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): November 10, 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 November 8, 2021, Talis Biomedical Corporation (the "Company") issued a press release announcing that on November 5, 2021, the United States Food and Drug Administration granted an Emergency Use Authorization for the Talis One COVID-19 Test System. 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 Number	Description
99.1	Press release dated November 8, 2021
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document).

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: November 10, 2021

TALIS BIOMEDICAL CORPORATION

By: /s/ J. Roger Moody, Jr.
J. Roger Moody, Jr.
Chief Financial Officer

Talis Biomedical Granted FDA Emergency Use Authorization (EUA) for COVID-19 Molecular Point-of-Care Test to Detect SARS-CoV-2

Authorized for use in a variety of healthcare and congregate settings, Talis One™ enables lab-quality results without the wait to detect or rule out COVID-19 in less than 30 minutes

Talis One's robust dual gene target design optimizes test sensitivity and inclusivity of variants including the highly transmissible Delta variant[1]

Company to provide additional details during its Q3 earnings conference call on November 15th

MENLO PARK, Calif., November 8, 2021 -- Talis Biomedical Corporation (NASDAQ: TLIS) today announced that the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for its Talis One™ COVID-19 Test System - a nucleic acid amplification test (NAAT). The Talis One COVID-19 test runs on an integrated system that includes a compact instrument, self-contained, single-use test cartridges and software for reporting results. Designed for use in a variety of healthcare and congregate settings, the Talis One system enables sample-to-answer molecular testing in less than 30 minutes.

"With the ongoing emergence of variants and prevalence of COVID-19 cases, the need for accurate and rapid high quality testing options remains critical, especially as our society returns to work, school and other congregate settings," said Kim Popovits, interim chief executive officer of Talis. "With the authorization of the Talis One COVID-19 Test System, we can now put testing in the hands of healthcare providers to help detect or rule out infection with confidence and prevent broader transmission while minimizing disruption to our daily lives."

In a clinical study, the Talis One COVID-19 Test System demonstrated 100% concordance with the comparator test results, including both the positive and negative percent agreements[2]. All samples were collected and tested in point-of-care settings.

The Talis One COVID-19 Test System targets two genes, ORF1ab and N, to optimize sensitivity and the inclusion of variants. The ORF1ab and N gene were selected for their conserved nature and their unique sequence specific for SARS-CoV-2. Designed for cloud connectivity, the instrument is being further developed to enable easy results sharing and simplified patient data management in the future.

Development of the Talis One COVID-19 Test System was supported by the NIH Rapid Acceleration of Diagnostics RADx[SM] initiative and has been funded in part with federal funds from National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N92020C00010.

As a participant in the RADx program, the company assessed the impact of ten distinct COVID-19 variants demonstrating high sensitivity of detection[3]. At the time of testing in June, the emerging Delta variant was not available to be included in the study. Subsequently, the company conducted a separate bioinformatic analysis for the Delta variant as well as testing *in vitro* transcript samples to support its EUA submission. In testing for all these variants, including Delta, no loss in sensitivity or impact on the Talis One COVID-19 Test System's performance was detected[4]. Talis is continuing to monitor new COVID variants as they arise.

1 https://talisbio.com/spring-2021/covid-19-assay-whitepaper Accessed August 2, 2021 and Talis data on file
2 https://talisbio.com/ifu/talis-one-covid-19-test
*"The combined data set of diluted specimens with neat clinical specimens (from IFU Table 3) demonstrated a PPA of 95.7% (95% CI: 85.5%-98.8%) and NPA of 100% (95% CI: 92.4%-100%)."
3 https://talisbio.com/ifu/talis-one-covid-19-test
4 https://talisbio.com/ifu/talis-one-covid-19-test

About the Talis One System
The Talis One system is a compact, sample-to-answer, molecular diagnostic solution that can be rapidly deployed into a variety of healthcare settings in the United States to diagnose infectious diseases at the point-of-care. The Talis One tests integrate robust sample preparation with highly-optimized and rapid isothermal nucleic acid amplification to achieve test performance faster than traditional polymerase chain reaction (PCR) tests. The Talis One test system is designed for use both in CLIA moderate and high complexity laboratory settings and non-laboratory CLIA-waived settings, such as physicians' offices, hospital emergency departments, urgent care clinics, ambulatory surgery centers, elder care/assisted living facilities, places of work and education or cancer treatment clinics and dialysis centers.

COVID-19 is the first infectious disease that the Talis One system is designed to detect. Future infectious disease indications may include tests for other respiratory infections, such as influenza, as well as sexually transmitted infections (STIs) and other infections impacting women's health. The Talis One system for the detection of SARS-CoV-2, authorized by the FDA for emergency use, provides intuitive and user-friendly software accessible through the embedded touchscreen for COVID-19 test result interpretation and reporting in less than 30 minutes. For more information on the Talis One COVID-19 Test System, visit talisbio.com.

About Talis Biomedical
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. The company is developing the Talis One, a compact, sample-to-answer, cloud-enabled, molecular diagnostic instrument. For more information, visit talisbio.com.

Forward-Looking Statements
This press release may contain forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Words such as "may," "might," "will," "should," "believe," "expect," "anticipate," "estimate," "continue," "predict," "forecast," "project," "plan," "intend" or similar expressions, or other words that convey uncertainty of future events or outcomes can be used to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our plans to scale our operational and commercial capabilities; enabling communication of patient results through cloud connectivity

; and our ability to grow and expand our business. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and other factors that could cause actual results and events to differ materially and adversely from those indicated by such forward-looking statements including, among others: the impact to our business of the ongoing COVID-19 pandemic, including any impact on our ability to market our products, demand for our products due to deferral of procedures using our products or disruption in our supply chain, our ability to achieve or sustain profitability, our ability to gain market acceptance for our products and to accurately forecast and meet customer demand, our ability to compete successfully, our ability to enhance our product offerings, development and manufacturing problems, capacity constraints or delays in production of our products, maintenance of coverage and adequate reimbursement for procedures using our products, product defects or failures. These and other risks and uncertainties are described more fully in the "Risk Factors" section and elsewhere in our filings with the Securities and Exchange Commission and available at www.sec.gov, including in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. Any forward-looking statements that we make in this announcement speak only as of the date of this press release, and Talis assumes no obligation to updates forward-looking statements whether as a result of new information, future events or otherwise after the date of this press release, except as required under applicable law.

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