

**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): October 26, 2022

TELA Bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-37526
(Commission
File Number)

45-5320061
(I.R.S. Employer
Identification No.)

**1 Great Valley Parkway, Suite 24
Malvern, Pennsylvania**
(Address of principal executive offices)

19355
(Zip Code)

Registrant's telephone number, including area code: (484) 320-2930

Not Applicable
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.001 per share	TELA	Nasdaq Global Market

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 October 26, 2022, TELA Bio, Inc. (the “Company”) issued a press release announcing the publication of the Company’s 24-month analysis from the BRAVO study in the *Annals of Medicine and Surgery*. A copy of this press release is filed as Exhibit 99.1 hereto and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being furnished herewith:

Exhibit No.	Document
99.1	Press Release of TELA Bio, Inc., dated October 26, 2022.
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.

TELA BIO, INC.

By: /s/ Antony Koblisch

Name: *Antony Koblisch*

Title: *President, Chief Executive Officer and Director*

Date: October 26, 2022

TELA Bio Announces Publication of 24-Month BRAVO Study Results Demonstrating Benefits of OviTex® Reinforced Tissue Matrix in Hernia Repair

Study results show a low 2.6% recurrence rate and clinically meaningful improvement in patient quality of life

MALVERN, PA, October 26, 2022 – TELA Bio, Inc. (NASDAQ: TELA), a commercial-stage medical technology company focused on providing innovative technologies that optimize clinical outcomes by prioritizing the preservation and restoration of the patient’s own anatomy, today announced the publication of the 24-month analysis from the BRAVO Study in *Annals of Medicine and Surgery*.

TELA Bio's prospective, single-arm, multi-center clinical trial was designed to evaluate the clinical performance of OviTex 1S with permanent polymer embroidery for primary or recurrent ventral hernias in 92 enrolled patients. This study included real-world clinical scenarios as OviTex 1S was utilized in open and minimally invasive procedures, various planes of placement, and various CDC wound classes. OviTex 1S Permanent demonstrated a 2.6% recurrence rate in ventral hernias repaired using open, laparoscopic, or robotic techniques at the 24-month time point. In addition, patient quality of life assessments showed statistically significant and clinically meaningful improvement from baseline as early as 3-months post-surgery and continued at the 12 and 24-month timepoints. Surgical site occurrences (SSOs) were observed in 38% of the study population, where 78% of all enrolled patients were characterized as high risk for experiencing an SSO based on at least one known risk factor. These risk factors included obesity, active smoking, COPD, diabetes mellitus, coronary artery disease, or advanced age (≥ 75 years).

“I want to thank the entire investigator team for their diligence in completing this important study,” said principal investigator, Dr. George DeNoto III, MD, FACS, Director of General Surgery at St. Francis Hospital in New York. “Hernia implant design is continually evolving and it’s critical that the surgeon community is committed to generating research on the clinical safety and efficacy of newer implants. Our results provide evidence that OviTex 1S Permanent in ventral hernia repair results in a low rate of recurrence and improved quality of life for patients over a two-year period.”

Over 400,000 ventral hernia repairs are performed in the U.S. annually, most of which require the use of a reinforcement device. Permanent synthetic mesh is often used for ventral hernia repair, however the significant, long-term foreign body footprint may lead to chronic inflammation, infection, and persistent pain. OviTex Reinforced Tissue Matrix was designed to offer surgeons and patients an alternative to permanent synthetic mesh that minimizes the use of permanent synthetic materials to provide a more natural repair.

“We are very proud to share the full, final results of our BRAVO study,” stated Antony Koblish, President and CEO of TELA Bio. “Since the founding of TELA Bio we have been committed to validating the performance of OviTex from the bench-top to the OR. This commitment continues with our ongoing BRAVO II study which will evaluate the use of OviTex in robot-assisted ventral and inguinal hernia repairs.”

About TELA Bio, Inc.

TELA Bio, Inc. (NASDAQ: TELA) is a commercial-stage medical technology company focused on providing innovative technologies that optimize clinical outcomes by prioritizing the preservation and restoration of the patient's own anatomy. The Company is committed to providing surgeons with advanced, economically effective soft-tissue reconstruction solutions that leverage the patient's natural healing response while minimizing long-term exposure to permanent synthetic materials. For more information, visit www.telabio.com.

About OviTex®

OviTex Reinforced Tissue Matrix is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include the repair of hernias and/or abdominal wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome. Do not use OviTex in patients known to be sensitive to materials of ovine (sheep) origin. For prescription use only. For additional important safety information, please see the OviTex Reinforced Tissue Matrix Instructions for Use.

The statements made or results achieved by TELA Bio customers described herein were achieved in their specific setting. Due to variations in clinical experience and technique, there is no guarantee that these results are typical. A surgeon must use his or her own clinical judgment when deciding which products are appropriate for treatment of a particular patient. Always refer to the package insert, product label, and/or instructions for use before using any TELA Bio product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets.

Caution Regarding Forward-Looking Statements

This press release contains 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 statements regarding intent, belief, or current expectations are forward-looking statements and reflect the current beliefs of TELA's management. 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, that data from earlier studies related to our products and interim data from ongoing studies may not be replicated in later studies or indicative of future data, that data from clinical studies using our product may not be indicative of outcomes in other surgical settings, and 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 TELA 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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