

**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): March 23, 2023

TELA Bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-39130
(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 March 23, 2023, TELA Bio, Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration has granted 510(k) clearance for the Company's OviTex PRS Long-Term Resorbable product. 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
<u>99.1</u>	<u>Press Release of TELA Bio, Inc., dated March 23, 2023.</u>
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: March 23, 2023



TELA Bio Announces 510(k) Clearance for OviTex® PRS Long-Term Resorbable for Plastic and Reconstructive Surgery

Company continues design advancements of biologic-based materials for soft tissue repair and reinforcement

MALVERN, PA March 23, 2023 – 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 that the U.S. Food and Drug Administration has granted 510(k) clearance for the Company’s OviTex PRS Long-Term Resorbable product. OviTex PRS Long-Term Resorbable is intended for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery.

OviTex PRS Long-Term Resorbable complements the Company’s existing OviTex PRS portfolio, which includes OviTex PRS Permanent and OviTex PRS Short-Term Resorbable configurations. The OviTex PRS portfolio consists of products with two or three layers of high-quality tissue derived from ovine rumen, which is reinforced with either permanent or resorbable polymer for added strength, stabilization, and controlled stretch. These products are designed to improve outcomes by facilitating functional tissue remodeling while controlling the degree and direction of stretch. OviTex PRS Long-Term Resorbable enhances the OviTex PRS portfolio with specific design features including bi-directional stretch and a fully resorbable, long-term polymer for reinforcement.

“The Ovitex PRS portfolio is integral to our mission to deliver next-generation soft-tissue repair solutions that offer clinical effectiveness and economic benefits,” said Antony Koblisch, President and CEO of TELA Bio. “This new offering expands the clinical utility of the OviTex PRS portfolio and demonstrates our ability to leverage the tunable design of OviTex PRS to meet the varying needs of surgeons and patients in plastic and reconstructive surgery.”

To learn more, please visit www.ovitexprs.com.

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 PRS

OviTex PRS Reinforced Tissue Matrix is intended for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The device is supplied sterile and is intended for one-time use.

Do not use OviTex PRS in patients with a known sensitivity to materials of ovine (sheep) origin. For prescription use only. For additional important safety information, please see the OviTex PRS Instructions for Use.

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 the impact to our business from macroeconomic conditions, including the ongoing response to the COVID-19 pandemic, recessionary concerns, banking instability, and inflationary pressures, potentially impacting our ability to market our products, demand for our products due to the deferral of elective procedures, the labor and staffing environment in the healthcare industry, disruption in our supply chain, or pricing pressures concerning our products or the procedures using our products; 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; 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 obtained from clinical studies using our product may not be indicative of outcomes in other surgical settings; 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 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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