) confirmed, Talis One had a high failure rate of up to 20% (meaning one in five results was unusable) and high invalid rates of up to 15%, which were viewed as unacceptable both internally and by the FDA (¶¶125, 131-32). Competing tests had invalid rates of just 1-2%, while central lab tests had invalid rates at or near zero (¶¶126, 146). At the time of the IPO, Talis One's unreliability and inaccuracy were known to Talis's most senior executives: the failure rate was discussed in weekly business review meetings that FE-6 attended with CEO Brian Coe, CFO Roger Moody, and COO Doug Liu (¶132). For obvious reasons, no physician or hospital wants a $15,000 testing device that routinely fails or generates unusable results, and Talis One's unreliability and inaccuracy foreclosed its commercial launch.

14. No risk disclosures can negate Defendants' false and misleading statements of historical fact. *See, e.g.*, *Livid Holdings Ltd. v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 948 (9th Cir. 2005). Indeed, nothing in the Registration Statement disclosed the existing, internally known facts that contradicted Defendants' public statements and made them materially

misleading, including that Talis had not ordered instruments, manufacturing had not even started, and no instruments had been delivered at the time of the IPO. Instead, the Registration Statement merely offered generic, hypothetical statements that Talis's "supply of products . . . ***may*** become limited or interrupted or may not be of satisfactory quality and quantity," that Talis faced "significant ***risk*** that we will not have sufficient quantities of our products," and that "[o]ur diagnostic tests ***may*** contain errors or defects or be subject to reliability issues." Given the facts that existed at the time of the IPO, such abstract disclosures of potential risks are deficient as a matter of law—like warning a hiking companion to walk slowly because there might be a ditch ahead, despite knowing that the Grand Canyon lies one foot away.

15. In addition to its affirmative false and misleading statements, the Registration Statement contained two independently actionable omissions of known, material uncertainties and material risks in violation of Item 303 and Item 105 of SEC Regulation S-K. These express SEC disclosure requirements protect investors by ensuring that issuers like Talis cannot simply remain silent as investors buy stock while unaware of key risks and uncertainties known to corporate insiders. They obligated Talis to disclose the known, material risks and uncertainties in the eyes of its management, thereby allowing investors to fairly and properly evaluate the risk of investing in Talis. Omissions in violation of Item 303 and Item 105 are actionable under the Securities Act.

16. First, the Registration Statement omitted the known, material uncertainty and material risk that the FDA would reject the comparator assay in Talis's submission for Emergency Use Authorization ("EUA") because it was not "high sensitivity" and violated FDA requirements (¶¶154-84 & 190-92).

17. Obtaining an EUA was a crucial step required for Talis to sell the Talis One COVID-19 test to customers. The FDA required companies seeking EUAs to use a "high sensitivity" comparator assay to validate the performance of their COVID-19 test. The FDA required "high sensitivity" comparator assays to have a limit of detection (LoD) of no more than 18,000 NAAT Detectable Units (NDU)/mL, meaning the threshold for triggering a positive result is 18,000 or fewer copies of the virus. (Lower numbers mean a more sensitive test.)

18. The comparator assay in Talis's January 2021 EUA submission violated the FDA's established, objective "high sensitivity" standard because it used a low-sensitivity comparator assay that required at least 180,000 viral copies to trigger a positive result. This was 10 times less sensitive than the FDA's standard of 18,000 or fewer copies. The fact that Talis used a "low-sensitivity" comparator assay was known to Defendants at the time of the IPO. Shortly before the IPO, Talis's own co-founder, Defendant Ismagilov—who signed the Registration Statement—recognized in his own scientific research that comparator assays requiring 180,000 viral copies to trigger a positive result are "low-sensitivity." A Ph.D. senior scientist who worked at Talis from February to October 2020 (FE-2) was less diplomatic, stating that Talis had used the "shittiest comparator [assay]" for its EUA submission.

19. Where the FDA required a "high sensitivity" comparator assay, Talis's use of a "low-sensitivity" comparator assay drastically increased the likelihood—if not guaranteed—that the FDA would reject the comparator assay and cause Talis's EUA submission to fail. Regardless of whether Defendants were certain that this would occur, at the time of the IPO, it was a known, material "uncertaint[y]" that required disclosure under the plain language of Item 303. It also raised a heightened, material risk that required disclosure under Item 105.

20. Second, the Registration Statement omitted the known, material uncertainty and material risk posed by Talis One's unreliability at the time of the IPO, which was reported to CEO Coe, CFO Moody, and COO Liu (FE-6) (¶¶185-92). Talis One's high invalid rate of up to 15% and failure rate of up to 20% were a known, material uncertainty and posed a material risk because they threatened to foreclose and/or dramatically delay the commercial launch of Talis's only product, with a materially negative impact on the Company's financial performance. In violation of Item 303 and Item 105, the Registration Statement omitted this known, material uncertainty and material risk.

21. Nothing in the Registration Statement warned investors of the specific, unusual, and material risks and uncertainties posed by the existing facts that (1) Talis had used a comparator assay that violated FDA requirements and was within the "low-sensitivity" range according to scientific research by Talis's own co-founder; and (2) Talis One suffered from unreliability that

foreclosed its commercial launch (¶¶194-98). For example, without disclosing that the existing EUA submission used a comparator assay that violated FDA requirements, the Registration Statement merely offered boilerplate language that there was "no assurance" that Talis would "be granted an EUA by the FDA." Similarly, without disclosing the present unreliability of the Talis One prototypes at the time of the IPO, the Registration Statement included an abstract statement that "[o]ur diagnostic tests may contain errors or defects or be subject to reliability issues." Such general, abstract disclosures are insufficient as a matter of law under Item 303 and Item 105.

22. Class members paid the price for the Registration Statement's material misstatements and omissions. The Talis One device never materialized because it remained a flawed, unreliable prototype. As the truth emerged, Talis's stock price fell precipitously from its $16.00 offering price (¶¶207-34). By the time this action was filed on January 7, 2022, Talis's share price had fallen to $3.31, and even then, its actual value was significantly lower. Talis has now abandoned the Talis One COVID-19 test, while all the cash raised in the IPO is gone and Talis stock trades below $0.60, leaving Class members with enormous losses.

II. JURISDICTION AND VENUE

23. The claims asserted herein arise under and pursuant to Sections 11 and 15 of the Securities Act (15 U.S.C. §§ 77K and 77o).

24. This Court has jurisdiction over the subject matter of this action pursuant to Section 22 of the Securities Act (15 U.S.C. § 77v). 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.

25. In connection with the acts alleged in this Amended 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.

26. 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 relevant period.

III. PARTIES

A. Lead Plaintiffs

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

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

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

30. Lead Plaintiffs purchased or otherwise acquired Talis common stock pursuant and/or traceable to the Registration Statement, as set forth in the previously filed Certifications (ECF 74 Exs. A-C). For instance, on February 12, 2021, Yu purchased 2,004 shares of Talis common stock, on February 16, 2021, Max Wisdom purchased 1,628 shares of Talis common stock, and on March 26, 2021, Dugan purchased 2,000 shares of Talis common stock.

31. As a result of the material misstatements and omissions in the Registration Statement, Lead Plaintiffs purchased or otherwise acquired Talis common stock at artificially inflated prices. When the relevant truth concerning the misstatements and omissions of material fact leaked out into the market, the price of Talis stock fell, causing Lead Plaintiffs and the Class to suffer losses.

B. Defendants

32. Each Defendant—Talis and the officers and directors who signed the Registration Statement—is statutorily liable under Sections 11 and/or 15 of the Securities Act for the material misstatements and omissions contained in and incorporated into the Registration Statement.

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

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

and control the contents of the Registration Statement. Coe also was a member of Talis's Board of Directors at the time of the IPO.

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

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

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

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

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

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

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

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

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

44. Talis and the Individual Defendants are collectively referred to herein as "Defendants."

IV. SUBSTANTIVE ALLEGATIONS

45. Lead Plaintiffs assert strict liability and negligence claims under Sections 11 and 15 of the Securities Act on behalf of all persons and entities that purchased or otherwise acquired Talis's common stock pursuant and/or traceable to the Registration Statement issued in connection with the Company's February 2021 IPO, and were damaged thereby. Lead Plaintiffs only assert non-fraud claims and expressly disclaim any allegations of fraud or intentional misconduct.

46. The allegations in this Amended 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 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. After Years of Developing Talis One, Talis Secures a Major Government Grant to Commercialize the Talis One COVID-19 Test

47. Talis purportedly seeks "to transform diagnostic testing through innovative molecular diagnostic products that enable customers to deploy accurate, reliable, low cost and rapid molecular testing at the point-of-care."

48. Talis (originally called SlipChip LLC) was founded in 2010 by Defendants Ismagilov and Coe to develop point-of-care ("POC") diagnostic tests for infectious diseases. (POC testing refers to medical diagnostic testing that takes place at or near the time and place of patient care, rather than in a central laboratory.)

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

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

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

52. The rapid spread of COVID-19 created an urgent need for reliable tests. For example, on April 17, 2020, a former American Medical Association President wrote that "[i]t is critically important that we dramatically expand our testing capacity, both diagnostic and antibody testing."

53. There are two basic types of COVID-19 diagnostic tests. Antigen tests (like those widely available at drugstores) detect specific viral proteins (antigens), but sacrifice accuracy for speed. By contrast, molecular diagnostic tests amplify genetic material to detect viral nucleic acid (viral RNA), offering greater accuracy but generally lower speed than antigen tests.

54. By summer 2020, Talis started to develop a COVID-19 molecular diagnostic test.

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

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

57. The RADx Contract—which was Talis's largest government contract and was signed by Defendant Coe—contained detailed milestones to obtain the $25 million in government funding, including that Talis would "complete verification and validation of its IVD platform, seek Emergency Use Authorization from the FDA for its COVID-19 assay, manufacture at least 3,300 instruments for sale, and design and construct three automated manufacturing lines, which combined have a total capacity of approximately 1 million cartridges per month." The RADx Contract required all of these milestones to be completed by July 29, 2021.

B. Talis Conducts the IPO and Touts a Near-Term Commercial Launch of Talis One

58. The Registration Statement asserted that Talis was preparing "for a potential commercial launch as early as the first quarter of 2021." This was crucial to create the impression that Talis had a working product and was on the verge of launching the Talis One COVID-19 test—the necessary foundation for a successful IPO.

59. Time was of the essence because the FDA had recently authorized the Pfizer and Moderna COVID-19 vaccines in December 2020, and there was a temporary—and rapidly closing—window to get a new COVID-19 test to market and quickly achieve sales before demand for testing began to cool.

60. Heightening the urgency, by late 2020, several competing COVID-19 molecular diagnostic tests were already on the market. As the Registration Statement explained, Talis faced "intense competition" from these COVID-19 tests, which had already "received an EUA" from the FDA that allowed them to be sold. Further, many of these competitors had "significantly greater financial resources and expertise" than Talis "in research and development, manufacturing, regulatory clearance approval and compliance, and sales and distribution."

61. In this market environment—with a rapidly closing window to launch a new COVID-19 test and intense competition from numerous tests that were already on the market—Talis's survival, let alone its value as a public company, depended entirely on both quickly obtaining FDA authorization and manufacturing the Talis One COVID-19 test quickly and at scale. As Talis acknowledged, its "success in the future depend[ed] on the timing of obtaining regulatory clearances and approvals, as well as the timing of [Talis's] ability to deliver instruments and consumables into the marketplace in significant volumes." Talis further stated that "we believe our . . . manufacturing scale will distinguish us from our competitors."

62. As a relatively late entrant in a crowded field, Talis's value also depended on having an accurate, reliable product. Thus, the Registration Statement touted "competitive advantages" that included "central lab levels of accuracy at the point-of-care."

63. After a decade of development, Talis appeared positioned to deliver a timely launch: As detailed above, Talis was founded in 2010 and since then had operated continuously under its co-founders, Defendants Ismagilov and Coe. Since 2013, Talis had "devoted substantially all" of its "efforts to research and development activities" and its "manufacturing capabilities," and even before the IPO had raised $351.5 million from private investors through the end of 2020. Further reinforcing the impression that Talis was on the verge of launch, the RADx Contract required Talis to "complete verification and validation" and "manufacture at least 3,300 instruments for sale" by July 29, 2021; by the February 11, 2021 IPO, Talis was over six months into the RADx Contract's one-year performance period.

C. The Registration Statement for the IPO Uses Material Misstatements and Omissions to Raise Over a Quarter-Billion Dollars from the Class

64. As the Supreme Court observed sixty years ago, the Securities Act of 1933 was "designed to eliminate certain abuses in the securities industry." *SEC v. Capital Gains Research Bureau*, 375 U.S. 180, 186 (1963). Its "fundamental purpose . . . was to substitute a philosophy of full disclosure for the philosophy of caveat emptor and thus to achieve a high standard of business ethics in the securities industry." *Id.*

65. Section 11 of the Securities Act prohibits both "untrue statement[s] of a material fact" in a registration statement and omissions of any "material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a). As the issuer, Talis is strictly liable for any material misstatement or omission, while the Individual Defendants are liable unless they prove that they conducted a reasonable investigation and had a reasonable ground to believe (and did believe) that there were no material misstatements or omissions.

66. In violation of the Securities Act, the Registration Statement for Talis's IPO contained two categories of material false and misleading statements. First, it stated that Talis One instruments had been ordered and were being manufactured and delivered. Specifically, it stated that Talis's "products are manufactured by several third parties, including a single contract manufacturer that provisions the parts and assembles our instrument," and that Talis had "ordered 5,000 instruments" from its "contract manufacturing partners to be delivered" from October 2020 through March 2021. Second, it stated that Talis One was "reliable," "highly accurate," and designed "to provide central lab levels of accuracy."

67. As detailed below, these statements were false and materially misleading when the Registration Statement became effective on February 11, 2021.

1. False and Misleading Statements That Talis One Was Being "Manufactured" and That Talis Had "Ordered 5,000 Instruments" from Its Third-Party Manufacturer

68. The Registration Statement stated:

> Our products are manufactured by several third parties, including a single contract manufacturer that provisions the parts and assembles our instrument.
>
> …
>
> We have ordered 5,000 instruments from our instrument contract manufacturing partners to be delivered beginning in the fourth quarter of 2020 through the first quarter of 2021.

69. These statements—about the manufacturing, ordering, and delivery of Talis's sole product—were false when made because at the time of the IPO, Talis had not "ordered 5,000 instruments"; Talis One instruments were not being "manufactured" or "assemble[d]" by Talis's "contract manufacturer"; and no "instruments" had been delivered to Talis, as detailed below.

70. Further, these statements were materially misleading when made because they gave reasonable investors the impression of a state of affairs that differed in a material way from the one that actually existed at the time of the IPO. Specifically, they gave reasonable investors the impression that after a decade of development, Talis had a working product that was presently being "manufactured" at scale, with 5,000 finished devices already "ordered," and that Talis One instruments were presently being "assemble[d]" for delivery to Talis (reinforced by the fact that the statements were made when the purported delivery period was about 75% complete).

71. That was simply not true. In reality, as detailed below:

a. Talis had not ordered instruments;

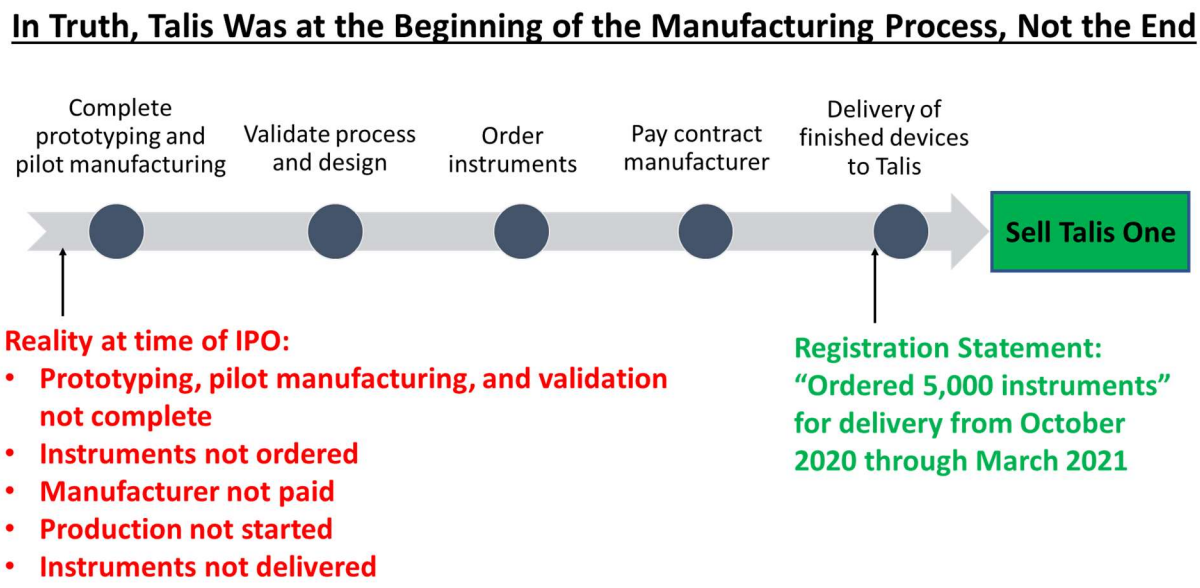
b. Talis's third-party manufacturer had not even started production because Talis's prototyping of Talis One was incomplete and necessary validation had not been performed;

c. As a prototype, Talis One was unreliable and generated unusable results up to 20% of the time;

d. Talis had not paid its third-party manufacturer for components (much less their assembly into thousands of finished devices); and

e. No instruments—much less 5,000—had been delivered to Talis from October 2020 through the February 2021 IPO.

72. Indeed, far from Talis having a working product that was being manufactured and delivered, at the time of the IPO, Talis One was only in the earliest stages of development. The following timeline shows the material difference between the positive impression that the Registration Statement created and the negative reality that existed at the time:



a. The Registration Statement's Claim That Talis Had Ordered "Instruments" Was Highly Material Because It Told Investors That Talis Had a Working Product That Was Ready for Sale Upon FDA Approval

73. In the statements that Talis's products "are manufactured" by a "single contract manufacturer that . . . assembles our instrument," and that Talis had "ordered 5,000 instruments" that were "to be delivered" from October 2020 through March 2021, the use of the word "instrument" (which appears well over 100 times in the Registration Statement) was highly material to investors because it created the impression that Talis had ordered functional, finished devices that were ready to be sold to generate revenue.

74. The Registration Statement made clear that an "instrument" is a complete, finished device:

75. A single Talis One instrument contained hundreds of separate components. For example, the Registration Statement stated that "[t]he manufacturing of our Talis One instrument and cartridge involves over 500 raw materials, intermediates and subassemblies."

76. Similarly, a patent for Talis One (excerpted below) shows the internal complexity of the Talis One instrument, which contained at least 175 separate subassemblies and an even larger number of components:[2]

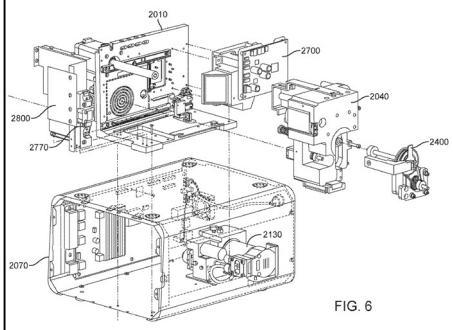


FIG. 6

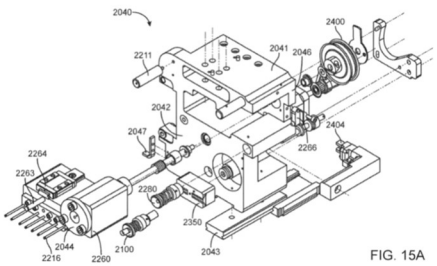


FIG. 15A

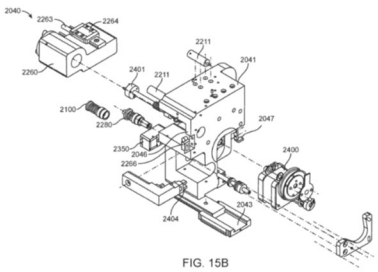


FIG. 15B

77. For purposes of FDA medical device regulations and financial disclosure, there is a material difference between (a) finished devices and (b) components that require time-consuming, complex assembly before sale.

78. Specifically, under FDA medical device regulations, a "finished device" is "any device . . . that is ***suitable for use or capable of functioning***." 21 C.F.R. § 820.3(l). By contrast, a "component" is "any raw material, substance, piece, part, software, firmware, labeling, or

[2] These figures are conservative because they only count the reference numbers in Talis's patent drawings; a single reference number may be assigned to a part comprised of multiple components.

assembly which is intended to be included as ***part of*** the finished, packaged, and labeled device." 21 C.F.R. § 820.3(c). FDA regulations thus carefully distinguish "components" from a "finished device" that is "suitable for use or capable of functioning." 21 C.F.R. § 820.3(c), (l).

79. The distinction between finished devices and components is also material from a financial perspective. Under U.S. Generally Accepted Accounting Principles (GAAP), ***only*** Talis One instruments—not raw materials such as components—were finished goods that could be sold to customers to generate revenue. In this regard, U.S. GAAP distinguishes (1) finished goods from (2) work in process and (3) raw materials. Authoritative literature on GAAP (the Financial Accounting Standards Board's Master Glossary) describes finished goods as those "held for sale in the ordinary course of business," which are distinct from items that are in "process of production for such sale" (work in process) and items "currently consumed in the production of goods or services to be available for sale" (raw materials).

80. Under U.S. GAAP, this distinction is critical because finished goods are by definition complete and ready for sale, while work in process and raw materials generally are not able to be sold (until they become finished goods). In this regard, the Financial Accounting Standards Board's Master Glossary states that "the term inventory embraces goods awaiting sale (the merchandise of a trading concern and the finished goods of a manufacturer)." U.S. GAAP emphasizes the importance of inventory, stating that "inventory has financial significance because revenues may be obtained from its sale." (ASC-330-10-05-2.)

81. Thus, it was highly material to investors that Talis had purportedly ordered finished devices because ***only*** finished devices are capable of functioning and ready to be sold to generate revenue. Indeed, the 5,000 instruments represented $77.5 million to $95.5 million in revenue for Talis because each instrument was to sell for between $15,500 and $19,500, as FE-4 confirmed. FE-4 was a territory account manager at Talis and oversaw the western region from February 1, 2021 to March 15, 2022, when FE-4 was laid off in the Company's reduction in force. FE-4 was based in San Diego and reported to National Sales Director Alex de los Reyes, who reported to Vice President, Sales & Commercial Strategy Anthony Green; Green reported to Rob Kelley, then-Chief Commercial Officer. FE-4 was recruited to Talis from a large medical device company after

a 20-year diagnostic testing equipment sales career, and was one of the first members of Talis's sales force. FE-4's personal knowledge of Talis One's status comes as a direct result of FE-4's position in Talis's sales force, including before the IPO. During training, FE-4 was told that each instrument had a minimum sale price of $15,500 and expected starting sale price of $19,500.

82. Selling 5,000 instruments at these prices translates to revenue of $77.5 million to $95.5 million. This would far outstrip Talis's revenue in prior years, which was just $4 million in 2019 and $10.7 million for the first three quarters of 2020 (all from grants). Each instrument also carried the potential for more revenue from the consumable cartridges, which were slated to sell for $35 to $55 each, as FE-4 was told during training.

b. At the Time of the IPO, Talis Had Not "Ordered" Any "Instruments" from Its Third-Party Manufacturer

83. Directly contrary to the Registration Statement, at the time of the IPO, Talis had not "ordered" any Talis One "instruments."

84. Instead, Talis merely had a capacity agreement with its third-party manufacturer, as confirmed by FE-6. FE-6, Talis's Vice President of Human Resources and Chief Human Resources Officer from 2018 to January 2022, was based at the Menlo Park headquarters and reported to CEO Coe. FE-6 was part of the executive team, participated in top-level business review meetings weekly, and was privy to information about Talis's third-party manufacturers and vendors. As FE-6 explained, the capacity agreement meant that Talis's manufacturer had only reserved capacity to produce instruments in the future. FE-6 indicated that at the time of the IPO, Talis had no working instrument for the contract manufacturer to build; rather, the instrument remained in the early prototype stage. FE-6 added that at the time of the IPO, basic issues related to the manufacturing, such as where the instruments would be assembled, were unresolved.

85. Thus, the Registration Statement's claim that Talis had "ordered 5,000 instruments" was false because Talis had not done so. Moreover, contrary to the Registration Statement, no Talis One instruments were being "manufactured" or "assemble[d]" for delivery to Talis at the time of the IPO. Indeed, at the time, Talis One was only a prototype, and Talis had not completed the steps necessary for its third-party manufacturer to begin production, as further detailed below.

c. At the Time of the IPO, No Instruments Had Been Manufactured, Assembled, or Delivered Because Talis One Was a Prototype—Not a Finished Device—and Necessary Validation Had Not Been Completed

86. The Registration Statement made clear that Talis had to complete "[d]esign work, prototyping and pilot manufacturing . . . in-house ***before*** outsourcing" its manufacturing "to third party contract manufacturers." In other words, Talis needed a consistent, working, final product ***before*** its third-party manufacturer could begin production of any instruments—much less 5,000.

87. Talis One's manufacturing was also governed by specific FDA requirements that prevented untested, unvalidated prototypes from being released into the market. Medical device manufacturers are subject to stringent FDA requirements known as the Quality System Regulations (21 C.F.R. § 820). As detailed below, both the Quality System Regulations and medical device industry practices mandated extensive validation of Talis One's production process and design before any finished devices could be delivered or sold to customers.

88. At the time of the IPO, however, Talis had not completed the prototyping of Talis One, and Talis One's production process and design had not been validated. Without a final, validated product, Talis had not ordered instruments from its third-party manufacturer, which had not started to build—or deliver—5,000 instruments at the time of the IPO. These facts made the Registration Statement's present-tense claim that Talis's "products are manufactured by" a "contract manufacturer that provisions the parts and assembles our instrument," and its statement that Talis had "ordered 5,000 instruments" from its "manufacturing partners to be delivered" between October 2020 and March 2021, materially false and misleading.

89. First, unknown to investors, Talis's third-party manufacturer had not started production because Talis One was merely a conceptual prototype at the time of the IPO. FE-1 worked at Talis from August 2016 to March 2021, first as a senior mechanical R&D engineer, and then as the new product introduction manager, and was based in the Company's Menlo Park, CA office. FE-1 holds master's and bachelor's degrees in mechanical engineering. FE-1 initially reported to Thomas "Trey" Cauley III, Talis's VP of Engineering, and then moved to manufacturing operations, reporting to James Harland. FE-1 has worked as an engineer over the

last two decades, focusing on the medical field for the last decade. FE-1 worked to make the cartridge for Talis One, as designed, more manufacturable.

90. FE-1's personal knowledge of Talis One's status comes as a direct result of FE-1's position as a Talis senior engineer. FE-1 explained that Talis One was a concept model and all the engineering was not there, and that to go from prototype to full production at volume—a 100-fold increase—was not possible at the time of the IPO. FE-1 recalled "a lot of finger-pointing" between Talis's research and development, operations, and finance teams. While "R&D said [Talis One] was flawless," FE-1 explained, "Operations said 'We can't build it.'" FE-1 added that Talis One was "a prototype instrument," and that "[j]ust because the skins of it look like a production thing doesn't mean it's production worthy."

91. Corroborating FE-1, FE-6 explained that the Talis One instrument (and cartridge) were too complicated to be manufactured efficiently. FE-6 attributed the overly complicated designs to the designer, Cauley, stating that the designs he produced might work in a Ph.D. program, but not in the real world. FE-6 added that Coe favored Cauley and ignored the flawed design he had produced.

92. FE-7 worked at Talis from January 2019 to March 2021, first as a system verification and validation intern (through May 2019), then as a quality engineer (through March 2020), and finally as a system and full-stack engineer (through March 2021). FE-7 was based at the Menlo Park headquarters and reported to FE-3 (identified below). FE-7's personal knowledge of Talis One's status comes as a direct result of FE-7's position as a Talis engineer.

93. Corroborating FE-1 and FE-6, FE-7 stated that at the time of the IPO, Talis was still in the prototyping and product development phase and had no product to manufacture at scale. "To my knowledge, there was no working product," FE-7 said. Instead, during FE-7's tenure (which ended in March 2021), Talis's engineers only had five to ten "working prototypes" of Talis One that they were tweaking. FE-7 knows this because FE-7 was part of the engineering team that worked on the prototype of Talis One.

94. FE-7 explained that the prototype had a number of issues at the time of the IPO, including with the user interface, where "many optimizations needed to be done," and that the

prototype was an imperfect product that did not meet Talis's internal benchmarks for a final product. FE-7 stated that Talis One was still in development and was a long way from being market-ready by March 2021.

95. A prototype is not a finished product. As the FDA's Design Control Guidance for Medical Manufacturers (March 1997) warns, "manufacturers should avoid falling into ***the trap of equating the prototype design with a finished product design***. Prototypes at this stage lack safety features and ancillary functions necessary for a finished product, and are developed under conditions which preclude adequate consideration of product variability due to manufacturing."[3] The same FDA guidance cautions that "[i]t ***may not be possible to determine the adequacy of full-scale manufacturing on the basis of successfully building prototypes*** or models in a laboratory and testing these prototypes or models."

96. The fact that Talis One remained a mere prototype (which itself did not meet Talis's internal benchmarks) corroborates that Talis's contract manufacturer had not started to build Talis One instruments at the time of the IPO. Despite this reality, the Registration Statement created the false impression that Talis One instruments were presently being "manufactured" and "assemble[d]" by Talis's "contract manufacturer," and that such instruments were being delivered to Talis starting in October 2020.

97. Second, while the RADx Contract explicitly required Talis to "complete verification and ***validation*** of its IVD platform," unknown to investors, Talis One's production process and design had not been validated at the time of the IPO. Even by the time FE-1 left Talis in March 2021 (a month after the IPO), Talis had no systems in place to actually bring Talis One to market, and the production process had not been validated.

98. Process validation is a term of art in the medical device industry. Under the FDA Quality System Regulations, "process validation" requires "objective evidence" that a process "consistently produces" a product "meeting its predetermined specifications." 21 C.F.R. § 820.3(z), (z)(1). Similarly, under authoritative industry guidance applicable to Talis and its

[3] *Available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-control-guidance-medical-device-manufacturers

contract manufacturer, "process validation is a term used in the medical device industry to indicate that a process has been subject to such scrutiny" that its result "can be practically guaranteed."[4] Talis and its contract manufacturer were subject to these validation requirements.[5]

99. Crucially, the Quality System Regulations require process validation to be completed ***prior to*** the release of finished devices. *See* 21 C.F.R. § 820.80. The absence of process validation further corroborates that Talis's contract manufacturer had not started to build instruments, much less deliver them to Talis for sale to customers, at the time of the IPO. Indeed, validation was impossible because the unresolved problems with Talis One's functionality, like its high failure rate and invalid rate (discussed below), meant that at the time of the IPO, there was no manufacturing process to produce a finished device that "consistently" met "its predetermined specifications" under the Quality System Regulations.

100. Moreover, because Talis One remained a prototype at the time of the IPO, design validation—another step required before instruments could be delivered to Talis or sold to end users—was not completed. Under the Quality System Regulations, "[d]esign validation" means "establishing by objective evidence that device specifications conform with user needs and intended use(s)." 21 C.F.R. § 820.3(z)(2). Further, "[d]esign validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents[,] and shall include testing of production units under actual or simulated use conditions." 21 C.F.R. § 820.30(g). Similarly, the International Organization for Standardization's manufacturing standards for medical devices, ISO 13485, apply to Talis and its contract manufacturer and required testing of "initial production units, batches or their equivalents" "***prior to release for use*** of the product to the customer." ISO 13485, Section 7.3.7.

[4] 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

[5] For example, former Talis employees' LinkedIn profiles refer to work from April 2020 to April 2021 "in accordance with Regulatory requirements including 21CFR820 and ISO13485" (https://www.linkedin.com/in/hamzah-najib-289334109), referring to both the FDA Quality System Regulations and ISO 13485 (discussed below), and Talis has posted jobs on LinkedIn indicating that the employee will "[p]roduce reagents and subcomponents in an FDA/ISO regulated environments [sic] (per 21 CFR 820 & ISO 13485)." The FDA has directed manufacturers to the GHTF industry guidance. *See* https://www.fda.gov/media/94074/download

101. In other words, medical devices must be validated by testing "initial production units" ***before*** any sale to customers. Because Talis One remained a prototype, however, there were no "initial production units," and this necessary testing had not occurred at the time of the IPO.

102. The fact that Talis One's production process and design had not been validated underscores that Talis's contract manufacturer had not started production and had not delivered any instruments to Talis at the time of the IPO.

d. At the Time of the IPO, the Talis One Prototype Failed to Work Reliably and Thus Could Not Be Manufactured or Delivered

103. Further, Talis's manufacturer had not started to build Talis One instruments because the Talis One prototype did not function reliably or meet internal and regulatory quality standards. As detailed below (¶¶129-44), at the time of the IPO, Talis One had invalid rates of up to 15%, which both Talis and the FDA viewed as unacceptable, and high failure rates of up to 20%.

104. The unreliability of the Talis One prototype foreclosed necessary process and design validation and meant that no devices could be delivered. Under the FDA Quality System Regulations, validation calls for "establishing by objective evidence that the particular requirements for a specific intended use can be consistently fulfilled"; specifically, for process validation, that the "process consistently produces a result or product meeting its predetermined specifications," and for design validation, that "device specifications conform with user needs and intended use(s)." Devices that do not meet these requirements cannot be delivered: the Quality System Regulations require that "[e]ach manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria." 21 C.F.R. § 820.80(d).

105. Because Talis One failed to work properly up to 20% of the time, it did not "consistently" meet "its predetermined specifications," "conform with user needs and intended use(s)," or meet the "acceptance criteria," as required for validation to be completed and finished devices to be delivered.

e. At the Time of the IPO, Talis Had Not Paid Its Manufacturer for Components, Much Less the Production of 5,000 Instruments

106. The fact that Talis had not paid its contract manufacturer at the time of the IPO further corroborates that Talis had not ordered any Talis One instruments and that no instruments had been manufactured or delivered to Talis at the time.

107. As the Registration Statement made clear, Talis had a "single contract manufacturer that provisions the parts and assembles our instrument." The Registration Statement concealed the material fact that Talis had not paid this contract manufacturer. While it stated that Talis had a "non-cancellable contractual obligation[]" of $33 million for Talis's purported "firm purchase commitment[]" for "Talis One instruments" as of September 30, 2020, it did not disclose that ***none*** of this amount had been paid by the time of the February 2021 IPO.

108. Six months after the IPO, Talis's August 10, 2021 Form 10-Q revealed for the first time that "[i]n ***July 2021***, the Company made a payment of $29.6 million to one of the Company's contract manufacturing organizations in connection with the purchase of certain instrument ***components***." In other words, Talis did not even begin to pay its contract manufacturer until July 2021—five months ***after*** the IPO and four months after all 5,000 instruments were supposed to have been delivered. Even then, Talis's $29.6 million payment only related to "the purchase of certain instrument ***components***"—not finished devices.[6]

f. At the Time of the IPO, No Instruments Had Been Delivered to Talis

109. Finally, the present-tense statement that Talis's "products are manufactured by . . . a single contract manufacturer that provisions the parts and assembles our instrument," and the statement that Talis had "ordered 5,000 instruments" from its "manufacturing partners to be delivered" between October 2020 and March 2021, were materially false and misleading when made because Talis's manufacturer had not delivered ***any*** Talis One instruments to Talis by the time of the IPO.

[6] The Form 10-Q also continued to assert that Talis had "ordered 5,000 Talis One instruments from our instrument contract manufacturer," which was not true.

110. Specifically, while the Registration Statement indicated that the instruments were "to be delivered" to Talis starting in October 2020, no instruments were delivered from October 2020 through the February 11, 2021 IPO. Instead, at the time of the IPO, Talis's engineers only had five to ten "working prototypes" (FE-7) that yielded unusable results up to 20% of the time (FE-6, FE-8), as detailed above.

111. Without a finished, functional device to show customers at the time of the IPO, Talis resorted to producing a "demo video." Since joining Talis on February 1, 2021, FE-4 repeatedly requested a working Talis One demo unit to show hospitals and physicians. In February 2021, de los Reyes told FE-4 that Talis would soon be producing a "demo video," but did not have an instrument and was limited in capital. (Notably, Talis uploaded a similar video to YouTube on December 10, 2021. *See* https://www.youtube.com/watch?v=ddlBUKfdOOo)

112. After the IPO, Talis's sales force had no product to sell. Nonetheless, Talis aggressively pushed its sales representatives to generate "presales." For example, FE-4 recalled that one representative was forced to obtain at least three signed contracts by the end of the quarter or face termination. In May 2021, FE-4's supervisor de los Reyes sent FE-4 an email promising a $10,000 bonus to quickly get signed contracts with a potential customer; when FE-4 asked de los Reyes about the reason for the rush, since Talis had no working units, de los Reyes stated that the Board wanted to see pre-sales and a revenue stream. As a result of these tactics, Talis's sales force ultimately obtained 140 presales. The executives took the sales, put them in a spreadsheet, then told Talis's Board they had substantial presales. FE-4 was concerned about this practice, since other firms prohibited marketing of products that were still in development, and violations could result in large penalties and fines from the FDA.

113. Months after the IPO, Talis's contract manufacturer still had not begun to produce instruments. Over several weeks in May 2021, FE-3 briefed CEO Coe on the serious issues with the manufacturing timelines for the Talis One. FE-3 worked at Talis from November 2016 to June 2021 as associate director, Consumables Engineering, based in Menlo Park. FE-3 initially reported to Cauley (VP of Engineering); in turn, Cauley reported to VP of Operations Martin Goldberg, who left the company in January 2020, and then to SVP Ramesh Ramakrishnan. FE-3 was hired

to work on projects related to the design of consumables (*e.g.*, cartridges) for testing. By the time FE-3 left, FE-3 was working on multiple items related to consumables design and the transfer of consumable designs to manufacturing. FE-3 also confirmed that Talis's timelines were overly aggressive, driven in part by company culture. When FE-3 mentioned concerns about the overly aggressive timelines to a scientific advisor on Talis's Board, the advisor responded that the aggressive timelines were "inspirational." FE-3 was infuriated and thought the timelines had no basis. FE-3's personal knowledge of Talis One's status comes as a direct result of FE-3's role in engineering and manufacturing.

114. Further, Talis could not provide working devices to its sales personnel, much less sell them to doctors and hospitals. As FE-4 explained, Talis's entire national sales force—sales teams in the Western, Eastern, Midwest, and South regions—did not have working Talis One devices. Instead, from approximately August to November 2021, each team only had two non-functional units—an empty "shell that had nothing inside of it," and a heavy demo unit. "They didn't work; none of them worked," FE-4 explained.

115. Talis's senior management was aware of the design and manufacturing problems with Talis One. FE-6 explained that the issues were reported to CEO Coe (among others) by Talis employees, but Coe ignored them, as a 360-degree review (described below) concluded in summer of 2021. FE-6 also recalled that shortly before Kim Langone, Talis's Senior Director of Assay Development, left Talis (in June 2021), Langone told FE-6 that Langone needed to leave because she did not think the Talis One system would work. Langone told FE-6 that, based on Langone's work on Talis One and the available data, Talis needed to take a year to fully redesign Talis One; FE-6 responded that Langone should tell Defendant Popovits.

116. As time passed, to maintain the illusion that Talis One was a real product, Talis sought to conceal the absence of production and lack of inventory from potential customers. In August 2021, FE-4 told de los Reyes that doctors and hospitals were asking about when Talis One would launch; in response, de los Reyes told FE-4 to provide vague answers, and that Talis was still evaluating Talis One and didn't know when it would launch.

117. By fall 2021, FE-4 had obtained signed contracts with several doctors, who were questioning when the Talis One analyzers would be delivered. When FE-4 pushed de los Reyes in fall 2021 about providing these doctors with working analyzers, de los Reyes responded that when Talis did obtain working analyzers, it was going to do a slow release and only make a handful of instruments at a time for an initial limited launch at 5 sites (with one to two analyzers per site). During the same conversation, de los Reyes stated that Talis was making instruments in-house by hand. In response, FE-4 rhetorically asked de los Reyes if he meant the instruments could be made in FE-4's garage; de los Reyes told FE-4 that it was expensive and difficult to manufacture the Talis One instruments, which had many components and had to be made by hand, and that Talis did not have a manufacturer of Talis One instruments at full scale. De los Reyes added that the manufacturing problems were why Talis did not have a working unit for sales personnel to show customers. This state of affairs in fall 2021 corroborates that Talis had not ordered 5,000 instruments and that its manufacturer had not even started production (much less delivered any instruments to Talis) at the time of the IPO months earlier.

118. Indeed, FE-4—who left Talis in March 2022—never saw a working analyzer, noting that Talis had a strong incentive to get any working devices to its sales representatives in the field. In FE-4's words, "Obviously, people want to see a working machine. We had no working analyzer—we never did—because you would send the working one to the hospital to show that it works." As FE-4 stated: "They don't exist."

g. No Risk Disclosures Revealed the Existing Facts That Talis One Was Only an Unreliable Prototype, Production of 5,000 Instruments Had Not Even Started, and No Instruments Had Been Delivered to Talis

119. Nothing in the Registration Statement revealed the existing, internally known facts that made the statements that Talis's "products are manufactured by several third parties, including a single contract manufacturer that provisions the parts and assembles our instrument," and that Talis had "ordered 5,000 instruments" from its "manufacturing partners" for delivery by the "first quarter of 2021," materially misleading.

120. For example, the Registration Statement contained hypothetical risk disclosures that Talis's "supply of products . . . ***may*** become limited or interrupted or may not be of satisfactory quality and quantity" and that Talis faced "significant ***risk*** that we will not have sufficient quantities of our products at an acceptable cost or quality." At the time of the IPO, however, Talis had not ordered instruments; Talis One was an unreliable prototype; Talis had not completed necessary validation; Talis's manufacturer had not started production; and no instruments had been delivered to Talis. Given these existing facts, Talis's inadequate risk disclosures were like warning a hiking companion to walk slowly because there might be a ditch ahead, despite knowing with near certainty that the Grand Canyon lies one foot away.

121. Further, the Registration Statement's disclosure that Talis's "instrument contract manufacturer is scaling up to be able to make up to 500 instruments per week" did not disclose the existing facts that Talis had not ordered instruments; that production had not even started (*i.e.*, the current production rate was zero); that no instruments had been delivered to Talis; that Talis One was only an unreliable prototype; or that necessary validation had not been completed. Instead, by omitting these facts and stating that production "is scaling up" (not that it would "start"), the Registration Statement reinforced the false impression that substantial production had already commenced by the time of the IPO. In the context of the present-tense statement that Talis's "products are manufactured" and the statement that Talis had "ordered 5,000 instruments . . . to be delivered beginning in the fourth quarter of 2020 through the first quarter of 2021"—made when the delivery period was about 75% complete—reasonable investors understood that Talis One instruments were being produced and delivered to Talis at the time of the February 2021 IPO. That was simply not true.

2. False and Misleading Statements That Talis One Was "Reliable" and "Highly Accurate" While It Was Unreliable and Inaccurate

122. Talis One's accuracy and reliability were highly material to investors. For obvious reasons, doctors and hospitals do not want COVID-19 tests that do not work. The Registration Statement explained that Talis's "success depend[ed] on physician and customer confidence that we can provide reliable and highly accurate diagnostic tests and enable better patient care," and

"physicians and other healthcare providers [were] likely to be particularly sensitive to defects, errors or reliability issues" in Talis's products.

123. That is because COVID-19 tests that do not generate usable results—regardless of the technical reason—are a waste of customers' and patients' time and money. Beyond the direct cost of the invalid or failed test, the medical provider typically must re-test and collect a new sample from the patient. Not only does this add cost and delay—directly contrary to Talis One's claimed advantage of providing rapid results at the point of care—but collecting a new sample is often difficult or impossible because the patient has already left the facility.

124. Talis One's failure rate (the percentage of tests that fail to meet their specified performance characteristics for specificity, sensitivity, or analytical sensitivity) was important to ensure that test results were accurate, rather than false negatives (*i.e.*, negative results for an infected patient) or false positives (positive results for a patient who was not infected).

125. Talis One's invalid rate—the percentage of tests that do not yield any result—was also crucial. As a March 2020 academic article noted, a test's invalid rate is an "important consideration when selecting an assay for clinical use."[7] The FDA requires invalid rates to be below 10% and prefers a rate under 5%. For example, the FDA's Molecular Diagnostic Template for Commercial Manufacturers (July 28, 2020) stated that in the context of "pooled" testing (combining multiple samples into several "pools," then following up with individual testing if any "pool" tests positive), COVID-19 tests should have an "invalid rate of < 5%." And as discussed below, Talis has admitted that the FDA requires invalid rates below 10% for a viable product.

126. In addition to meeting the FDA's requirements to launch Talis One, a reliable and accurate device was crucial for Talis to compete with competitors who had already launched COVID-19 tests similar to Talis One that were available at the time of Talis's IPO and boasted invalid rates of just 1-2%. For example, Talis's competitor Lucira explained in a Form S-1 filed with the SEC on January 15, 2021 that its COVID-19 test had an invalid rate of 0.99%,

[7] Kanwar N. et al., Comparison of the ID Now Influenza A & B 2, Cobas Influenza A/B, and Xpert Xpress Flu Point-of-Care Nucleic Acid Amplification Tests for Influenza A/B Virus Detection in Children, Journal of Clinical Microbiology, Vol. 58 Issue 3 (March 2020), *available at* https://doi.org/10.1128/JCM.01611-19

meaning that only 1 of 101 samples generated an invalid result.[8] A company that Talis identified as one of its competitors, Roche, reported that a study of 287 clinical samples using its COVID-19 test yielded five invalid results, for an invalid rate of 1.7%.[9] A January 2021 academic study of this test—described as "the first U.S. Food and Drug Administration (FDA)-authorized POC RT-PCR for detection of SARS-CoV-2 in 20 min[utes]"—found an "initial invalid rate" of "1.66% [6/360])."[10]

127. In this context, the Registration Statement touted the Talis One as "reliable," "highly accurate," and designed "to provide central lab levels of accuracy":

> The Talis One Platform incorporates core proprietary technologies into a compact, easy-to-use instrument, that utilizes single use test cartridges and software, including a central cloud database, which are designed to work together to ***provide levels of testing accuracy equivalent to a central laboratory***.
>
> …
>
> We designed the Talis One platform to provide ***central lab levels of accuracy*** at the point-of-care.
>
> …
>
> The test cartridge for COVID-19 diagnosis contains a NAAT designed for optimal sensitivity and specificity to provide ***highly accurate results***.
>
> …
>
> ***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

[8] Lucira also disclosed that its study involved "two additional retests (1.98%) that were due to user errors where study staff prematurely provided a second test kit prior to letting the test complete to a possible invalid result."

[9] *See* cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System, at 32, *available at* https://www.fda.gov/media/142193/download The FDA granted an EUA for this test on September 14, 2020. *See* https://www.fda.gov/media/142190/download

[10] Hansen G. et al., Clinical Performance of the Point-of-Care cobas Liat for Detection of SARS-CoV-2 in 20 Minutes: a Multicenter Study, Journal of Clinical Microbiology, Vol. 59 Issue 2 (Jan. 2021), *available at* https://doi.org/10.1128/JCM.02811-20

> agreement (NPA) for detection of SARS-CoV-2, the virus that causes COVID-19.
>
> …
>
> An important factor in our ability to commercialize our products is collecting data that supports the value proposition of our products, and in particular that our tests are ***just as accurate and reliable as central lab testing***.

128. These statements were materially false and misleading when made. As detailed below, at the time of the IPO, the Talis One prototypes were highly unreliable and inaccurate, with up to 20%—or one in five tests—failing to yield usable results, and up to 15% of tests yielding no result at all. A test that does not work up to one out of five times is not accurate or reliable. Talis One's unreliability and inaccuracy were driven by inherent design and manufacturing issues that existed at the time of the IPO, including cartridge chamber sizes that were too small and a non-functional gasket and plastic piece in the cartridge. Because Talis One frequently failed or generated unusable results, it did not do what it was claimed to do—it was neither "reliable" nor "highly accurate," and was far from being "just as accurate and reliable as central lab testing."

129. Three former Talis employees confirmed that at the time of the IPO, Talis One was neither accurate nor reliable, with an invalid rate of up to 15% and a failure rate of up to 20%.

130. The "invalid rate" refers to tests that do not yield ***any*** result at all. The FDA requires invalid rates to be below 10% and prefers a rate under 5%, and many manufacturers' comparable COVID-19 tests had invalid rates of 1-2%, as detailed above.

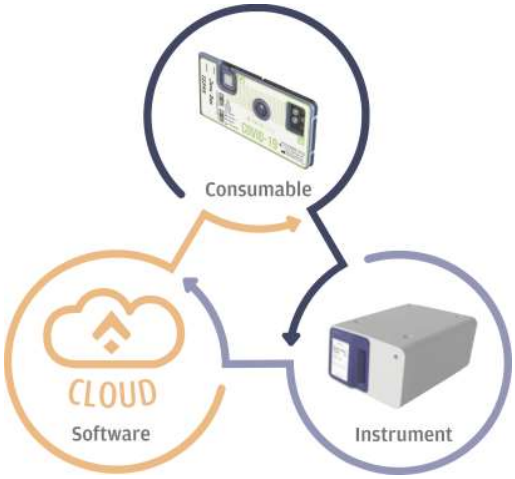
131. At the time of Talis's IPO, Talis One's invalid rate was far higher. FE-8 was a Vice President of Product at Talis from January 2016 to April 2022, when FE-8 was laid off in the Company's reduction in force. FE-8 was based at the Menlo Park headquarters and reported to CEO Coe and the commercial unit. FE-8 stated that at the time of Talis's IPO, there were different lots of prototype devices, and the invalid rate ranged from 5% to 15% among these lots. A 5% rate was acceptable, but rates over 10% were considered unacceptable. FE-8's personal knowledge of Talis One's invalid rate comes as a direct result of FE-8's position as a senior Talis executive focused on sales at the time of the IPO.

132. The "failure rate" is broader than the invalid rate and refers to the percentage of tests that fail to meet their specified performance characteristics for specificity, sensitivity, or analytical sensitivity (limit of detection), including invalid tests (*i.e.*, those that do not yield any result). FE-6 stated that in February 2021, Talis One had a failure rate that was between 10% and 20%. FE-6 knows this from attending weekly business review meetings with CEO Coe, CFO Moody, and COO Liu (among other senior Talis executives) where the failure rate was discussed. FE-6 also confirmed that invalid test results accounted for a portion of the failure rate. FE-6's personal knowledge of Talis One's failure rate comes as a direct result of FE-6's attendance at Talis's weekly business review meetings and position as a senior Talis executive who reported directly to CEO Coe.

133. Corroborating FE-6 and FE-8, FE-2 stated that it was known well before the Company submitted its first EUA application (in late January 2021) that the test had a high invalid rate. FE-2 holds a Ph.D. in molecular genetics and worked at Talis as a senior scientist from February 2020 to October 2020. FE-2 was hired to work on infectious disease diagnostics and assay development, and with the advent of COVID-19, FE-2 shifted focus to the virus. Based in Talis's Menlo Park, CA location, FE-2 reported to Hédia Maamar, the VP of R&D Assay, who in turn reported to SVP Ramakrishnan. FE-2 worked on developing a test kit as well as the Talis One test platform. FE-2's personal knowledge of Talis One's invalid rate and other issues comes as a direct result of FE-2's position as a Talis senior scientist focused on the Talis One assay shortly before the IPO.

134. FE-2 indicated that the high invalid rate should have been no surprise, as Talis One was not developed with the biology in mind, and was developed by engineering without much input from the assay department that developed the biological testing. Specifically, FE-2 described poor communication between the engineering and assay teams, resulting in a lack of pretesting in the Talis One design and design issues such as the size of the cartridges. FE-2 indicated that the chamber sizes in the Talis One's cartridges were created without sufficient volume for proper limits of detection (the lowest concentration that a test can consistently identify with high probability) because some of the chambers were too small.

135. The flawed cartridges—which were necessary to operate Talis One because they contained the patient sample and the assay used to test it—meant Talis One as a whole was neither accurate nor reliable. In this regard, the Registration Statement described Talis One as "an integrated platform that includes a compact instrument, single-use test cartridges and software" and stated that "[a]t the core of our platform is the Talis One cartridge." The Registration Statement depicted this "integrated platform" as follows:



136. FE-2 also pointed to an overall lack of processes and internal review, stating that "There are certain gates if you do the IVD [In Vitro Diagnostics] process properly. You either pass or fail those gates. You want to sample specifications stringently before you start. And Talis did not have any processes in place. They had no good standard practices." FE-2 recalled: "Nothing was properly vetted. It was like a runaway train."

137. After the IPO, the inaccuracy and unreliability that FE-6, FE-8, and FE-2 identified did not suddenly disappear. To the contrary, FE-4 and FE-5 confirmed that the invalid rate remained high and prevented Talis from showing Talis One to potential customers.

138. As FE-4—the territory account manager who joined Talis in February 2021—explained, Talis One was little more than a "dummy box" that sales representatives were instructed not to turn on in meetings at doctors' offices and hospitals because Talis did not have a working, reliable product. For example, in April 2021, FE-4's supervisor Alex de los Reyes and his supervisor, Anthony Green, told FE-4 and other sales personnel to show a demo video because Talis did not have any working analyzers. FE-4 also received a non-functional sample cartridge

marked with a production date of May 25, 2021, indicating that Talis did not have a working cartridge by May 2021.

139. By approximately June 2021, de los Reyes and Green told FE-4 that Talis One's invalid rate was over 10%, and the Company was trying to reduce it below 10% to meet FDA requirements but had not done so. On or around November 12, 2021, FE-4 observed that the Talis One had a high invalid rate when FE-4 turned on the device and it said "invalid, invalid, invalid" 20 or 30 times. The same day, FE-4 told de los Reyes that all the tests were invalid; de los Reyes told FE-4 that the analyzer had such a high invalid rate that Talis could not take a chance by attempting to operate the machine in front of potential clients.

140. 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, led the creation of processes and procedures to support FDA launch requirements, and ran a team of five technical support specialists focused on the development of process and procedures for the Talis One launch. FE-5 reported to Emily Korkofigas, senior director of customer success, who reported to Kelley (Chief Commercial Officer, and later CEO). FE-5's personal knowledge of Talis One's invalid rate and other issues comes as a direct result of FE-5's position focused on the Talis One launch.

141. FE-5 confirmed that by fall 2021, it was known inside Talis that the invalid rate was above 10%. FE-5 knows this based on attending internal meetings every 6 to 8 weeks where COO Liu provided updates (including virtual town halls and at least one in-person meeting in Chicago), and based on communications between FE-5 and FE-5's supervisor Korkofigas. FE-5 did not believe the invalid rate was ever below 10%. As FE-5 explained, "You don't want a customer to get an invalid answer, because it's a waste of time and money. Higher invalid rates mean you're wasting time and money."

142. Even by December 2021, Talis's sales force had no working analyzer to show customers; at the time, de los Reyes and/or Green told FE-4 that they had one working unit but were still trying to reduce the invalid rate.

143. On or around December 6, 2021, during a business trip in California, FE-4 confronted Mai Nguyen (Product Manager) about Talis One's high invalid rate. Nguyen indicated to FE-4 that Talis One had not worked to date, and that two parts inside the cartridge didn't work; one of the non-functional parts was a gasket, and the other was a plastic piece. Similarly, FE-5 was told in the fall 2021 meetings with COO Liu and in communications with Korkofigas that the high invalid rate arose from problems with the cartridge.

144. The detail, corroborating nature, and duration of five former Talis employees' observations of Talis One's high failure rate and invalid rate—spanning from 2020 to December 2021—confirm that the statements touting Talis One's "central lab levels of accuracy," "highly accurate results," and "reliable" tests were materially false and misleading when made.

145. Moreover, any data on invalid rates that Talis submitted to the FDA was not representative of Talis One's actual invalid rate at the time of the IPO. During the December 6, 2021 conversation described above, FE-4 asked Nguyen how Talis had been able to submit data to the FDA. Nguyen indicated that, based on her interactions with Talis personnel who ran the studies, including Michelle Roeding (Sr. Director Quality and Regulatory Affairs) and Lori Lai (Director of Product Management), they had performed "simulations" and the FDA did not physically inspect testing devices to ensure that they worked. After this conversation, FE-4 told co-workers that Talis had never had a working test, and that they should update their resumes to prepare for new employment.

146. Finally, Talis One's performance was nowhere near "central lab levels of accuracy," contrary to the Registration Statement's claim. As detailed above, at the time of the IPO, Talis One had invalid rates of up to 15%. By contrast, according to a January 2021 academic study, "the most widely used RT-PCR laboratory test, the cobas 68/8800 SARS-CoV-2 test," had ***zero*** invalid results out of 357 samples.[11] Where up to 15% of Talis One tests were invalid at the

[11] Hansen G. et al., Clinical Performance of the Point-of-Care cobas Liat for Detection of SARS-CoV-2 in 20 Minutes: a Multicenter Study, Journal of Clinical Microbiology, Vol. 59 Issue 2 (Jan. 2021), at 3-4, *available at* https://doi.org/10.1128/JCM.02811-20 The study started with 444 samples, of which 84 were ineligible due to improper collection or other reasons unrelated to the central lab test's performance. Three additional samples were excluded because "they were

time of the IPO, while central lab tests had an invalid rate at or near zero, claiming that Talis One was designed "to provide central lab levels of accuracy" was materially false and misleading. As detailed below, Talis One's high invalid rates have foreclosed its launch to this day.

D. The Registration Statement Violates SEC Disclosure Requirements by Omitting Known, Material Uncertainties and Material Risks That Made Investing in Talis Highly Risky and Speculative

147. Separate and independent of its affirmative misstatements, the Registration Statement contained actionable omissions in violation of SEC disclosure requirements.

148. Specifically, the Registration Statement omitted the known, material uncertainties that (1) the FDA would reject Talis's comparator assay because it was not "high sensitivity" and violated FDA requirements, and (2) Talis One's high invalid rate of up to 15% and failure rate of up to 20% threatened to foreclose and/or dramatically delay commercial launch. Item 303 of SEC Regulation S-K required disclosure of these known "uncertainties" because they threatened to have a "material" and "unfavorable" impact on Talis's revenues, net sales, and income.

149. Item 105 of SEC Regulation S-K required disclosure of "material factors" that made an investment in Talis and the IPO "speculative or risky." In violation of Item 105, the Registration Statement omitted the material risks of the comparator assay that violated FDA requirements and Talis One's high invalid rate and failure rate, all of which threatened to delay—or prevent—Talis One's launch as the window rapidly closed.

150. The need for the specific disclosures that Item 303 and Item 105 require was paramount because Talis One was Talis's only product. The Registration Statement indicated that Talis's "future success will depend in large part on our ability to effectively launch the Talis One platform with our COVID-19 test and subsequently introduce enhanced or new tests for the Talis One platform," that a "significant portion of our commercial strategy is dependent upon the initial commercialization of our Talis One platform with COVID-19 test pursuant to an EUA, if granted," and that "[s]ubstantially all of our revenue will initially be dependent upon" sales of the "Talis

invalid" on the point-of-care device being evaluated (not the central lab test). The remaining 357 samples were evaluated using both tests.

One platform with our COVID-19 test in the United States." As a result, the omitted uncertainties and risks were highly material.

1. Material Omissions in Violation of Item 303

151. The failure to disclose a material uncertainty in violation of Item 303 is an omission that is actionable under the Securities Act. As relevant here, Item 303 required Talis to:

> Describe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations.[12]

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

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

153. In violation of Item 303, the Registration Statement omitted two known, material uncertainties.

a. Omission of the Known, Material Uncertainty That the FDA Would Reject Talis's Comparator Assay, Which Violated FDA Requirements

154. The Registration Statement violated Item 303 by omitting the known, material uncertainty that the FDA would reject Talis's comparator assay because it was not "high sensitivity" and violated FDA requirements. As detailed below, despite the FDA requirement to

[12] 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.

use a "high sensitivity" comparator assay, Talis selected a comparator assay that was "***low-sensitivity***," as Defendant Ismagilov acknowledged shortly before the IPO.

155. Whether Talis was ***certain*** that the FDA would reject the "low-sensitivity" comparator assay is irrelevant to Defendants' disclosure obligation under Item 303. Because the comparator assay violated FDA requirements, it raised a heightened, material risk of rejection—a known ***uncertainty*** that required disclosure under Item 303.

156. As background, Talis was required to obtain Emergency Use Authorization from the FDA before marketing or selling the Talis One COVID-19 test.[13] Talis's ability to quickly procure an EUA was highly material to investors, as this was a necessary step for Talis to launch Talis One and generate revenue. Not only was time of the essence, with increasing vaccination rates and multiple competitors' products already on the market, but obtaining and maintaining an EUA was required under Talis's $25 million RADx Contract, which provided that "[s]uccessful performance under this contract requires [Talis] to obtain and maintain an Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA)."

157. Talis applied for an EUA on January 29, 2021. By then, the EUA process was well-established; the FDA had granted EUAs to other COVID-19 molecular diagnostic tests as early as April 2020, and authorized dozens of such tests by the end of 2020.[14]

158. The FDA's Molecular Diagnostic Template for Commercial Manufacturers (July 28, 2020) provided specific guidance to companies like Talis seeking EUAs.

159. Applicants were required to submit, among other things, studies demonstrating their test's performance. Certain of these studies measure important data points called positive percentage agreement (PPA) and negative percentage agreement (NPA). PPA and NPA are the percentages of specimens that a new test correctly identifies as positive or negative relative to a

[13] Under Section 564 of the FD&CA, the FDA "may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening disease." The U.S. Department of Health and Human Services originally authorized the FDA to grant EUAs related to COVID-19 on February 4, 2020.

[14] *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

prior test, known as the comparator assay. For example, if a comparator assay identifies 100 samples as positive and the new test identifies 99 of the 100 as positive, the new test's PPA is 99%. Likewise, if the comparator assay identifies 100 negative samples and the new test identifies 99 of the 100 as negative, the new test's NPA is 99%. These results are shown below:

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

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

161. 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	120	80	200
New Test Accuracy	**82.5%** (99 of 120 correct)	**80.8%** (80 of 99 correct)	

162. For this reason, it was critical that Talis's EUA submission use a highly sensitive comparator assay that correctly identified the SARS-CoV-2 virus and minimized false negative results. The John Hopkins Center Bloomberg School of Public Health's Center for Health Security

has explained that sensitivity "measures the proportion of positive test results out of all truly positive samples. In other words, a test's sensitivity is its ability to correctly identify those with the disease (the true positives) while minimizing the number of false negative results."[15] Tests with low sensitivity miss significant percentages of infected samples.

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

a) "We recommend using ***only a high sensitivity EUA RT-PCR assay*** which uses a chemical lysis step followed by solid phase extraction of nucleic acid (e.g., silica bead extraction)."

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

164. Similarly, the FDA's Template for Manufacturers of Molecular and Antigen Diagnostic COVID-19 Tests for Non-Laboratory Use (July 29, 2020), urged manufacturers to use "one of the more sensitive EUAs on the FDA website (supported by peer reviewed literature, comparative studies testing the FDA reference material, etc.)."

165. Meeting the FDA's requirements was mandatory to obtain Emergency Use Authorization and market a COVID-19 test. The FDA's requirement to use a "high sensitivity" comparator assay was an objective, established requirement that dozens of other manufacturers had successfully followed to obtain their own EUAs by January 2021.

166. The FDA required all "high sensitivity" comparator assays to have a limit of detection (LoD)[16] better than 18,000 NDU/mL, meaning that 18,000 or fewer viral copies per milliliter of sample trigger a positive result. (Because sensitivity measures the number of viral

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

[16] The limit of detection, 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.

copies required to trigger a positive result, lower numbers mean a test is more sensitive.) As of January 2021, dozens of tests met this standard.

167. Nonetheless, Talis's January 2021 EUA submission used a comparator assay that had a limit of detection of 180,000 NDU/mL, meaning that it required at least 180,000 viral copies per milliliter of sample to trigger a positive result. This was ***10 times*** less sensitive than the FDA's "high sensitivity" standard of 18,000 NDU/mL. As a result, Talis's comparator assay violated the FDA's "high sensitivity" requirement at the time of the IPO.

168. Confirming the point, Defendant Ismagilov—a Ph.D. scientist who co-founded Talis, serves on its Board, and signed the Registration Statement—explained that a test requiring at least 180,000 viral copies per milliliter of sample to trigger a positive result, like Talis's comparator assay, is not "high sensitivity."

169. First, in an article released in draft form in December 2020, before the IPO, Ismagilov wrote that "low-sensitivity tests" had limits of detection of at least 100,000 viral copies per milliliter ("~10^5–10^7 [100,000 to 10 million] RNA copies/mL"), meaning that they required at least 100,000 viral copies to trigger a positive result.[17] With an LoD of 180,000 NDU/mL, Talis's comparator assay was well within the "low-sensitivity" category.[18]

170. Ismagilov was not simply an academic; he was personally involved in developing Talis One, including in the months leading up to the IPO. As the Registration Statement explained, "Dr. Ismagilov, during a partial sabbatical from Caltech from August 2020 through December 2020, devoted three days per week to support our efforts to complete development of our Talis One platform." Even as Ismagilov spent over half his time working on Talis One, Talis used a

[17] A preprint of this article was posted on December 11, 2020 to medRxiv, an online distribution server for unpublished manuscripts (preprints) in the medical, clinical, and related health sciences. *See* https://www.medrxiv.org/content/10.1101/2020.12.09.20239467v1

[18] Nothing in the Registration Statement revealed that Talis's comparator assay was not "high sensitivity," and investors and analysts were unaware of this fact at the time of the IPO. Further, the Registration Statement specifically stated that Talis had not authorized any representations outside the prospectus and disclaimed any responsibility for information provided by others. In this regard, the Registration Statement stated: "We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you."

comparator assay with a sensitivity level that Ismagilov himself viewed as "low-sensitivity," while the Registration Statement made no mention of that fact.

171. Second, shortly after the IPO, Ismagilov again acknowledged, based on research started before the IPO, that tests like Talis's comparator assay are "low-sensitivity." Ismagilov co-authored an article released in draft form in April 2021[19] where he wrote that "***[h]igh-sensitivity*** tests have LOD values equivalent to ~10^2 to 10^3 [*i.e.*, 100 to 1,000] copies/mL of sample, whereas ***low-sensitivity tests*** have LOD values equivalent to ~10^5 to 10^7 [*i.e.*, 100,000 to 10 million] copies/mL."[20] This article was based on research started in September 2020, before the IPO,[21] and "high-sensitivity" is the ***same*** term used in the FDA's July 2020 requirement. Ismagilov's use of the terms "high-sensitivity" and "low-sensitivity" was quantitative and objective, not subjective. Any "high-sensitivity" test under Ismagilov's definition (*i.e.*, had an LoD at or below 1,000 copies/mL) also met the FDA's definition of "high sensitivity." Similarly, the tests that Ismagilov identified as "low-sensitivity" did not meet the FDA's requirement for a "high sensitivity" comparator assay. Indeed, Ismagilov's April 2021 article specifically identified a test with a limit of detection of 180,000 NDU/mL—the same as Talis's comparator assay—as "substantially less sensitive."[22]

172. Underscoring that Ismagilov understood the difference between low sensitivity and high sensitivity assays, an April 9, 2021 Twitter post from his lab (https://twitter.com/ismagilovlab) stated that "Tests with high sensitivity are KEY to early detection." This was not a new revelation, as he had published on this issue in December 2020.

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[19] A preprint of this article was posted on April 7, 2021 to medRxiv. *See* https://www.medrxiv.org/content/10.1101/2021.04.02.21254771v1?versioned=true

[20] The article indicated that "FDA's NDU/mL is approximately equivalent to the copy/mL scale used in this paper."

[21] The final, peer-reviewed version, published in February 2022, stated that the study forming the basis for the article was "conducted between September 2020 and June 2021." https://journals.asm.org/doi/10.1128/jcm.01785-21

[22] Specifically, the article stated that the "sensitivity of RT-qPCR tests ranges from highly sensitive (e.g., 180 NDU/mL for PerkinElmer and 450 NDU/mL for Zymo Research) to substantially less sensitive (*e.g.*, 180,000 NDU/mL for TaqPath COVID-19 Combo Kit and 540,000 NDU/mL for Lyra Direct SARS-CoV-2 Assay)."

173. FE-2—the former Talis senior scientist with a Ph.D. in molecular genetics who worked at Talis from February to October 2020—stated that Talis had used the "shittiest comparator [assay]" as a benchmark for its EUA submission to the FDA.

174. Indeed, the sensitivity of Talis's comparator assay ranked at the very bottom of all FDA-authorized tests. (The fact that a COVID-19 test is "FDA-authorized" does not mean that it complies with the FDA's "high sensitivity" requirement for comparator assays.) In September 2020, Modern Healthcare—a healthcare news source accessible only through a paid subscription—published an article discussing the FDA's recent release of data about the LoDs of 55 FDA-authorized COVID-19 molecular diagnostic tests. The article reported that the "best-performing" test had a "reported limit of detection of 180 NDU/ml," while singling out the three least sensitive tests, which had LoD values of "180,000 NDU/ml," or "10,000 fold" higher than the most sensitive test. Moreover, 52 of the 55 FDA-authorized tests—all but the three least sensitive—met the FDA's "high sensitivity" standard of 18,000 NDU/mL.

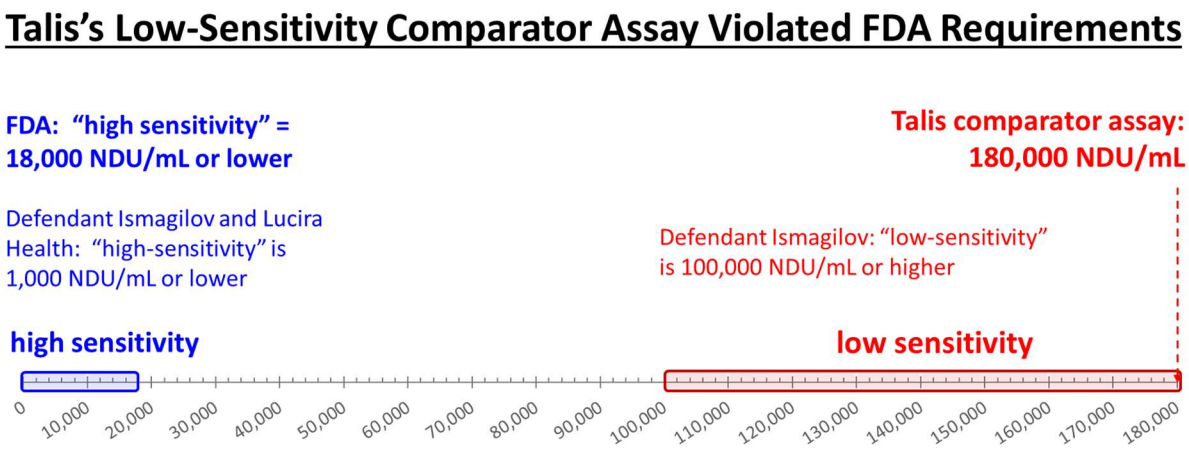
175. Thus, with an LoD of 180,000 NDU/mL Talis's comparator assay was (a) the least sensitive COVID-19 test the FDA had authorized by September 2020, and (b) far less sensitive than the 52 FDA-authorized tests that were "high-sensitivity."[23]

176. Further, at the time of the IPO, Talis's competitors understood the term "high sensitivity." Talis's competitor Lucira explained in a Form S-1 filed with the SEC on January 15, 2021, weeks before Talis's IPO, that "***[a]ll*** the FDA EUA authorized ***high sensitivity*** molecular assays have an LoD of 1,000 [copies]/mL VTM equivalent or lower," consistent with the statements in Ismagilov's articles. Talis's comparator assay—with an LoD of 180,000 NDU/mL—was far above this threshold and was not "high sensitivity."

177. In short, at the time of the IPO, Talis's comparator assay—with an LoD of 180,000 NDU/mL—was (a) far outside the definition of a "high sensitivity" test as understood by the FDA,

[23] While the FDA authorized additional COVID-19 molecular diagnostic tests after September 2020, Talis's comparator assay remained among the least sensitive. For example, out of 117 tests authorized as of March 1, 2021, only ***two*** were less sensitive than Talis's comparator assay.

Defendant Ismagilov, and Talis's competitors, and (b) squarely within the "low-sensitivity" category as defined in Defendant Ismagilov's research. This is shown below:



178. The FDA also encouraged Talis to seek advance guidance about its comparator assay and provided a dedicated email address to do so. As indicated above, the FDA's July 2020 guidance stated "Please contact CDRH-EUA-Templates@fda.hhs.gov to discuss options to establish sensitivity." In addition, before the IPO, in weekly "virtual town halls" the FDA emphasized that applicants should use the "best possible standard" (Sept. 16, 2020). Defendants thus had clear notice of the FDA's emphasis on a highly sensitive comparator assay and every opportunity to consult with the FDA in advance if they had questions.

179. Finally, before the IPO, the FDA requested additional information from Talis, strongly suggesting that the FDA had already raised concerns about the comparator assay that was within the "low-sensitivity" range according to Ismagilov's scientific research. Nonetheless, on February 9, 2021, Defendants accelerated the IPO. They cryptically mentioned the FDA's concerns only in the final Registration Statement filed on February 11, 2021, the same day the IPO was completed, stating that "[d]uring its preliminary review of our EUA submission, the FDA requested that we provide it with additional information on our test prior to initiating its substantive review of the submission, which we expect to promptly provide," without disclosing the topic of the FDA's inquiry or providing any detail about the "additional information" the FDA requested.

180. Thus, at the time of the IPO, Defendant Ismagilov—who signed the Registration Statement—described tests like Talis's comparator assay as "low-sensitivity" in his own academic

work; Talis had chosen the "shittiest" comparator assay for its submission, as FE-2 confirmed; Talis's comparator assay was the least sensitive FDA-authorized COVID-19 test and 10 times less sensitive than the FDA's "high sensitivity" threshold of 18,000 NDU/mL; the FDA had repeatedly emphasized the importance of a high-sensitivity comparator assay; and the FDA had contacted Talis shortly before the IPO seeking additional information.

181. On these facts, even if Talis was not ***certain*** that the FDA would reject the comparator assay, the comparator assay's violation of FDA requirements raised a heightened, material risk of rejection—a known ***uncertainty*** that required disclosure under Item 303. Indeed, Talis's use of a "low-sensitivity" comparator assay (and the least sensitive test the FDA had authorized) maximized the probability that the FDA would reject Talis's comparator assay and cause its EUA submission to fail. At minimum, Talis could not determine that the FDA's rejection of the comparator assay was "not reasonably likely to occur" under the first step of Item 303's disclosure test detailed above.

182. Talis also reasonably expected that the known uncertainty that the FDA would reject Talis's comparator assay would have a material unfavorable impact on the Company's revenues, net sales, and income. In particular, any FDA rejection would cause—at minimum—months of delay while Talis performed new studies using a different comparator assay and made another EUA submission. This significant delay—while the window to launch a new COVID-19 test rapidly closed—would be materially unfavorable. At minimum, Talis could not determine that a material effect on its financial condition or results of operations was "not reasonably likely to occur" under the second step of Item 303's disclosure test detailed above, and disclosure was required.

183. Nonetheless, in violation of Item 303, the Registration Statement omitted the known, material uncertainty that the FDA would reject Talis's comparator assay because it was not "high sensitivity" and violated FDA requirements. No general disclaimers about the risks of the FDA process immunized Defendants' omission, which went well beyond ordinary risks. For example, the Registration Statement generically warned that "[t]here can be no assurance that the COVID-19 test we are developing for the detection of the SARS-CoV-2 virus will be granted an

EUA by the FDA," and that Talis "may not be able to obtain marketing authorization for our Talis One platform or for any test." No such disclaimers warned investors that Talis had used a comparator assay that was within the "low-sensitivity" range, according to scientific research by Talis's own co-founder, and violated the FDA requirement to use a "high sensitivity" comparator assay.

184. The known uncertainty materialized only days after the IPO, when the FDA confirmed that Talis's comparator assay lacked sufficient sensitivity to meet FDA requirements (a fact Defendants then concealed for at least 10 days, as detailed below).

b. Omission of the Known, Material Uncertainty of Talis One's High Invalid Rate and Failure Rate

185. The Registration Statement separately violated Item 303 by omitting the known, material uncertainty that Talis One's high invalid rate of up to 15%—which was well above the FDA's 10% maximum and Talis also considered unacceptable—and its failure rate of up to 20% would foreclose or dramatically delay its commercial launch.

186. As detailed above, the high invalid rate and failure rate were existing, internally known facts at the time of the IPO. Before the IPO, FE-2 observed the high invalid rate in 2020 and attributed it to an inherent design issue (cartridge chamber sizes that were too small). At the time of the IPO, FE-8 confirmed that the invalid rate was up to 15% (well within the "unacceptable" range) and FE-6 confirmed that Talis One had a failure rate of up to 20%.

187. These facts were known to Talis's management at the time of the IPO. The high invalid rate and failure rate were observed by FE-6 and FE-8, senior Talis executives who reported directly to CEO Coe. Talis One's failure rate of up to 20% at the time of the IPO was reported to CEO Coe, CFO Moody, and COO Liu in business review meetings that FE-6 attended. Further, the high invalid rate resulted from the Talis One cartridge's design, which is detailed in multiple patents filed with the U.S. Patent and Trademark Office, including patents invented by senior Talis executives, such as Cauley, Talis's VP of Engineering, and Maamar, the VP of R&D Assay. At the time of the IPO, both Cauley and Maamar reported to SVP Ramakrishnan, who reported to

Coe,[24] strongly indicating that Cauley, Maamar, Ramakrishnan, Coe, and other senior executives were aware of the high invalid rate at the time of the IPO. The observations of FE-4 and FE-5 underscore that the invalid rate was not resolved and remained persistently high even after the IPO.

188. The known fact of Talis One's high invalid rate and failure rate raised a materially heightened risk of foreclosing and/or dramatically delaying commercial launch—a known uncertainty that required disclosure. Talis One's reliability and accuracy were crucial to a successful and timely launch. Given the FDA's requirement of an invalid rate below 10%, Talis One's unreliability and inaccuracy raised specific, heightened, and material risks that Talis would be unable to launch Talis One in a timely manner—or at all—as the window to launch a new test rapidly closed, and that customers would not purchase the device. At minimum, Talis could not determine that the delay or failure of Talis One's launch was "not reasonably likely to occur" under the first step of the disclosure test detailed above.

189. Talis also reasonably expected that this known uncertainty would have a material unfavorable impact on the Company's revenues, net sales, and income. Substantially all of Talis's revenue depended on launching Talis One, competitors' tests with far lower invalid rates were already on the market, and Talis's success "depend[ed] on physician and customer confidence that we can provide reliable and highly accurate diagnostic tests . . . ." At minimum, Talis could not determine that a material effect on its financial condition or results of operations was "not reasonably likely to occur" under the second step of the disclosure test detailed above.

2. Material Omissions in Violation of Item 105

190. Item 105 of SEC Regulation S-K required the Registration Statement to disclose "the material factors that make an investment in the registrant [Talis] or offering [the IPO] speculative or risky." The SEC has confirmed that Item 105's definition of "material" is consistent with the Supreme Court's longstanding definition: that is, "there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having

[24] *See* Talis Letter of Employment dated April 23, 2019, confirming Ramakrishnan's "full-time position of SVP, R&D, reporting to Brian Coe, Co-Founder and CEO," *available at* https://www.sec.gov/Archives/edgar/data/1584751/000119312521014914/d25171dex1011.htm

significantly altered the 'total mix' of information made available." *TSC Industries, Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976). Omissions in violation of Item 105 are actionable under the Securities Act.

191. The Registration Statement violated Item 105 by omitting two material risk factors: (1) that the FDA would reject Talis's comparator assay because it was not "high sensitivity" and violated FDA requirements, and (2) that Talis One's known high invalid rate of up to 15% and failure rate of up to 20% would foreclose and/or dramatically delay its commercial launch.

192. The facts supporting these Item 105 violations are detailed above. These omitted risk factors made an investment in Talis and the IPO highly speculative and risky because they materially heightened the risk that Talis would be unable to launch its only product in a timely manner, or at all. For example, where the FDA required a "high-sensitivity" comparator assay, the fact that Talis used a comparator assay of a type that its own founder viewed as "low-sensitivity" raised an unusual, heightened risk by placing the prospect of obtaining an EUA on a razor's edge, threatening months of delay if Talis's first EUA submission failed. Likewise, the fact that Talis One failed to work properly up to 20% of the time raised an unusual, heightened risk regarding whether the high failure rate and invalid rate could be fixed at all, much less within the rapidly closing window to launch.

193. Again, these concealed risks materialized after the IPO when the FDA rejected Talis's comparator assay (causing months of delay) and Talis One's persistent unreliability has prevented its commercial launch to this day.

3. The Registration Statement's Generic Risk Disclosures Did Not Satisfy Item 303 or Item 105

194. While the Registration Statement provided generic, hypothetical warnings that an EUA might not be granted or Talis's products might suffer from performance or reliability issues in the future, these boilerplate warnings do not satisfy Item 303 or Item 105 because they did not cover the specific, existing, material risks and uncertainties posed by the present reality of Talis's comparator assay that violated FDA requirements and Talis One's high failure rate and invalid rate at the time of the IPO.

195. For example, the Registration Statement stated:

> There can be ***no assurance*** that the COVID-19 test we are developing for the detection of the SARS-CoV-2 virus will be granted an EUA by the FDA.
>
> We ***may*** not be able to obtain marketing authorization for our Talis One platform or for any test.
>
> There can be ***no assurances*** that the FDA will authorize either of these requests and if we do not receive both authorizations, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

196. These hypothetical warnings of potential risks made no mention of the existing reality that Talis's EUA submission used a comparator assay of a type that Talis's own co-founder viewed as "low-sensitivity," despite the FDA requirement to use a "high-sensitivity" comparator assay, or that Talis's comparator assay was the least sensitive "FDA-authorized" assay and 10 times less sensitive than the FDA's "high sensitivity" threshold of 18,000 NDU/mL. In omitting the specific, material uncertainty and risks arising from these existing, internally known facts, the Registration Statement violated Item 303 and Item 105.

197. Likewise, the Registration Statement hypothetically stated that "[o]ur diagnostic tests ***may*** contain errors or defects or be subject to reliability issues," that "quality issues ***may*** arise during scale-up activities," that Talis One "***may*** contain undetected errors or defects when first introduced," that "[t]here is ***no guarantee*** that the accuracy and reproducibility we have demonstrated to date will continue as our product deliveries increase," and that "[a]n operational, technological or other failure . . . ***may*** cause our products to malfunction."

198. Such hypothetical warnings did not disclose the existing, internally known fact that Talis One presently suffered from invalid rates of up to 15%—well above the FDA's maximum, within the range Talis deemed "unacceptable," and far above those of other manufacturers—or failure rates of up to 20%. In omitting the specific, material uncertainty and risks related to these existing, internally known facts, the Registration Statement violated Item 303 and Item 105.

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

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

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

201. On February 9, 2021, Talis requested that the SEC accelerate the effective date of the Registration Statement to February 11, 2021.

202. On February 11, 2021, Talis filed an Amendment No. 2 to the Registration Statement on Form S-1, including a revised preliminary prospectus with the same date, which revealed for the first time that the FDA had responded to Talis's EUA submission by requesting "additional information on our test prior to initiating its substantive review of the submission."

203. At 4:30 PM on February 11, 2021, Talis's Registration Statement was declared effective.

204. The Registration Statement's false and misleading statements and material omissions about Talis One made the IPO a rousing success: it raised $253.9 million for Talis (before deducting underwriting discounts and commissions and offering expenses). Defendants completed the IPO on February 11, 2021, and 15,870,000 shares of Talis common stock (including 2,070,000 shares sold pursuant to the exercise in full by the underwriters of their option to purchase additional shares) were offered at $16.00 per share.

205. Talis's common stock began trading on the NASDAQ on February 12, 2021. In the first day of trading, the share price popped to $27.80, its all-time peak.

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

F. Post-IPO, Talis Remained Unable to Produce or Launch Talis One

207. Corroborating material falsity, the misstated and concealed facts that existed at the time of the IPO ultimately doomed Talis One's commercial prospects. After the IPO, Talis was unable to launch the Talis One COVID-19 test because Talis's January 2021 EUA submission violated FDA requirements; Talis One was only an unreliable prototype; Talis had not completed prototyping or validation; Talis had not ordered instruments from its third-party manufacturer, which had not started production or delivered any instruments to Talis; and Talis One suffered from persistently high invalid rates and failure rates. These were same facts the Registration Statement misstated and concealed. As the concealed truth gradually emerged, Talis's stock price fell precipitously.

208. By the time this action was filed on January 7, 2022, Talis's share price had fallen from the $16.00 offering price to $3.31 per share. Even then, its actual value was significantly lower, and after January 7, 2022, the price of Talis common stock further declined as the truth continued to emerge in piecemeal fashion, including through the events detailed below.

1. The FDA Swiftly Rejects Talis's Comparator Assay

209. Shortly after the IPO, by late February 2021, the FDA told Talis that the comparator assay Talis used was not of "sufficient sensitivity to support Talis's EUA application." Talis later admitted that this occurred in "late February," meaning that the FDA had likely communicated its conclusion to Talis by Friday, February 26, 2021—the last business day of the month.

210. Rather than promptly disclosing this material event in a Form 8-K, Talis concealed the FDA's rejection from investors for at least 10 days, only reporting it on March 8, 2021. This sequence of events is shown below:

- January 29, 2021: Talis filed its EUA submission.
- February 9, 2021: Talis accelerated the IPO.
- February 11, 2021: IPO completed. First mention that the FDA had requested "additional information" from Talis.
- By February 26, 2021: The FDA rejected Talis's comparator assay.
- March 8, 2021 (at least 10 days later): Talis revealed the FDA's rejection.

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

> [Talis] has withdrawn its current application pursuing U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for the Talis One™ COVID-19 test . . . . In late February, the FDA informed the company that it cannot ensure the comparator assay used in the primary study has sufficient sensitivity to support Talis's EUA application.

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

2. August 10, 2021: Talis First Admits Delays

213. On August 10, 2021, after the market closed, Talis held an earnings call where Defendant Coe revealed that "development time lines have been extended by delays in the launching of [Talis's] COVID-19 test and manufacturing scale." As a result, Talis "expect[ed] to see [its] first meaningful revenue ramp in 2022." This was the Company's first public acknowledgement of manufacturing delays with Talis One.

214. This news caused the Company's stock price to fall 6% to close at $8.39 per share on August 11, 2021.

3. August 30, 2021: CEO Coe Departs Abruptly

215. On August 30, 2021, Talis announced that Defendant Coe had "stepped down" as its President, CEO, and Director, effective immediately, and, without a permanent replacement, appointed its Chairman of the Board, Defendant Kimberly J. Popovits, as Interim CEO.

216. Talis offered no public explanation for Defendant Coe's abrupt departure. However, FE-6—who was Talis's Vice President of Human Resources and Chief Human Resources Officer at the time—explained that Coe left Talis after the Board engaged an outside consultant in summer 2021 to perform a 360-degree review of Coe's management. (A 360-degree review involves soliciting feedback on an executive's or employee's performance from various stakeholders, including the individual's supervisors, peers, and those who report to them.) FE-6

stated that this review, which included scrutiny of Talis One's development process, concluded that Coe ignored the reality being reported by the Talis employees on the ground.

217. On the news of Coe's departure, the Company's stock price fell 11% to close at $8.06 per share on August 31, 2021.

4. November 15, 2021: Talis Reveals "Limited Rollout"

218. On November 15, 2021, after the market closed, Talis held an earnings call where Interim CEO Popovits revealed that Talis would execute a "controlled product rollout" using a "measured approach." Chief Commercial Officer Rob Kelley reiterated that Talis had "decided to take a phased approach for rolling out the Talis One System," with a "limited rollout" to begin "in the first quarter of 2022" that would involve "a small number of sites representative of the customers we are targeting . . . ."

219. On this news, the Company's stock price fell 17.93% to close at $4.76 per share on November 16, 2021.

5. December 8, 2021: New CEO Blaser Leaves After Only a Week

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

221. While Talis claimed that Blaser departed "due to personal matters," FE-6—the former Vice President of Human Resources and Chief Human Resources Officer—explained that after starting as Talis's CEO, Blaser attended a two-day meeting in California with Talis's technical leadership, including COO Liu. During the meeting, Blaser probed the technical details of Talis One. After the meeting, Blaser was scheduled to attend a dinner with Talis personnel. However, he did not show up to the dinner and tendered his resignation the next day. FE-6 learned about these events from Liu and others who attended the meeting with Blaser. When FE-6 asked colleagues why Blaser had not shown up to the dinner, they responded that Blaser must have "figured out what was going on here."

222. After Blaser departed Talis, FE-6 contacted him by email to arrange for delivery of his final paycheck; Blaser indicated that he did not want the paycheck from Talis, and FE-6 responded (shortly before Christmas) that Blaser could donate the money to a charity of his choice. Blaser's LinkedIn profile makes no mention of his one-week tenure as Talis's CEO.[25]

223. On the news of Blaser's departure, the Company's stock price fell 11.39% to close at $4.28 per share on December 8, 2021.

6. March 15, 2022: First Disclosure of High Invalid Rates

224. On March 15, 2022, Talis—in its first financial reporting under new management after CEO Coe's departure—reported a barrage of new, negative information arising from the facts that the Registration Statement misstated and concealed.

225. First, while Talis had claimed in the Registration Statement and four subsequent SEC filings to have "ordered 5,000" Talis One "***instruments***," on March 15, 2022, Talis filed a Form 10-K admitting that Talis had merely "ordered ***components*** for ***up to*** 5,000 instruments." This was not a mere semantic change; over a year after the IPO, Talis ***removed*** the statement that it had ordered "instruments" and ***replaced*** it with a statement that it had only "ordered components." Indeed, Talis had never ordered "instruments," but merely had a capacity agreement at the time of the IPO, as detailed above. The revised language in Talis's 2020 Form 10-K revealed that even 13 months after the IPO, Talis was still at the earliest stage of the manufacturing process.

226. Second, Talis revealed that it "has not started its phased launch of the Talis One™ COVID-19 Test System." CEO Kelley admitted that "the yield and consistency of our current manufacturing process is not yet sufficient to support commercialization," and that "our current process is not yet optimized to produce a minimum monthly yield [of instruments] to support a commercial launch." This was the same state of affairs that existed at the time of the IPO and should have been disclosed to investors at that time.

227. Third, Kelley disclosed that "the rate of invalid or failed tests remains higher than what we believe is acceptable," conceding that the invalid rates were "above 10%," while the FDA

[25] *See* https://www.linkedin.com/in/brian-blaser-443503159 (last accessed Jan. 12, 2023).

"mentioned that you had to be below 10% to have a viable product and a preferred test [sic] that were under 5% invalid rates." This was Defendants' first public recognition—over a year after the IPO—that the Talis One suffered from high invalid rates.

228. On this news, the Company's stock price fell 23.08% to close at $1.30 per share on March 16, 2022.

7. August 2022: Talis Abandons the Talis One COVID-19 Test

229. Finally, on August 2, 2022, Talis reported that it had abandoned the Talis One COVID-19 test entirely. Talis explained that there was "declining market demand" for polymerase chain reaction (PCR)-based COVID-19 tests like Talis One, and that "the investments required to commercialize in the COVID-19 market outweigh the potential economic return." On August 12, 2022, Talis disclosed that it "no longer planned to pursue commercialization of the Talis One COVID-19 Test System in the United States."

230. In other words, the 18 months of delays—driven by the fact that Talis had not ordered instruments at the time of the IPO, the failure of the first EUA submission, and Talis One's persistent unreliability—had caused Talis to miss the window to launch a viable COVID-19 test.

231. Talis's August 2, 2022 Form 10-Q also reported for the first time that Talis had finally "received components to build 5,000 Talis One instruments." Thus, 18 months after falsely claiming to have "ordered 5,000 instruments" for delivery from October 2020 through March 2021, Talis admittedly had just received the "components to build" them.

232. In addition, Talis reported on August 2, 2022 that it had received a notice from NASDAQ that it faced delisting because Talis's share price "had been below $1.00 per share for 31 consecutive business days," and that Talis could be delisted from NASDAQ as early as January 23, 2023 unless it "regain[ed] compliance with the minimum bid price requirement."

233. On November 3, 2022, Talis reported that it has "used all of the net proceeds" of $233 million from the IPO. In other words, all of the cash Talis raised from the Class is gone.

234. Unsurprisingly, the market has given up on Talis as a viable company. As of January 12, 2023, Talis common stock traded at $0.53 per share.

V. THE INDIVIDUAL DEFENDANTS FAILED TO PERFORM REASONABLE DILIGENCE BEFORE THE IPO

235. As the issuer, Talis is strictly liable under the Securities Act for any material misstatements or omissions in the Registration Statement. The Individual Defendants are also liable because they acted negligently and cannot establish any due diligence defense to liability.

236. The Individual Defendants failed to perform a reasonable investigation. Defendants Coe and Moody were officers of Talis, as its CEO and CFO, and were directly involved with Talis One prior to the IPO and present in weekly business review meetings where Talis One's failure rate was discussed (FE-6). The remaining Individual Defendants, members of Talis's Board of Directors, are experienced medical diagnostics investors, executives, and scientists. For example, Defendant Baker holds a Ph.D. in immunology, has been active in biotechnology investing since the early 1990s, and serves on numerous corporate boards, while Defendant Cheong holds an M.D. and a Ph.D. in biomedical engineering from Johns Hopkins University. According to Talis's website, Defendant Popovits is the former CEO of Genomic Health; Defendant Posard is the founder of a life sciences and diagnostics consulting firm; Defendant Scott is the founder of a genomic medicine company; and Defendant Gilliam is "a highly accomplished physician and research scientist."[26] Defendant Ismagilov is one of Talis's co-founders and thus intimately familiar with its operations and the status of the Talis One at the time of the IPO. Such individuals are necessarily familiar with the EUA submission process and the design and manufacturing of diagnostic products, and had the Individual Defendants conducted a reasonable investigation, they could not have believed (or had reasonable ground to believe) that the Registration Statement contained no materially false or misleading statements or omissions.

237. The misstated and omitted facts that render the Registration Statement materially false and misleading existed at the time of the IPO and would have been discovered with a reasonable investigation. For example, in the exercise of reasonable care, the Individual Defendants should have reviewed Talis's timelines for production, contracts and other evidence relevant to the Registration Statement's claims that Talis's "products are manufactured" and that

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

Talis had "ordered 5,000 instruments," and reviewed the results of Talis's internal testing of Talis One with regard to design problems, invalid rates and failure rates. Further, the RADx Contract (signed by Defendant Coe) required Talis "to provide data and reports (e.g., manufacturing, supply chain, production rates)" to the NIH, provided that if "a milestone deliverable is delayed," Talis was "responsible for reporting the reason and providing an updated schedule," and provided that Talis "must meet regularly (at least weekly) with NIH officials to update on progress toward deliverables; anticipated and ongoing issues and problems; and timelines for deliverable completion." These data, reports, updated schedules, and materials related to meetings with NIH officials existed and should have been reviewed by the Individual Defendants in the exercise of reasonable care.

238. Similarly, the material uncertainty and risk that the FDA would reject Talis's comparator assay because it was not "high sensitivity" and violated FDA requirements existed at the time of the IPO and would have been discovered with a reasonable investigation. Defendant Ismagilov himself wrote articles before (and shortly after) the IPO detailing the criteria for "high sensitivity" and "low-sensitivity" COVID-19 tests. Further, the FDA's request for "additional information" in connection with Talis's EUA submission strongly suggests that before the IPO, the FDA had already raised concerns about the comparator assay that was within the "low-sensitivity" range according to Ismagilov's scientific research. The FDA's request should have been carefully reviewed by the Individual Defendants in the exercise of reasonable care.

239. Reviewing production timelines and results; contracts and other documentation regarding Talis One instruments or components; Talis's internal testing results; data, reports, and schedules provided to the NIH; and correspondence with the FDA was particularly important because the IPO occurred at a crucial point when Talis's ability to manufacture at scale, obtain an EUA from the FDA, and quickly launch an accurate, reliable COVID-19 test were of critical importance to investors.

240. A reasonable investigation would have uncovered the existing facts that the Registration Statement misstated and concealed, including that (a) at the time of the IPO, Talis One was merely a prototype, Talis had not completed the steps necessary for large-scale

production, and no instruments had been ordered, manufactured, or delivered, and (b) Talis One was not "accurate" or "reliable," but suffered from high invalid rates and failure rates at the time of the IPO. A reasonable investigation would also have revealed that the Registration Statement omitted known, material uncertainties and risks, in violation of Item 303 and Item 105, arising from Talis One's high invalid rate and Talis's January 2021 EUA submission using a comparator assay that was not "high sensitivity" and violated FDA requirements.

VI. CLASS ACTION ALLEGATIONS

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

- All persons and entities that purchased or otherwise acquired common stock issued by Talis pursuant and/or traceable to the Registration Statement issued in connection with the Company's February 2021 initial public offering, and were damaged thereby.

242. Excluded from the Class are: (i) Defendants and any affiliates or subsidiaries thereof; (ii) present and former officers and directors of Talis and their immediate family members (as defined in Item 404 of SEC Regulation S-K, 17 C.F.R. § 229.404, Instructions (1)(a)(iii) & (1)(b)(ii)); (iii) Defendants' liability insurance carriers, and any affiliates or subsidiaries thereof; (iv) any entity in which any Defendant had or has had a controlling interest; (v) Talis's employee retirement and benefit plan(s); and (vi) the legal representatives, heirs, estates, agents, successors, or assigns of any person or entity described in the preceding categories.

243. The Class is so numerous that joinder of all members is impracticable. Lead Plaintiffs believe that the Class members number at least in the thousands. Talis sold 15,870,000 shares of common stock in the IPO and, as of June 30, 2022, had over 26 million shares of common stock outstanding. Talis common stock traded actively in the United States during the relevant period.

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

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

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

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

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

c) Whether the Individual Defendants were controlling persons under Section 15 of the Securities Act; and

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

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

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

VII. INAPPLICABILITY OF STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE

249. The protections applicable to forward-looking statements under certain circumstances do not apply to any of the false or misleading statements alleged herein. The statements complained of herein concerned then-present or historical facts or conditions that existed at the time the statements were made. No cautionary language could, or did, protect Defendants' material misstatements of present and historical fact. Further, all of the challenged statements were "made in connection with an initial public offering," 15 U.S.C. § 77z-2(b)(2)(D), and thus are expressly excluded from the PSLRA safe harbor.

250. To the extent any of the false or misleading statements alleged herein can be construed as forward-looking, the bespeaks caution doctrine does not apply because any such statements lacked "sufficient cautionary language or risk disclosure such that reasonable minds could not disagree that the challenged statements were not misleading," *Livid Holdings*, 416 F.3d at 947 (alteration and internal quotation marks omitted), and any purported cautionary language did not "relate directly to that to which plaintiffs claim to have been misled." *In re Worlds of Wonder Sec. Litig.*, 35 F.3d 1407, 1415 (9th Cir. 1994).

VIII. CLAIMS FOR RELIEF

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

251. Lead Plaintiffs repeat and reallege each and every allegation above as if fully set forth herein.

252. This Count does not sound in fraud. Any allegations of fraud or fraudulent conduct and/or motive are specifically excluded, except that any challenged statements of opinion or belief made in the Registration Statement are alleged to have been materially misstated statements of opinion or belief when made and at the time of the IPO. Lead Plaintiffs do not allege that any Defendant acted with intentional, reckless, or otherwise fraudulent intent.

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

254. Defendants were responsible for the content and dissemination of the Registration Statement.

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

256. The other Defendants acted negligently in that none of them made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and not misleading, and that the Registration Statement did not

omit any material facts required to be stated therein or necessary to make the statements made therein not misleading.

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

258. When they acquired Talis common stock pursuant and/or traceable to the Registration Statement, Lead Plaintiffs and others similarly situated did not know, nor in the exercise of reasonable care could they have known, of the untruths and omissions contained (and/or incorporated by reference) in the Registration Statement.

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

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

260. Lead Plaintiffs repeat and reallege each and every allegation above as if fully set forth herein.

261. This Count does not sound in fraud. Any allegations of fraud or fraudulent conduct and/or motive are specifically excluded, except that any challenged statements of opinion or belief made in the Registration Statement are alleged to have been materially misstated statements of opinion or belief when made and at the time of the IPO. Lead Plaintiffs do not allege that any Defendant acted with intentional, reckless, or otherwise fraudulent intent.

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

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

264. The Individual Defendants had the power to, and did, control the decision-making of Talis, including the content and issuance of the statements contained (and/or incorporated by reference) in the Registration Statement; they were provided with or had unlimited access to copies of the Registration Statement (and/or documents incorporated by reference) alleged herein to contain actionable statements or omissions prior to and/or shortly after such statements were issued, and had the power to prevent the issuance of the statements or omissions or to cause them to be corrected; and they signed the Registration Statement and were directly involved in or responsible for providing false or misleading information contained in the Registration Statement (and/or documents incorporated by reference therein) and/or certifying and approving that information.

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

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

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

IX. JURY DEMAND

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

X. PRAYER FOR RELIEF

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

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

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

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

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

Dated: January 13, 2023

By: */s/ Joseph A. Fonti*

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CERTIFICATE OF SERVICE

I hereby certify that on January 13, 2023, 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 January 13, 2023.

/s/ Joseph A. Fonti
Joseph A. Fonti