# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, DC 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 24, 2021**

# TELA Bio, Inc.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **3841** | **45-5320061** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Primary Standard Industrial Classification Code Number)** | **(I.R.S. Employer Identification No.)** |

| **1 Great Valley Parkway, Suite 24, Malvern, Pennsylvania** | **19355** |
|---|---|
| **(Address of principal executive offices)** | **(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 (see General Instruction A.2. below):

☐ 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** | **Name of Exchange on Which Registered** |
|---|---|---|
| **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 24, 2021, TELA Bio, Inc. (the "Company") updated information reflected in a corporate slide deck, which representatives of the Company will use in various meetings with investors from time to time. A copy of the presentation is attached hereto as Exhibit 99.1, 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 | Corporate Slide Deck, dated March 24, 2021. |

**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 Koblish
*Name:* *Antony Koblish*
*Title:* *President, Chief Executive Officer and Director*

Date: March 29, 2021


TELA BIO INC
SURGICAL RECONSTRUCTION COMPANY
ADVANCING SOFT TISSUE RECONSTRUCTION
Investor Presentation
March 2021

# Forward Looking Statements

This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this document, including but not limited to statements regarding possible or assumed future results of operations, business strategies, development plans, regulatory activities, market opportunity competitive position, potential growth opportunities, and the effects of competition, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause TELA Bio, Inc.'s (the "Company") actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this presentation are only predictions. The Company has based these forward-looking statements largely on its current expectations and projections about future events and financial trends that it believes may affect the Company's business, financial condition and results of operations. These forward-looking statements speak only as of the date of this presentation and are subject to a number of risks, uncertainties and assumptions, some of which cannot be predicted or quantified and some of which are beyond the Company's control, including, among others: changes resulting from the finalization of the Company's financial statements for the year ended December 31, 2020, information or new changes in facts or circumstances that may occur prior to the filing of the Company's Annual Report on Form 10-K for the year ended December 31, 2020 that are required to be included in such annual report, the impact to the Company's business of the ongoing COVID-19 pandemic, including but not limited to any impact on the Company's ability to market its products, demand for the Company's products due to deferral of procedures using the Company's products or disruption in the Company's supply chain, the Company's ability to achieve or sustain profitability, the Company's ability to gain market acceptance for the Company's products and to accurately forecast and meet customer demand, the Company's ability to compete successfully, the Company's ability to enhance the Company's product offerings, development and manufacturing problems, capacity constraints or delays in production of the Company's products, maintenance of coverage and adequate reimbursement for procedures using the Company's products, product defects or failures. These and other risks and uncertainties are described more fully in the "Risk Factors" section and elsewhere in the Company's filings with the Securities and Exchange Commission and available at www.sec.gov. You should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in the Company's forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, the Company operates in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that the Company may face. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

TELA BIO™ INC
SURGICAL RECONSTRUCTION COMPANY

*Redefining soft tissue reconstruction with a differentiated category of tissue reinforcement materials*

- ~$2B U.S Market Opportunity[1]
  *in hernia repair, abdominal wall reconstruction and plastic and reconstructive surgery*
- Innovative Products
- Compelling Clinical Evidence
- Products Offer Attractive Value Proposition for Hospitals

[1] Management estimate. $2B total equals $1.5B hernia & abdominal wall reconstruction and $0.5B plastic reconstructive surgery.

# Creating Advanced Biologic Materials

**Purposefully designed to address shortcomings & unmet clinical needs**

Novel Biologic Tissue
*(derived from sheep)*

\+

Polymer Fibers
*(permanent or resorbable)*

**Innovative Textile Engineering**

Hernia & Ab Wall Reconstruction

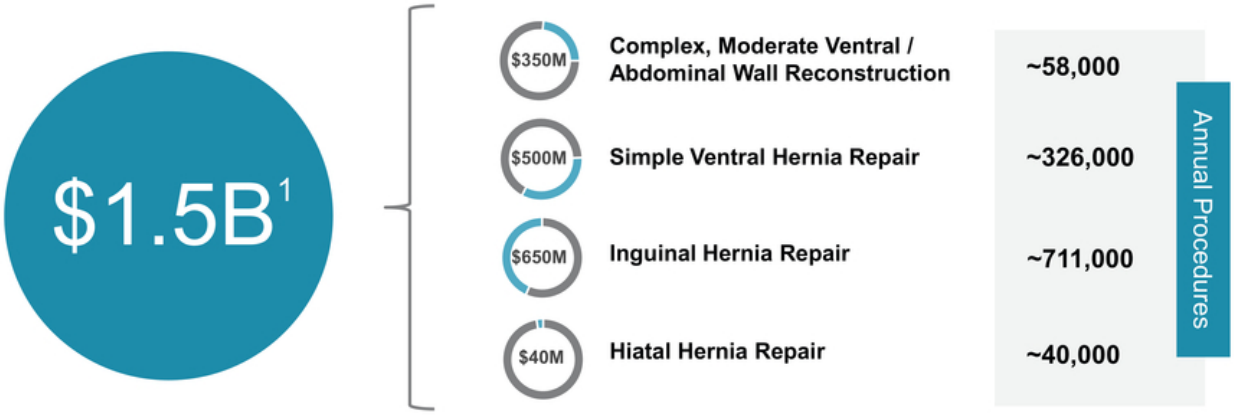
Plastic Reconstruction

**Issued patents protect underlying biologic tissue and product design**



TELA BIO

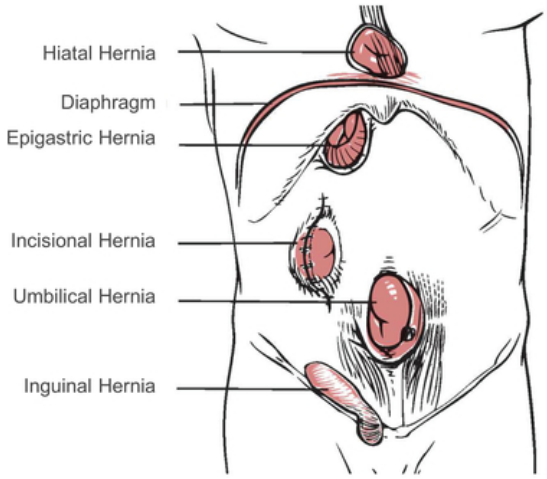
# OviTex: ~$1.5 Billion Annual U.S. Hernia Market Opportunity






Source: Millennium Research Group Reports, IMS Health Data
[1]Management estimate. Market size based volume weighted average selling price for OviTex

# Hernias Occur Throughout the Abdomen




## What is a hernia?

- Occurs when an internal part of the body pushes through a weakness (that is natural occurring or from a previous surgical incision) or hole in the muscle or surrounding tissue
- Likelihood of developing a hernia increases with age & obesity

## Treating a hernia

- Standard of care: Surgical repair of a hernia with a reinforcing material (mesh)
- ~90% of hernia patients receive a mesh repair[1]
- Mesh intended to reinforce the defect and provide long-term support



[1] Funk LM, Perry KA, Narula VK, Mikami DJ, Melvin WS. Current national practice patterns for inpatient management of ventral abdominal wall hernia in the United States. *Surg Endosc*. 2013;27(11):4104-4112.

TELA BIO

# Ventral Hernia Patients Range in Complexity

## Ventral Hernia Complexity

| SIMPLE | MODERATE | COMPLEX |
| --- | --- | --- |
| • CDC Wound Class I (clean)<br>• Healthier patients - no co-morbidities<br>• Primary hernia repair | • CDC Wound Class II (clean-contaminated)<br>• Patient co-morbidities (i.e., obesity, diabetes, COPD)<br>• May have prior hernia repair failure | • CDC Wound Class III (contaminated) & IV (infected)<br>• Large defects<br>• Infected synthetic mesh removals<br>• Multiple prior hernia repair failures |

**Objective: provide patients the best repair the first time to prevent the simple patient from becoming the complex**



TELA BIO

# Current Ventral Hernia Treatment Options: No Perfect Product

***Natural Repair Products***

| PERMANENT SYNTHETIC MESH | RESORBABLE SYNTHETIC MESH | BIOLOGIC MESH |
|---|---|---|
| BARD Parietex™<br>Medtronic ProGrip™ + Ventralight™<br>Johnson & Johnson PROCEED® | BARD PHASIX™ Mesh<br>GORE® BIO-A® | LifeCell Strattice™<br>INTEGRA SurgiMend®<br>ACell Gentrix®<br>BARD XenMatrix™ |
| **LIMITATIONS** | | |
| ▫ Persistent inflammatory response<br>▫ Encapsulation of implant<br>▫ Chronic post operative pain<br>▫ Scar tissue / lack of remodeling<br>▫ Mesh infections / Significant costs of re-operation<br>▫ Organ erosion or perforation | ▫ Inflammatory response until absorbed<br>▫ Encapsulation of implant or contraction until absorbed<br>▫ Scar tissue / lack of remodeling<br>▫ Mesh infection until resorbed<br>▫ Organ erosion or perforation<br>▫ Lack of mid-term and long-term reinforcement | ▫ Lack of strength or durability<br>▫ Prone to laxity and stretching<br>▫ Challenges to surgeon handling<br>▫ Difficult to use in laparoscopic or robotic surgery<br>▫ High costs |
| **Simple Ventral Hernia**<br>**Inguinal Hernia** | **Complex, Moderate Ventral Repair / Abdominal Wall Reconstruction**<br>**Hiatal Hernia Repair** | |



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# Growing Need for Alternative to Permanent Synthetic Mesh

**59%** of surgeons agree that use of permanent synthetic mesh puts patients at long-term risk of complications[1]

**1 in 5** Hernia patients have voiced concern over use of permanent synthetic mesh in the past 12 months, according to surgeons[1]

**~15K** Lawsuits against permanent synthetic meshes estimated to be assembled across the U.S.[2]




[1] Hernia and Abdominal Surgeries Survey (Oct 2020).
[2] www.drugwatch.com (October 2020)

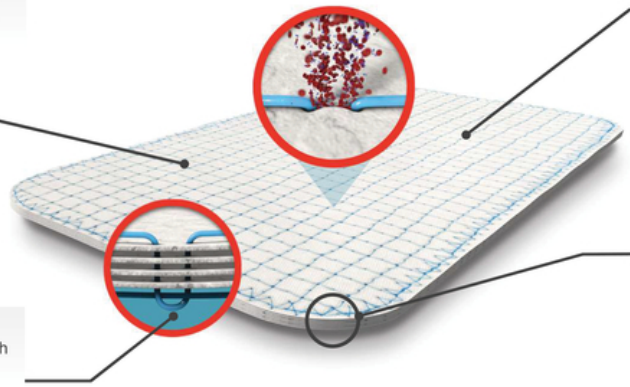
TELA BIO

# OviTex Reinforced Tissue Matrix: a More Natural Hernia Repair™

**An innovative reinforced tissue matrix designed to reduce stretch compared to biologic matrices and long-term complications experienced with resorbable and permanent synthetic meshes**

**Unique permeable design** facilitates rapid fluid transfer and movement of cells through the device

**Lockstitch embroidery pattern** creates a ripstop effect and prevents unraveling when cut



**Layers of biologic material** enable functional tissue remodeling

**Interwoven polymer** for added strength and improved handling



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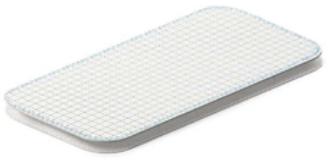
# Comprehensive Portfolio for a Broad Range of Hernia Types and Surgical Techniques

**Each configuration is available with either permanent (polypropylene) polymer or resorbable (polyglycolic acid) polymer reinforcing the same biologic material.**

PRODUCT DESIGN

**OviTex**
4-layer device, not intended for intraperitoneal placement

**Strength*:** +
**Common Procedures:** Moderate ventral hernia (pre-peritoneal placement), inguinal hernia, hiatal hernia



**OviTex 1S**
6-layer device, with "smooth side" suitable for intraperitoneal placement

**Strength*:** ++
**Common Procedures:** Moderate to complex ventral hernia

**OviTex 2S**
8-layer device, with 2 "smooth sides" suitable for intraperitoneal placement

**Strength*:** +++
**Common Procedures:** Complex ventral hernia and abdominal wall reconstruction and can be used for bridging

Images represent permanent polymer OviTex products. Resorbable polymer products have clear polymer.
* Biomechanical data on file.



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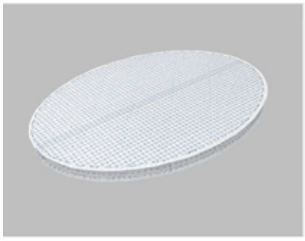
# OviTex LPR for Laparoscopic & Robotic Hernia Repair

## Increase in Robotic-Assisted Hernia Repair

- Surgeons have adopted robotic-assisted techniques, primarily for inguinal & simple ventral Hernia repair, due to perceived patient and technique benefits
- Legacy biologic products are difficult to use minimally invasively (MIS) due to their thickness and handling properties



**Our Solution: OviTex LPR**

Tailored OviTex product designed for improved handling in MIS techniques and trocar accessibility



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# Compelling Clinical Evidence

## 18 Presentations / Publications — Ventral Hernia

- Low hernia recurrence
- Low rate of surgical site occurrences & infections (SSO/SSI)
- Ease of use

## 5 Presentations / Publications — Inguinal Hernia

- Low hernia recurrence
- Low incidence of chronic post-operative pain
- Low SSO / SSI
- Ease of use

## 4 Presentations / Publications — Hiatal Hernia

- Low hernia recurrence
- Compatibility with MIS approaches

## BRAVO Study

- Multi-center, prospective study with 92 patients enrolled
- Moderate-to-complex ventral hernia patients
- Patient follow-up at 3, 12 & 24-months
- Additional data readout expected by YE 2020 and upon study completion in mid-2021

OviTex supported by data from **~500 hernia patients** across multiple hernia types



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# BRAVO Study Shows Low Recurrence Rate at 12 and 24-months

**OviTex BRAVO Study**

| Product Name | Tissue Reinforcement Material | Hernia Recurrence Rate | Number of Hernia Recurrence | Number of Patients who Completed Follow-up | Follow-up Period in Months |
|---|---|---|---|---|---|
| OviTex | Reinforced Tissue Matrix | 2.6% | 2 | 76 | 12 |
| OviTex | Reinforced Tissue Matrix | 0% | 0 | 51 | 24 |

**Results from Post-Market Clinical Studies of Competitive Materials**

| Product Name | Tissue Reinforcement Material | Published Hernia Recurrence Rate | Number of Hernia Recurrence, (%) * | Number of Patients who Completed Follow-up | Follow-up Period in Months |
|---|---|---|---|---|---|
| Phasix | Resorbable Synthetic Mesh | 4.1% | 5 (5.3%) | 95 | 12[1] |
| Phasix | Resorbable Synthetic Mesh | 9% | 11 (11.6%) | 95 | 18[2] |
| Phasix | Resorbable Synthetic Mesh | 17.9% | 19 (23.2%) | 82 | 36[3] |
| Strattice | Biologic Matrix | 19% | 15 (21.7%) | 69 | 12[4] |
| Strattice | Biologic Matrix | 28% | 22 (32.8%) | 67 | 24[4] |

1 Roth, J. S., Prospective Evaluation Of Poly-4-Hydroxybutyrate Mesh in Cdc Class I/High-Risk Ventral and Incisional Hernia Repair: 1 Year Follow-Up. Poster presented at: AHS 18th Annual Hernia Repair Meeting; 2017 March 8 – 11; Cancun, Mexico
2 Roth, J. S., Anthone, G. J., Selzer, D. J., Poulose, B. K., Bittner, J. G., Hope, W. W., . . . Voeller, G. R. (2018). Prospective evaluation of poly-4-hydroxybutyrate mesh in CDC class I/high-risk ventral and incisional hernia repair: 18-month follow-up. *Surg Endosc, 32*(4), 1929-1936. doi:10.1007/s00464-017-5886-1
3 Roth, J. S., Anthone, G. J., Selzer, D. J., Poulose, B. K., Pierce, R. A., Bittner, J. G., . . . Voeller, G. R. (2021). Prospective, multicenter study of P4HB (Phasix) mesh for hernia repair in cohort at risk for complications: 3-Year follow-up. *Ann Med Surg (Lond), 61*, 1-7. doi:10.1016/j.amsu.2020.12.002
4 Itani, K. M., Rosen, M., Vargo, D., Awad, S. S., Denoto, G., 3rd, Butler, C. E., & Group, R. S. (2012). Prospective study of single-stage repair of contaminated hernias using a biologic porcine tissue matrix: the RICH Study. *Surgery, 152*(3), 498-505. doi:10.1016/j.surg.2012.04.008
* Hernia Recurrence Rate based on number of hernia recurrences reported in patients who completed follow up and patients who reported recurrent hernia before the specified follow up period. Clinical literature and conference presentations included hernia recurrence rates based on number of hernia recurrences in patients who comprised the initial intent-to-treat population (including those who did not complete the follow up period and did not report a hernia recurrence).

# OviTex PRS: ~$500 Million Annual U.S. Plastic & Reconstructive Surgery Market Opportunity


**Surgeons use products to reinforce soft tissue during various reconstructive surgeries, including:**

- Breast reconstruction
- Head and neck surgery
- Chest wall reconstruction
- Pelvic reconstruction
- Extremities reconstruction

**Market dominated by human acellular dermal matrices (HADMs)**

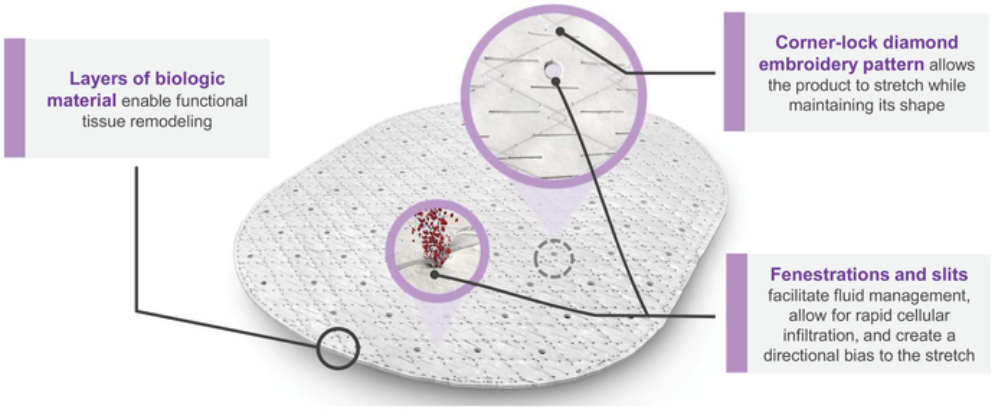
- Prone to high degree of stretch
- Expensive, putting pressure on hospital systems
- Often experience supply shortages, particularly when large pieces of material are required



[1] Management estimate. Market size based on sales of current biologics

# OviTex PRS: Purposely Designed for Plastic and Reconstructive Surgery

**An innovative reinforced tissue matrix designed to improve outcomes by facilitating fluid management and controlling degree and direction of stretch**




**Expanded commercial launch in June 2020 following limited launch initiated in 2019**

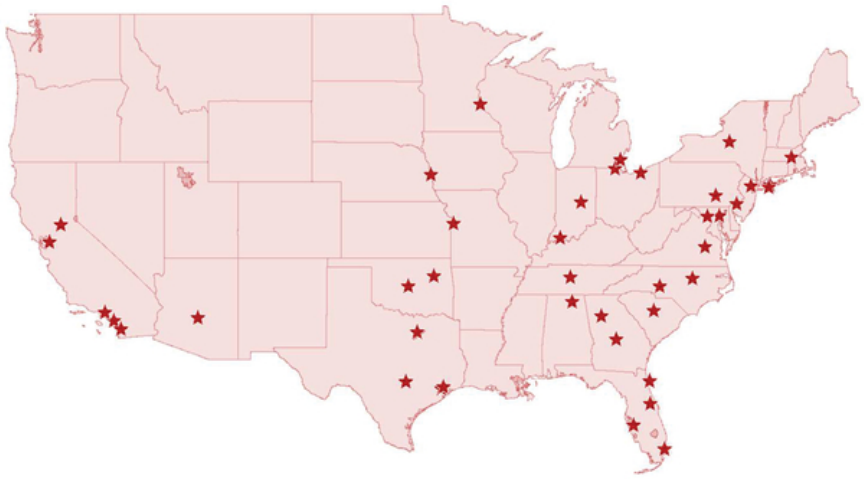
# Commercial Organization

## 45 sales territories as of December 31, 2020

- OR-based Account Managers call on General, Plastic Recon, Colorectal & Trauma surgeons
- Carry full OviTex & OviTex PRS portfolios

## 6 sales regions

- Plan to scale existing regions until each region has ~8 territories
- Supported by Clinical Development and Strategic Customer Relations teams



# Growth Strategy

## INCREASE ADOPTION

- Promote broader awareness of OviTex & OviTex PRS products
- Employ virtual sales & marketing programs, including TELA LIVE
- Drive market awareness of risks of permanent synthetic mesh use
- Publish BRAVO clinical data

## COMMERCIAL EXECUTION

- Scale direct sales force
- Drive account manager productivity
- Increase utilization within health systems under GPO contracts
- Secure additional contracts with high-potential IDNs and GPOs

## MARKET EXPANSION

- Launch new product features and designs for OviTex and OviTex PRS
- Initiate robotic hernia post-market study
- Support investigator-led clinical studies for OviTex PRS

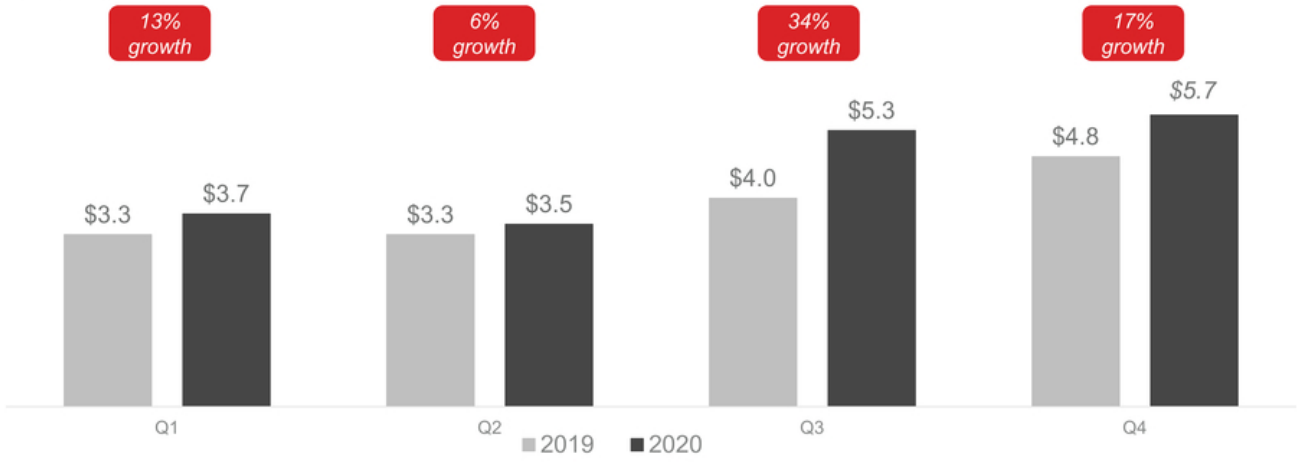


TELA BIO

# Delivering Revenue Growth

**Quarterly Results**

($ millions)




**Cash and cash equivalents at December 31, 2020 were $74.4 million**

# Investment Highlights

- Advanced reinforced tissue matrix portfolio supported by compelling clinical evidence
- Focused on ~$2.0 billion annual U.S. total addressable markets
- Driving commercial adoption with targeted direct-sales approach
- Recent product launches in growing markets: robotic hernia surgery + plastic and reconstructive surgery
- Broad intellectual property portfolio
- Established DRG-based reimbursement pathway for hernia repair
- Industry leading executive team with proven track record