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9 [Additional Counsel on Signature Page]

10 **UNITED STATES DISTRICT COURT**

11 **NORTHERN DISTRICT OF CALIFORNIA**

13 JOHN MODRAK, Individually and on Behalf  
14 of All Others Similarly Situated,

15 Plaintiff,

16 v.

17 TALIS BIOMEDICAL CORPORATION,  
18 BRIAN COE, J. ROGER MOODY, JR.,  
19 FELIX BAKER, RAYMOND CHEONG,  
MELISSA GILLIAM, RUSTEM F.  
20 ISMAGILOV, KIMBERLY J. POPOVITS,  
MATTHEW L. POSARD, RANDAL SCOTT,  
21 J.P. MORGAN SECURITIES LLC, BOFA  
SECURITIES, INC., PIPER SANDLER &  
22 CO., and BTIG, LLC,

23 Defendants.

Case No.

**CLASS ACTION COMPLAINT**

**DEMAND FOR JURY TRIAL**

1 Plaintiff John Modrak (“Plaintiff”), individually and on behalf of all others similarly  
2 situated, by and through his attorneys, alleges the following upon information and belief, except as  
3 to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff’s  
4 information and belief is based upon, among other things, his counsel’s investigation, which  
5 includes without limitation: (a) review and analysis of regulatory filings made by Talis Biomedical  
6 Corporation (“Talis” or the “Company”) with the United States (“U.S.”) Securities and Exchange  
7 Commission (“SEC”); (b) review and analysis of press releases and media reports issued by and  
8 disseminated by Talis; and (c) review of other publicly available information concerning Talis.

9 **NATURE OF THE ACTION AND OVERVIEW**

10 1. This is a class action on behalf of persons and entities that purchased or otherwise  
11 acquired Talis common stock pursuant and/or traceable to the registration statement and prospectus  
12 (collectively, the “Registration Statement”) issued in connection with the Company’s February 2021  
13 initial public offering (“IPO” or the “Offering”). Plaintiff pursues claims against under the Securities  
14 Act of 1933 (the “Securities Act”).

15 2. Talis purportedly develops diagnostic tests to enable accurate, reliable, low cost, and  
16 rapid molecular testing for infectious diseases and other conditions at the point-of-care. The Talis  
17 One tests are being developed for respiratory infections, infections related to women’s health, and  
18 sexually transmitted infections.

19 3. On February 12, 2021, the Company filed its prospectus on Form 424B4 with the  
20 SEC, which forms part of the Registration Statement. In the IPO, the Company sold 15,870,000  
21 shares of common stock at a price of \$16.00 per share. The Company received net proceeds of  
22 approximately \$232.6 million from the Offering. The proceeds from the IPO were purportedly to be  
23 used for commercial activities (including the hiring and training of sales and marketing personnel),  
24 research and development, and working capital and other general corporate purposes.

25 4. On March 8, 2021, Talis announced that it had withdrawn its EUA application for  
26 the Talis One COVID-19 test. In a press release, the Company revealed that “[i]n late February, the  
27 FDA informed the company that it cannot ensure the comparator assay used in the primary study  
28 has sufficient sensitivity to support Talis’s EUA application.” As a result, Talis “intends to initiate

1 its previously planned clinical validation study in a point-of-care environment” to submit its EUA  
2 application “early in the second quarter of 2021.” This study “was designed with a different  
3 comparator study, which Talis believes will address the FDA’s concerns.”

4 5. On this news, the Company’s stock price fell \$1.80, or 12%, to close at \$12.85 per  
5 share on March 8, 2021.

6 6. Then, on August 10, 2021, Talis revealed that its “development timelines have been  
7 extended by delays in the launching of [Talis’s] COVID-19 test and manufacturing scale.” As a  
8 result, Talis “expect[s] to see [its] first meaningful revenue ramp in 2022.”

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

11 8. On August 30, 2021, after the market closed, Talis announced that its Chief  
12 Executive Officer, Brian Coe, had “stepped down” as President, CEO, and Director. On this news,  
13 the Company’s stock price fell \$1.00, or 11%, to close at \$8.06 per share on August 31, 2021, on  
14 unusually heavy trading volume.

15 9. On November 15, 2021, Talis announced that Brian Blaser was appointed as  
16 President, Chief Executive Officer, and Director of Talis effective December 1, 2021. However, a  
17 week after his appointment, on December 8, 2021, Talis announced that Brian Blaser had stepped  
18 down from his positions. On this news, the Company’s stock price fell \$0.55 per share, or more than  
19 11%, to close at \$4.28 per share on December 8, 2021.

20 10. By the commencement of this action, Talis stock has traded as low as \$3.81 per share,  
21 a more than 76% decline from the \$16 per share IPO price.

22 11. The Registration Statement was false and misleading and omitted to state material  
23 adverse facts. Specifically, Defendants failed to disclose to investors: (1) that the comparator assay  
24 in the primary study lacked sufficient sensitivity to support Talis’s EUA application for Talis One  
25 COVID-19 test; (2) that, as a result, Talis was reasonably likely to experience delays in obtaining  
26 regulatory approval for the Talis One COVID-19 test; (3) that, as a result, the Company’s  
27 commercialization timeline would be significantly delayed; and (4) that, as a result of the foregoing,  
28

1 Defendants' positive statements about the Company's business, operations, and prospects, were  
2 materially misleading and/or lacked a reasonable basis.

3 12. As a result of Defendants' wrongful acts and omissions, and the precipitous decline  
4 in the market value of the Company's securities, Plaintiff and other Class members have suffered  
5 significant losses and damages.

6 **PARTIES**

7 13. Plaintiff John Modrak, as set forth in the accompanying certification, incorporated  
8 by reference herein, purchased or otherwise acquired Talis common stock pursuant and/or traceable  
9 to the Registration Statement issued in connection with the Company's IPO, and suffered damages  
10 as a result of the federal securities law violations and false and/or misleading statements and/or  
11 material omissions alleged herein.

12 14. Defendant Talis is incorporated under the laws of Delaware with its principal  
13 executive offices located in Menlo Park, California. Talis's common stock trades on the NASDAQ  
14 under the symbol "TLIS."

15 15. Defendant Brian Coe ("Coe") was, at all relevant times, the Chief Executive Officer  
16 and a Director of the Company, and signed or authorized the signing of the Company's Registration  
17 Statement filed with the SEC.

18 16. Defendant J. Roger Moody, Jr. ("Moody") was, at all relevant times, the Chief  
19 Financial Officer of the Company, and signed or authorized the signing of the Company's  
20 Registration Statement filed with the SEC.

21 17. Defendant Felix Baker ("Baker") was a director of the Company and signed or  
22 authorized the signing of the Company's Registration Statement filed with the SEC.

23 18. Defendant Raymond Cheong ("Cheong") was a director of the Company and signed  
24 or authorized the signing of the Company's Registration Statement filed with the SEC

25 19. Defendant Melissa Gilliam ("Gilliam") was a director of the Company and signed or  
26 authorized the signing of the Company's Registration Statement filed with the SEC.

27 20. Defendant Rustem F. Ismagilov ("Ismagilov") was a director of the Company and  
28 signed or authorized the signing of the Company's Registration Statement filed with the SEC.





1 38. Common questions of law and fact exist as to all members of the Class and  
2 predominate over any questions solely affecting individual members of the Class. Among the  
3 questions of law and fact common to the Class are:

4 (a) whether the Securities Act was violated by Defendants' acts as alleged  
5 herein;

6 (b) whether the Registration Statement and statements made by Defendants to  
7 the investing public in connection with the Company's IPO omitted and/or misrepresented material  
8 facts about the business, operations, and prospects of Talis; and

9 (c) to what extent the members of the Class have sustained damages and the  
10 proper measure of damages.

11 39. A class action is superior to all other available methods for the fair and efficient  
12 adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the  
13 damages suffered by individual Class members may be relatively small, the expense and burden of  
14 individual litigation makes it impossible for members of the Class to individually redress the wrongs  
15 done to them. There will be no difficulty in the management of this action as a class action.

16 **SUBSTANTIVE ALLEGATIONS**

17 **Background**

18 40. Talis purportedly develops diagnostic tests to enable accurate, reliable, low cost, and  
19 rapid molecular testing for infectious diseases and other conditions at the point-of-care. The Talis  
20 One tests are being developed for respiratory infections, infections related to women's health, and  
21 sexually transmitted infections.

22 **The Company's False and/or Misleading**  
23 **Registration Statement and Prospectus**

24 41. On February 11, 2021, the Company filed its final amendment to the Registration  
25 Statement with the SEC on Form S-1/A, which forms part of the Registration Statement. The  
26 Registration Statement was declared effective the same day.

27 42. On February 12, 2021, the Company filed its prospectus on Form 424B4 with the  
28 SEC, which forms part of the Registration Statement. In the IPO, the Company sold 15,870,000

1 shares of common stock at a price of \$16.00 per share. The Company received net proceeds of  
2 approximately \$232.6 million from the Offering. The proceeds from the IPO were purportedly to be  
3 used for commercial activities (including the hiring and training of sales and marketing personnel),  
4 research and development, and working capital and other general corporate purposes.

5 43. The Registration Statement was negligently prepared and, as a result, contained  
6 untrue statements of material facts or omitted to state other facts necessary to make the statements  
7 made not misleading, and was not prepared in accordance with the rules and regulations governing  
8 its preparation.

9 44. Under applicable SEC rules and regulations, the Registration Statement was required  
10 to disclose known trends, events or uncertainties that were having, and were reasonably likely to  
11 have, an impact on the Company's continuing operations.

12 45. The Registration Statement disclosed the following about Talis's regulatory strategy  
13 for the Talis One test to diagnose COVID-19 and its production timeline, stating that the Company  
14 had submitted its Emergency Use Authorization ("EUA") to the U.S. Food and Drug Administration  
15 ("FDA") in January 2021:<sup>1</sup>

16 We are developing Talis One tests for respiratory infections, infections related to  
17 women's health and sexually transmitted infections. ***In January 2021, we submitted***  
18 ***a request for an Emergency Use Authorization (EUA) to the U.S. Food and Drug***  
19 ***Administration (FDA) for our Talis One platform with COVID-19 molecular***  
20 ***diagnostic assay for the automated detection of nucleic acid from the SARS-CoV-***  
21 ***2 virus in nasal swab samples from individuals suspected of COVID-19 by their***  
22 ***healthcare provider.*** Our regulatory strategy is to initially submit for the equivalent  
23 of a CLIA-moderate authorization to be followed shortly thereafter with a subsequent  
24 filing for the equivalent of a CLIA-waived authorization for use in non-laboratory  
25 settings. We are also developing influenza A and influenza B tests to be included as  
26 part of a respiratory panel with our COVID-19 test (COVID-Flu Panel). In addition,  
27 we plan to initiate a clinical trial to support clearance of a pre-market notification  
28 under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDCA) of our  
Talis One instrument with a test for chlamydia and gonorrhea in the second half of  
2021 and submit a 510(k) pre-market notification in the first half of 2022. To support  
our anticipated commercial launch of our COVID-19 test, we have invested in  
automated cartridge manufacturing lines capable of producing one million cartridges  
per month, which are scheduled to begin to come on-line in the first quarter of 2021  
and we expect will scale to full capacity through 2021. We estimate that the potential  
annualized market opportunity for COVID-19 point-of-care diagnostic tests in the  
United States exceeds \$7.0 billion.

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<sup>1</sup> Unless otherwise stated, all emphasis in bold and italics hereinafter is added.

1 46. Regarding the data used to assess the performance of the Talis One platform, the  
2 Registration Statement stated:

3 *Performance of the Talis One COVID-19 test*

4 As part of our development of our COVID-19 test we assessed the performance of  
5 the Talis One platform using anterior or mid-turbinate nasal specimens to tests  
6 conducted in a centralized laboratory using the Centers for Disease Control and  
7 Prevention (CDC) quantitative polymerase chain reaction assay. In a preclinical  
8 assessment comparing the Talis One platform to a reference lab test on 60 matched  
9 anterior or mid-turbinate nasal specimens, the Talis One test results exactly matched  
10 the central lab results with 100% positive percentage agreement (PPA) and 100%  
11 negative percentage agreement (NPA) for detection of SARS-CoV-2, the virus that  
12 causes COVID-19. ***The high PPA and NPA is suggestive of clinical sensitivity and  
13 specificity in the broader clinical population*** and is driven by the very low limits of  
14 detection possible on the Talis One platform, e.g. 500 viral particles per milliliter.

15 47. The Registration Statement purported to warn of certain risks impacting Talis's EUA  
16 for the Talis One for COVID-19, stating in relevant part:

17 ***There can be no assurance that the COVID-19 test we are developing for the  
18 detection of the SARS-CoV-2 virus will be granted an Emergency Use  
19 Authorization (EUA) by the U.S. Food and Drug Administration (FDA). If no  
20 EUA is granted or, once granted, it is revoked or the emergency declaration is  
21 terminated, we will be unable to sell this product in the near future and will be  
22 required to pursue 510(k) clearance or other marketing authorization, which  
23 would likely be a lengthy and expensive process.***

24 We submitted a request for an EUA to the FDA in January 2021 for our Talis One  
25 platform with COVID-19 molecular diagnostic assay for the automated detection of  
26 nucleic acid from the SARS-CoV-2 virus in nasal swab samples from individuals  
27 suspected of COVID-19 by their healthcare provider. Our regulatory strategy is to  
28 initially submit for the equivalent of a CLIA-moderate authorization to be followed  
shortly thereafter with a subsequent filing for the equivalent of a CLIA-waived  
authorization for use in non-laboratory settings. ***During its preliminary review of  
our EUA submission, the FDA requested that we provide it with additional  
information on our test prior to initiating its substantive review of the submission,  
which we expect to promptly provide. 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.***

An EUA would allow us to market and sell our platform with this assay without the  
need to pursue the lengthy and expensive 510(k) clearance process or any other  
marketing authorization process. The FDA may issue an EUA during a public health  
emergency if it determines that, based on the totality of the scientific evidence, that  
it is reasonable to believe that the product may be effective, that the known and  
potential benefits of a product outweigh the known and potential risks, that there is  
no adequate, approved and available alternative and if certain additional regulatory  
criteria are met. These standards for marketing authorization are lower than if the  
FDA were to review our test under its traditional marketing authorization pathways,  
and we cannot assure you that our COVID-19 test would be cleared or approved  
under those more onerous clearance and approval standards. ***As a result, if we do not***

1 *receive an EUA for our Talis One platform with COVID-19 test, the commercial*  
2 *launch of such products could be significantly delayed, which would adversely*  
3 *impact our business, financial condition and results of operations.* The effects of  
any such delay would also be exacerbated if the demand for COVID-19 tests declines  
prior to our receipt of any marketing authorization.

4 (First emphasis in original.)

5 48. The Registration Statement was materially false and misleading and omitted to state:  
6 (1) that the comparator assay in the primary study lacked sufficient sensitivity to support Talis’s  
7 EUA application for Talis One COVID-19 test; (2) that, as a result, Talis was reasonably likely to  
8 experience delays in obtaining regulatory approval for the Talis One COVID-19 test; (3) that, as a  
9 result, the Company’s commercialization timeline would be significantly delayed and (4) that, as a  
10 result of the foregoing, Defendants’ positive statements about the Company’s business, operations,  
11 and prospects, were materially misleading and/or lacked a reasonable basis.

12 **The Subsequent Disclosures**

13 49. On March 8, 2021, Talis announced that it had withdrawn its EUA application for  
14 the Talis One COVID-19 test. In a press release, the Company revealed that “[i]n late February, the  
15 FDA informed the company that it cannot ensure the comparator assay used in the primary study  
16 has sufficient sensitivity to support Talis’s EUA application.” As a result, Talis “intends to initiate  
17 its previously planned clinical validation study in a point-of-care environment” to submit its EUA  
18 application “early in the second quarter of 2021.” This study “was designed with a different  
19 comparator study, which Talis believes will address the FDA’s concerns.”

20 50. On this news, the Company’s stock price fell \$1.80, or 12%, to close at \$12.85 per  
21 share on March 8, 2021.

22 51. Then, on August 10, 2021, Talis reported its second quarter 2021 financial results in  
23 a press release, which stated that the Company had “[c]ompleted a clinical validation study for Talis  
24 One COVID-19 assay in a point-of-care environment to support an Emergency Use Authorization  
25 (EUA) application submission to the FDA” and that it had “[s]ubmitted an EUA application for  
26 Talis One System and Talis One COVID-19 Assay to the FDA on July 23, 2021.” However, during  
27 the related conference call, Defendant Coe revealed that its “development timelines have been  
28 extended by delays in the launching of [Talis’s] COVID-19 test and manufacturing scale.”

1 Defendant Moody stated that “[i]t’s difficult to predict how much product revenue we will recognize  
2 this year, given the uncertainty around the timing of the EUA, our controlled launch, manufacturing  
3 scale-up and the variability of COVID testing market.” He went on to state that Talis “expect[s] to  
4 see [its] first meaningful revenue ramp in 2022.”

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

7 53. On August 30, 2021, after the market closed, Talis announced that its Chief  
8 Executive Officer, Brian Coe, had “stepped down” as President, CEO, and Director. On this news,  
9 the Company’s stock price fell \$1.00, or 11%, to close at \$8.06 per share on August 31, 2021, on  
10 unusually heavy trading volume.

11 54. On November 15, 2021, Talis announced that Brian Blaser was appointed as  
12 President, Chief Executive Officer, and Director of Talis effective December 1, 2021. However, a  
13 week after his appointment, on December 8, 2021, Talis announced that Brian Blaser had stepped  
14 down from his positions. On this news, the Company’s stock price fell \$0.55 per share, or more  
15 than 11%, to close at \$4.28 per share on December 8, 2021.

16 55. By the commencement of this action, Talis stock has traded as low as \$3.81 per share,  
17 a more than 76% decline from the \$16 per share IPO price.

18 **FIRST CLAIM**

19 **Violation of Section 11 of the Securities Act**  
20 **(Against All Defendants)**

21 56. Plaintiff repeats and re-alleges each and every allegation contained above as if fully  
22 set forth herein.

23 57. This Count is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. § 77k,  
24 on behalf of the Class, against the Defendants.

25 58. The Registration Statement for the IPO was inaccurate and misleading, contained  
26 untrue statements of material facts, omitted to state other facts necessary to make the statements  
27 made not misleading, and omitted to state material facts required to be stated therein.  
28

1 59. Talis is the registrant for the IPO. The Defendants named herein were responsible  
2 for the contents and dissemination of the Registration Statement.

3 60. As issuer of the shares, Talis is strictly liable to Plaintiff and the Class for the  
4 misstatements and omissions.

5 61. None of the Defendants named herein made a reasonable investigation or possessed  
6 reasonable grounds for the belief that the statements contained in the Registration Statement was  
7 true and without omissions of any material facts and were not misleading.

8 62. By reasons of the conduct herein alleged, each Defendant violated, and/or controlled  
9 a person who violated Section 11 of the Securities Act.

10 63. Plaintiff acquired Talis shares pursuant and/or traceable to the Registration Statement  
11 for the IPO.

12 64. Plaintiff and the Class have sustained damages. The value of Talis common stock  
13 has declined substantially subsequent to and due to the Defendants' violations.

14 **SECOND CLAIM**

15 **Violation of Section 15 of the Securities Act**  
16 **(Against the Individual Defendants)**

17 65. Plaintiff repeats and re-alleges each and every allegation contained above as if fully  
18 set forth herein.

19 66. This count is asserted against the Individual Defendants and is based upon Section  
20 15 of the Securities Act.

21 67. The Individual Defendants, by virtue of their offices, directorship, and specific acts  
22 were, at the time of the wrongs alleged herein and as set forth herein, controlling persons of Talis  
23 within the meaning of Section 15 of the Securities Act. The Individual Defendants had the power  
24 and influence and exercised the same to cause Talis to engage in the acts described herein.

25 68. The Individual Defendants' positions made them privy to and provided them with  
26 actual knowledge of the material facts concealed from Plaintiff and the Class.

27 69. By virtue of the conduct alleged herein, the Individual Defendants are liable for the  
28 aforesaid wrongful conduct and are liable to Plaintiff and the Class for damages suffered.

1 **PRAYER FOR RELIEF**

2 WHEREFORE, Plaintiff prays for relief and judgment, as follows:

3 (a) Determining that this action is a proper class action under Rule 23 of the Federal  
4 Rules of Civil Procedure;

5 (b) Awarding compensatory damages in favor of Plaintiff and the other Class members  
6 against all defendants, jointly and severally, for all damages sustained as a result of Defendants'  
7 wrongdoing, in an amount to be proven at trial, including interest thereon;

8 (c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this  
9 action, including counsel fees and expert fees; and

10 (d) Such other and further relief as the Court may deem just and proper.

11 **JURY TRIAL DEMANDED**

12 Plaintiff hereby demands a trial by jury.

13 DATED: January 7, 2022

**GLANCY PRONGAY & MURRAY LLP**

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**SWORN CERTIFICATION OF PLAINTIFF**

**TALIS BIOMEDICAL CORPORATION SECURITIES LITIGATION**

I, John Modrak, certify that:

1. I have reviewed the Complaint, adopt its allegations, and authorize the filing of a Lead Plaintiff motion on my behalf.
2. I did not purchase the Talis Biomedical Corporation securities that are the subject of this action at the direction of plaintiff's counsel or in order to participate in any private action arising under this title.
3. I am willing to serve as a representative party on behalf of a class and will testify at deposition and trial, if necessary.
4. My transactions in Talis Biomedical Corporation securities during the Class Period set forth in the Complaint are as follows:

(See attached transactions)

5. I have not sought to serve, nor served, as a representative party on behalf of a class under this title during the last three years, except for the following:
6. I will not accept any payment for serving as a representative party, except to receive my pro rata share of any recovery or as ordered or approved by the court, including the award to a representative plaintiff of reasonable costs and expenses (including lost wages) directly relating to the representation of the class.

I declare under penalty of perjury that the foregoing are true and correct statements.

12/22/2021

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Date



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John Modrak

**John Modrak's Transactions in Talis Biomedical Corporation (TLIS)**

<b>Date</b>	<b>Transaction Type</b>	<b>Quantity</b>	<b>Unit Price</b>
2/12/2021	Bought	350	\$26.6600