

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): May 11, 2023

Talis Biomedical Corporation

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40047
(Commission File Number)

46-3122255
(IRS Employer
Identification No.)

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

94065
(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 2.02 Results of Operations and Financial Condition.

On May 11, 2023, Talis Biomedical Corporation (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2023. A copy of the press release is attached hereto as Exhibit 99.1.

The information contained under this Item 2.02, 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 7.01 Regulation FD Disclosure.

On May 11, 2023, the Company posted an investor presentation to its website at <https://investors.talisbio.com>. A copy of the investor presentation is attached hereto as Exhibit 99.2.

The information contained under this Item 7.01, including Exhibit 99.2 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.

(d) Exhibits.

Exhibit	Description
99.1	Press release dated May 11, 2023.
99.2	Corporate Presentation dated May 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: May 11, 2023

By: /s/ Rebecca L. Markovich

Rebecca L. Markovich
Interim Chief Financial Officer

Talis Biomedical Announces Business Update and First Quarter 2023 Financial Results*Conference call and webcast today at 4:30pm Eastern/1:30pm Pacific*

REDWOOD CITY, Calif. – May 11, 2023 – Talis Biomedical Corporation (Nasdaq: TLIS), a diagnostic company 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, today announced a business update and reported financial results for the first quarter ended March 31, 2023.

Business Update

- Established ability to manufacture cartridges and instruments that puts us on a path to meaningful margins at scale, at the pace and quality needed to execute the company's business strategy
- Prioritized development of four Talis One[®] test panels to address significant unmet needs in the women's and sexual health markets, consisting of:
 1. Influenza A, influenza B and COVID-19 respiratory panel
 2. Chlamydia, gonorrhea and trichomonas vaginalis (CT/NG/TV) panel
 3. Herpes simplex virus (HSV1-2) panel
 4. Vaginal infection panel
- Received feedback from the FDA on pre-submissions to support 510(k) clearance of respiratory and CT/NG/TV test panels
- Delivered 62% improvement in net cash used in operating activities year-over-year, extending our cash runway into 2025

"With significant advances in our manufacturing capabilities, a clearly defined product menu and disciplined regulatory strategy to minimize risk, Talis Biomedical is executing on our plan to deliver multiple women's and sexual health test panels at the point of care," said Rob Kelley, chief executive officer of Talis Biomedical. "We are well capitalized and have an experienced team in place to unlock this large and untapped \$3 billion market with our differentiated Talis One system."

First Quarter 2023 Financial Results

Revenue was \$1.2 million for the first quarter of 2023, compared to \$3.2 million for the same period in 2022. This includes \$1.1 million of NIH grant revenue and \$0.1 million of product revenue from antigen testing sales.

Operating expenses were \$20.2 million in the first quarter of 2023, compared to \$36.2 million for the same period in 2022. The decrease was primarily driven by lower antigen test and raw card inventory expenses and the realization of benefits from the cost reduction measures implemented during 2022. The Company also incurred \$3.1 million of non-recurring expenses to obtain a license to patents and cartridge raw materials in connection with the termination of a supply agreement with one of its contract manufacturers.

Net loss was \$17.8 million for the first quarter of 2023, compared to \$33.1 million for the same period in 2022.

Cash and Liquidity

Unrestricted cash and cash equivalents as of March 31, 2023, were \$113.0 million.

Net cash used in operating activities for the first quarter of 2023 was \$16.5 million, as compared to \$43.8 million in the first quarter of 2022. This decrease was primarily driven by lower headcount costs from the Company's spending reduction program as well as declines in payments for antigen test and raw card inventory.

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: our plans to advance our pipeline, including the plans to develop Talis One assays in the women's and sexual health markets; the size and potential of our opportunity in the women's and sexual health markets; our ability to capitalize on any competitive advantages; our ability to position the Company to provide durable value to our shareholders; the benefits of our regulatory strategy; our future revenue growth and profit margins; and our ability to lower our cash burn, extend operations and extend our cash runway. 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: risks and uncertainties associated with development and regulatory approval, the impact to our business from global economic conditions, including inflationary pressures, the ongoing COVID-19 pandemic and any related impact on our ability to develop our pipeline products, our ability to achieve or sustain profitability, our ability to launch and gain market acceptance for our pipeline products and to accurately forecast and meet customer demand, our ability to compete successfully, our ability to enhance our product offerings, development and manufacturing, capacity constraints or delays in production of 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. 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 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.

Contact

Media & Investors

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Talis Biomedical Corporation
Condensed Balance Sheets
(in thousands)

	March 31 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 112,959	\$ 130,191
Restricted cash	1,010	—
Accounts receivable, net	127	308
Prepaid expenses and other current assets	1,492	2,783
Total current assets	115,588	133,282
Property and equipment, net	3,634	3,312
Operating lease right-of-use-assets	12,289	30,920
Other long-term assets	1,542	1,776
Total assets	\$ 133,053	\$ 169,290
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,871	\$ 3,768
Accrued compensation	2,733	4,212
Accrued liabilities	1,614	989
Operating lease liabilities, current portion	2,962	3,703
Total current liabilities	11,180	12,672
Operating lease liabilities, long-term portion	11,749	29,879
Total liabilities	\$ 22,929	\$ 42,551
Stockholders' equity:		
Series 1 convertible preferred stock	3	3
Common stock	3	3
Additional paid-in capital	605,903	604,687
Accumulated deficit	(495,785)	(477,954)
Total stockholders' equity	110,124	126,739
Total liabilities and stockholders' equity	\$ 133,053	\$ 169,290

Talis Biomedical Corporation
Condensed Statements of Operations and Comprehensive Loss (Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2023	2022
Revenue		
Grant revenue	\$ 1,081	\$ 874
Product revenue, net	137	2,313
Total revenue, net	1,218	3,187
Operating expenses:		
Cost of products sold	20	3,521
Research and development	13,796	20,703
Selling, general and administrative	6,399	11,930
Total operating expenses	20,215	36,154
Loss from operations	(18,997)	(32,967)
Other income (expense), net	1,166	(84)
Net loss and comprehensive loss	\$ (17,831)	\$ (33,051)



Decentralizing Women's and Sexual Health Testing

Talis Biomedical Corporate Presentation

May 2023



Disclaimer

This presentation may contain forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would,” or the negative of these words or other similar terms or expressions. Talis Biomedical (“Talis Bio,” “we,” “our”) has based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and results of operations. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our plans to advance our pipeline, including our plans to develop Talis One assays in the women’s and sexual health markets; the size and potential of our opportunity in the women’s and sexual health markets; our ability to capitalize on any competitive advantages; the potential to realize the benefit of our restructuring plan in the fourth quarter of 2022; our ability to position Talis Bio to provide durable value to our shareholders; our future revenue growth and profit margins; and our ability to lower our cash burn, extend operations and our cash runway. 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: risks and uncertainties associated with development and regulatory approval, the impact to our business from global economic conditions, including the ongoing COVID-19 pandemic, and inflationary pressures and any related impact on our ability to develop our pipeline products, our ability to achieve or sustain profitability, our ability to launch and gain market acceptance for our pipeline products and to accurately forecast and meet customer demand, our ability to compete successfully and our ability to enhance our product offerings, development and manufacturing, capacity constraints or delays in production of 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 presentation speak only as of the date of this presentation, and Talis Bio assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise after the date of this presentation, except as required under applicable law.

This presentation also contains estimates and information concerning our industry and business, including estimated market size and projected growth rates of the markets in which Talis Bio participates. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Talis Bio has not independently verified the statistical and other industry data generated by independent parties and contained in this presentation and, accordingly, we cannot guarantee their accuracy or completeness. In addition, projections, assumptions and estimates of our future performance and the future performance of the industries in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by Talis Bio.

Differentiated to Lead in Significant Untapped Market

Advancing health equity and outcomes by delivering accurate infectious disease testing in the moment of need, at the point of care



TALIS ONE® SYSTEM

Established innovative, high-performing diagnostic platform at the point of care



PROMISING PIPELINE OPPORTUNITY

Refocused product roadmap in growing women's and sexual health markets



OPERATIONAL OPTIMIZATION

Demonstrated scalable manufacturing capabilities with path to attractive margins



WELL-POSITIONED FOR COMMERCIALIZATION

Built strong commercial infrastructure



Women's/Sexual Health Providers Eager to Test at Point-of-Care (POC)



INHERENT CLINICAL ADVANTAGE

Accurate, immediate treatment reduces empirical prescribing, office visits and patients lost to follow-up



ECONOMIC BENEFIT

Shifts reimbursement to those providing care



COVID ACCELERATED POC PLATFORM ADOPTION

Created demand and channel for broader infectious disease testing at the point of care



Large and Growing Market Opportunity

Tailwinds will accelerate and sustain transition from lab-based testing to POC

40M

CT, NG + TV
tests performed
annually¹

24M

UTI, Vaginitis,
GBS + HSV
tests performed
annually²

\$3B

U.S. market
opportunity with
2022 W&SH testing
converted to POC²

- Incidence of STIs increasing and a growing public-health priority
- Patients are becoming engaged consumers, expecting convenience and immediacy
- Physicians want test results while patients are there
- Practices seeking new, profitable revenue streams
- Untapped opportunity with only 56% of sexually active females aged 16-24 screened for chlamydial infections³

The Talis One System is Designed to Win in POC Market



SENSITIVITY & SPECIFICITY

Embedded Sample Prep,
Nucleic Acid Extraction



RAPID TURNAROUND

Results in <30 Minutes



DESIGNED FOR UNTRAINED USERS

CLIA Waiver for POC Market



RELEVANT MENU

Women's & Sexual Health
Menu + Respiratory



LOW COST

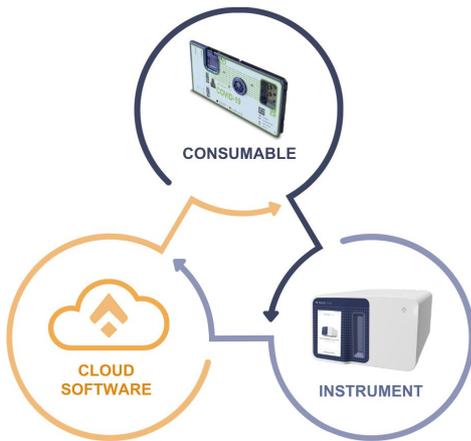
Automated Manufacturing
Drives Down Cost

Talis One System

Technology Overview



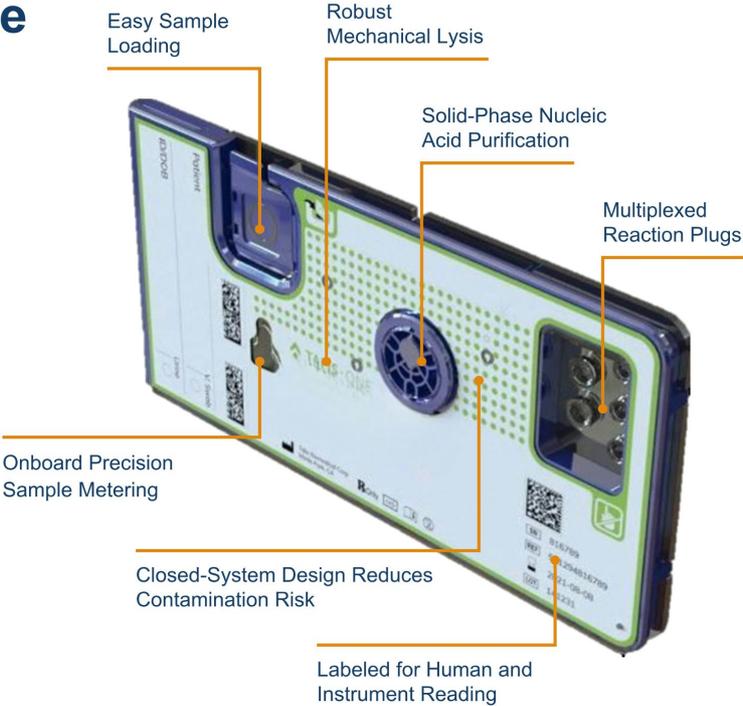
Differentiated to Lead in Women's/Sexual Health Market



- ✓ POC sample-to-result in <30 minutes
- ✓ Demonstrated ease of use for untrained users¹
- ✓ Integrated DNA/RNA extraction, purification, detection and results management
- ✓ Proven to lyse difficult pathogens in <4 minutes²
- ✓ Multiple system interface capabilities or standalone function

Integrated Test Cartridge Enables Sample Prep, Menu Expansion

Self-Contained, Single Use Consumable



Instrument Designed for Ease-of-Use

- ✓ Designed for Untrained User
- ✓ Touchscreen Interface
- ✓ Cloud Connectivity
- ✓ Flexible Multiplexing



3 Simple Steps to Rapid, Accurate Results



1 Label with patient ID:
Barcode or handwritten



2 Add specimen
to cartridge



3 Insert cartridge
into instrument



Results

Established Ability to Manufacture at Scale

Investment in automation provides advantages of quality, throughput and cost

- ✓ >\$100M investment in automated manufacturing to deliver 1M tests/month at full scale
- ✓ High speed assembly lines consistently produce cartridges
- ✓ Ability to build instruments efficiently
- ✓ Talis One System performing well in hands of study users



Three Tiers of Cartridge Manufacturing Lines Provide Flexibility and Stability as Business Scales

1. Manual



2. Semi Automated



3. Fully Automated



Business Use	<ul style="list-style-type: none"> • Research & Development 	<ul style="list-style-type: none"> • Clinical Studies/Early Commercialization 	<ul style="list-style-type: none"> • Full-Scale Commercialization
Capacity	<ul style="list-style-type: none"> • 300 cartridges/day 	<ul style="list-style-type: none"> • 2,000 cartridges/day¹ 	<ul style="list-style-type: none"> • 40,000 cartridges/day²
Benefit	<ul style="list-style-type: none"> • Flexibility to customize production for different assays in small batches 	<ul style="list-style-type: none"> • Additional volume with some customization and lower card to card variability 	<ul style="list-style-type: none"> • Volume to support commercial scale and attractive margins
Location	<ul style="list-style-type: none"> • Redwood Shores, CA (Talis) 	<ul style="list-style-type: none"> • Chicago, IL (Talis) 	<ul style="list-style-type: none"> • Phoenix, AZ (Contract Manufacturer)



¹ Assumes one 8-hour shift; ² Assumes operating all three lines simultaneously

Delivering Clinical and Economic Value to Physicians



Minimal capital costs and lower practice overhead with better informed diagnosis and treatment



Pricing below established CPT codes



Redirects reimbursement from central lab to providers



Not All POC Tests are Created Equal

Important Questions to Ask

- Does it include sample preparation to ensure lab-quality results?
- Can it generate a result in less than 30 minutes while the patient is in the office?
- Can an untrained user operate?
- Can it deliver multiplex panels with difficult to lyse organisms to meet customer needs?
- Can it be produced at scale for low cost?



SENSITIVITY & SPECIFICITY

Embedded Sample Preparation,
Nucleic Acid Purification



RAPID TURNAROUND

Results in <30 Minutes



EASE OF USE

CLIA Waiver for POC Market



RELEVANT MENU

High-Value Women's and
Sexual Health Tests



LOW COST

Automated Manufacturing
Drives Down Cost

Talis One Uniquely Positioned to Meet Key Customer Needs

Prioritizing Assay Development to Accelerate Market Entry

1



Market Entrant

Respiratory Panel

Influenza A, Influenza B and SARS-CoV-2

- ✓ Symptomatic patients
- ✓ Nasopharyngeal swab
- ✓ Ob/Gyn demand confirmed
- ✓ 510(k) pre submission complete

2



Volume Driver

CT/NG/TV

Chlamydia trachomatis, neisseria gonorrhoeae and trichomonas vaginalis

- ✓ Asymptomatic and Symptomatic patients
- ✓ Vaginal swab (physician and self collection)
- ✓ Female and male urine
- ✓ 510(k) pre submission complete

3



Platform Differentiator

HSV-1/2

Herpes Simplex Virus oral and genital

- ✓ Symptomatic patients
- ✓ Vaginal swab
- ✓ Assay design underway

4



Platform Differentiator

Vaginal Panel

Bacterial vaginosis, vulvovaginal candidiasis and trichomonas vaginalis

- ✓ Symptomatic patients
- ✓ Vaginal swab
- ✓ Feasibility studies underway
- ✓ Multi color detection and ability to lyse yeast on cartridge demonstrated

Roadmap for Menu Expansion



Talis Biomedical Wins Over Time



Large unmet need with shifting diagnostic testing from centralized labs to the point of care



Nascent and growing \$3B U.S. market opportunity addressing women's and sexual health testing



Talis One System designed to deliver accuracy, speed, and ease of use



High-value efficient product roadmap and clear path to attractive margins



Capitalized to execute strategy into 2025 with cash ending 1Q23 of \$113M



Thank you.