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): July 27, 2023

Talis Biomedical Corporation

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40047**	**46-3122255**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1100 Island Drive Suite 101 Redwood City, California	**94065**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (650) 433-3000

(Former Name or Former Address, if Changed Since Last Report)

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:

☐ 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 7.01 Regulation FD Disclosure.

On July 27, 2023, the Company issued a press release announcing new data supporting the development of its planned chlamydia, gonorrhea and trichomonas and vaginal infection panels that the Company will present at the 2023 Annual Meeting of the Infectious Diseases Society for Obstetrics and Gynecology in Denver, Colorado. A copy of the press release is attached hereto as Exhibit 99.1.

The information contained under this Item 7.01, including Exhibit 99.1 attached, hereto are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall they be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Exhibit Title
99.1	Press release dated July 27, 2023.
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document).

SIGNATURES

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

TALIS BIOMEDICAL CORPORATION

Date: July 27, 2023

By: /s/ Rebecca L. Markovich

Rebecca L. Markovich
Interim Chief Financial Officer

New Data Presented at the Infectious Disease Society for Obstetrics and Gynecology (IDSOG) Annual Meeting Differentiate Talis Biomedical's Women's and Sexual Health Product Menu

Preliminary data suggest a chlamydia, gonorrhea and trichomonas (CT/NG/TV) multiplex test is feasible on a molecular point-of-care (POC) test system with time to result in less than 30 minutes

Ability to effectively lyse challenging fungal pathogens, including Candida, in under four minutes on Talis One® system positions Company to develop POC vaginal infection panel

REDWOOD CITY, Calif. – July 27, 2023 – Talis Biomedical Corporation (Nasdaq: TLIS) today announced new data supporting the development of its planned CT/NG/TV and vaginal infection panels. Results from these studies, presented in poster sessions at the 2023 IDSOG Annual Meeting in Denver, Colorado, support Talis Biomedical's mission to advance health equity and outcomes through the delivery of accurate infectious disease testing in the moment of need, at the point of care.

"The COVID-19 pandemic accelerated the development of numerous molecular point-of-care platforms to bring rapid respiratory testing closer to patients. Unfortunately, very few are designed to effectively address the needs of women's and sexual health," said Rob Kelley, chief executive officer at Talis Biomedical. "The ability to lyse difficult targets and to purify and concentrate nucleic acids to deliver lab quality results in less than 30 minutes is what we believe will set the Talis One system apart from current platforms. These data presented at IDSOG give us confidence we are on the path to developing viable and differentiated CT/NG/TV and vaginal infection tests that can be performed at the point of care, before a patient leaves the doctor's office."

Data Highlights from Talis Biomedical Presentations at IDSOG Annual Meeting July 27-29, 2023:

Feasibility and preliminary performance of development-stage CT/NG/TV test for Talis One® system

A series of analytical studies were conducted to characterize preliminary analytical sensitivity, exclusivity, inclusivity and clinical performance of a development-stage CT/NG/TV test as part of Talis Biomedical's planned test menu.

To determine preliminary analytical sensitivity of its sample-to-answer test in development to detect CT/NG/TV in less than 30 minutes, company scientists co-spiked 20 self-collected vaginal swabs and 7 male urine samples with live CT serovar D, NG 19424, and TV G3 for testing on the Talis One system. In females, CT and TV were detected in 19/20 contrived vaginal swab samples at concentrations of 1 IFU/mL and 5 cells/mL, respectively. NG was detected in 20/20 vaginal swabs at a concentration of 50 CFU/mL. In males, CT, NG, and TV were detected in 7/7 urine samples at concentrations of 1.5 IFU/mL, 50 CFU/mL, and 5 cells/mL, respectively.

To characterize exclusivity, closely related target organisms tested at 1E6 units/mL or 1E5 genome copies/mL were not detected by the Talis One development-stage CT, NG, or TV assays. Conversely, the assays were inclusive of all strains and serovars.

Preliminary clinical performance of the Talis One development-stage CT/NG/TV test was assessed using residual clinical samples initially tested by widely used, on-market molecular tests that require up to 90 minutes to generate a result. In neat male urine, positive percent agreement (PPA) was 100% for CT, NG and TV. Negative percent agreement (NPA) was 100% for CT and NG, and 98% for TV. In female vaginal swabs where only positive samples were tested, PPA was 100% for CT and NG, and 90% for TV.

“As we approach this new era of STI testing, it is encouraging to see a development-stage point-of-care CT/NG/TV assay achieve clinical performance that is comparable to widely used on-market tests being run at central laboratories,” said Glenn Harnett, M.D., chief executive officer at No Resistance, a clinical trial site management organization and former chief medical officer at American Family Care. “Access to STI test results during a single patient visit will allow providers to make more informed treatment decisions, reduce the use of unnecessary antibiotics, and provide an opportunity for more directed and meaningful patient education.”

On-cartridge bead beating differentiates Talis One lysis for future development of vaginal panel

Talis Biomedical conducted a series of analytical studies to test different mechanical lysis conditions on the Talis One system to determine the feasibility of nucleic acid recovery from difficult-to-lyse fungal pathogens.

Company scientists performed initial experiments to determine lysis efficiency with and without beads added to the Talis One’s on-cartridge mechanical (stir bar containing) lysis chamber. The lysis conditions were evaluated and selected using intact *Candida albicans* as a model pathogen. With stir bar mixing alone, target nucleic acids were only detected 100% of the time (3/3) at 1000 CFU/mL. When beads (bead-beating) were added to the stir bar containing lysis chamber on the Talis One cartridge, target nucleic acids were detected 100% of the time (6/6) at concentrations as low as 125 CFU/mL, delivering an 8-fold increase in lysis efficiency. The lysis time was as short as 4 minutes.

Additional experiments performed to further challenge the Talis One system included using contrived specimens of five different *Candida* species diluted in a DNA/RNA transport and storage medium at concentrations of 100,000, 10,000 and 1000 CFU/ml. The contrived specimens were lysed using the Talis One’s bead beating, mechanical lysis system. On bench detection was demonstrated down to the lowest concentration tested (1000 CFU/ml in 3/3 replicates) for all five *Candida* species.

These studies demonstrate that incorporating mechanical lysis on the Talis One system led to lysing fungal cells and releasing target nucleic acids for detection at a concentration level that is comparable to the limits of detection (LODs) of three on-market vulvovaginal candidiasis in vitro diagnostic (IVD) tests. Based on these positive early results, Talis Biomedical may be able to achieve these LODs while having a turnaround time that is approximately 30-90 minutes faster.

“The availability of accurate and reliable point-of-care testing for vaginitis will be invaluable in the women’s healthcare space. More than 30 percent of women of all ages suffer from symptoms of a vaginal infection and often receive deferred treatment with delays in diagnosis,” said Annelise Skor Swigert, M.D., FACOG, medical director, Premier Ob/Gyn of Minnesota. “I believe access to immediate and definitive testing results would clearly have an instant impact on care for these patients.”

Talis Biomedical plans to perform additional testing at lower concentrations to determine the effectiveness of lysing each fungal pathogen for amplification and detection. LODs will be confirmed once a fully developed vulvovaginal candidiasis assay is integrated on the Talis One test cartridge.

About the Talis One System

The Talis One system is a compact, sample-to-answer molecular testing platform designed to enable rapid, highly accurate point-of care infectious disease testing in non-laboratory settings. The Talis One test cartridge is a fully self-contained, closed device that includes all the necessary reagents to perform a Talis One test. When loaded into the Talis One instrument, each cartridge fully automates sample lysis, nucleic acid extraction and purification, isothermal amplification, and target detection. The Talis One test system is not authorized, cleared, or approved by the FDA and is not available for sale.

About Talis Biomedical

Talis Biomedical is dedicated to advancing health equity and outcomes through the delivery of accurate infectious disease testing in the moment of need, at the point of care. The Company plans to develop and commercialize innovative products on its sample-to-answer Talis One® system to enable accurate, low cost, and rapid molecular testing. 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,” “would,” “should,” “believe,” “expect,” “anticipate,” “could,” “estimate,” “continue,” “predict,” “potential,” “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, the potential clinical performance of assays on the Talis One system, or results of additional research and development studies. 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 performance of future Company products, the Company’s development pipeline, results of additional research and development studies and other risks and uncertainties that 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. These statements are based upon information available to us as of the date of this press release, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all

potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. Any forward-looking statements that we make in this announcement speak only as of the date of this press release, and Talis Biomedical assumes no obligation to update 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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