UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 8, 2021

Talis Biomedical Corporation
(Exact name of registrant as specified in its charter)

Delaware	001-40047	46-3122255
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

230 Constitution Drive
Menlo Park, California 94025
(Address of principal executive offices, including zip code)

(650) 433-3000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**TLIS**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On March 8, 2021, Talis Biomedical Corporation (the "Company") issued a press release titled "Talis Provides Update on Regulatory Pathway for Emergency Use Authorization (EUA) of its Talis One™ COVID-19 Test." A copy of the Company's press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated March 8, 2021

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 8, 2021

TALIS BIOMEDICAL CORPORATION

By: /s/ Brian Coe
Brian Coe
Chief Executive Officer

Exhibit 99.1

Talis Provides Update on Regulatory Pathway for Emergency Use Authorization (EUA) of its Talis One™ COVID-19 Test

MENLO PARK, Calif. – March 8, 2021 – Talis Biomedical Corporation (Nasdaq: TLIS), a company dedicated to developing innovative molecular diagnostic tests for infectious diseases at the point-of-care, today announced that it 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 the CLIA moderate setting, in favor of focusing on its planned EUA application in the CLIA waived setting. In late February, the FDA informed the company that it cannot ensure the comparator assay used in the primary study has sufficient sensitivity to support Talis's EUA application.

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

"The company's business priority remains focused on serving health care providers and their patients in the point-of-care setting, where we continue to see the greatest need for high quality testing," said Brian Coe, Chief Executive Officer of Talis. "Given the recent correspondence from the Agency and its stated prioritization of point-of-care platforms, we feel this course of action offers a faster path to market."

About Talis

Talis is dedicated to transforming diagnostic testing by developing and commercializing innovative products that are designed to enable accurate, low cost and rapid molecular testing for infectious diseases at the point-of-care, beginning with COVID-19. The company is developing Talis One, a compact, sample-to-answer, cloud-enabled, molecular diagnostic platform. Talis is headquartered in Menlo Park, California. For more information, please visit talis.bio.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "focus," "pursue," "will," "intends," "potential" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These statements include those related to Talis' regulatory strategy, including its intention to prioritize an EUA application for its Talis One COVID-19 test in CLIA waived settings and its ability to submit an EUA early in the second quarter of 2021; and Talis' ability to initiate a new clinical validation study and a limit-of-detection study for its Talis One COVID-19 test in CLIA waived settings, and the timing thereof. These forward-looking statements are based upon the Company's current expectations. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks that the Talis One COVID-19 test that the Company is developing will be granted an EUA by the FDA; risks that the FDA may require additional information or data in connection with the Company's EUA; risks and uncertainties associated with the costly and time-consuming development and regulatory approval process and the uncertainty of success; and those discussed in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our prospectus dated February 11, 2021, as filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act 1933, as amended, which is available on the SEC's website at www.sec.gov. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this press release.

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