

**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 9, 2021

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 November 9, 2021, TELA Bio, Inc. (the “*Company*”) issued a press release announcing the publication of the Company’s 12-month analysis from the BRAVO study in the *Journal of Clinical Medicine*. 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 exhibit is being filed herewith:

Exhibit No.	Document
99.1	Press Release of TELA Bio, Inc., dated November 9, 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, 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: November 9, 2021



TELA Bio Announces Publication of 12-Month Results from the BRAVO Study with Continued Positive Outcomes Through 24 months

- 12-month follow-up data in 75 patients treated with OviTex[®] Reinforced Tissue Matrix (RTM) for ventral hernia repair demonstrates an overall hernia recurrence rate of 2.7%.
- Final 24-month analysis shows hernia recurrence rate remains below 5%.

MALVERN, PA November 9th, 2021 – TELA Bio, Inc. (NASDAQ: TELA), a commercial-stage medical technology company focused on designing, developing, and marketing innovative tissue reinforcement materials to address unmet needs in soft tissue reconstruction, today announced the publication of the 12-month analysis from the BRAVO Study in the *Journal of Clinical Medicine*.

TELA Bio’s prospective, single arm, multicenter, post market BRAVO study was designed to evaluate the clinical performance of OviTex 1S with permanent polymer for primary or recurrent ventral hernias. A total of 75 patients were evaluated at 12 months, with only two (2.7%) patients demonstrating hernia recurrence adjacent to the original repair, leaving the primary hernia repair and OviTex intact. The 12-month analysis also showed low surgical site occurrence and surgical site infection rates. Twenty-four-month follow-up has been completed with overall hernia recurrence rates remaining below 5%. Final analysis is underway and the 24-month BRAVO study results will be presented in a future peer-reviewed publication.

“On behalf of the entire investigator team, we are pleased to see the 12-month clinical data of the BRAVO study in publication. These 12-month results are quite encouraging and appear to be staying steady in our 24-month assessments. These results are all the more promising as our hernia recurrence rates are low and 79% of our BRAVO patient population at 12 months presented with one or more comorbidities known to increase risk of complications in hernia repair,” said principal investigator, Dr. George DeNoto III, MD, FACS, Director of General Surgery at St. Francis Hospital in New York. “With more and more patients expressing reservations about traditional hernia mesh to their doctors, it’s critical that newer hernia reinforcement materials such as OviTex are rigorously evaluated in the clinical setting.”

In addition to primary surgical outcomes, patient quality of life was also assessed as part of the BRAVO study. The authors reported that all patient-reported assessments showed significant improvement in quality of life at 12 months post-surgery.

“This initial publication of the BRAVO study represents an important checkpoint for TELA Bio’s corporate mission. Since inception, our overarching goal has been to address the very well documented shortcomings of legacy synthetic and biologic hernia mesh. During the design process of OviTex, we incorporated input from over 100 general and plastic surgeons and prior to commercialization conducted what we believe to be the most extensive pre-clinical research of its kind to validate performance,” stated Antony Koblisch, President and CEO of TELA Bio. “We believe this published research demonstrates that we’re succeeding in our mission and further supports what we’ve been seeing over the past five years and in nearly 20,000 commercial implantations of our products of which more than 18,000 were for hernia applications.”

About TELA Bio, Inc.

TELA Bio Inc. (NASDAQ: TELA) is a commercial-stage medical technology company focused on designing, developing, and marketing innovative tissue reinforcement materials to address unmet needs in soft tissue reconstruction. The company is committed to providing patients with advanced, economically effective biologic material repair solutions to minimize long-term exposure to permanent synthetic materials and improve clinical outcomes. TELA Bio's OviTex[®] and OviTex PRS Reinforced Tissue Matrix products are purposefully designed to address the shortcomings of existing reinforcement materials in hernia repair, abdominal wall reconstruction and plastic and reconstructive surgery. 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. Such forward-looking statements include statements relating to the results of our 24-month BRAVO study. 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 and the development of new variants of COVID-19, such as the delta variant, including but not limited to any impact on our ability to market our products, demand for our products due to deferral of procedures using our products, the labor and staffing environment in the healthcare industry, 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, 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, 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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