

# ADVANCING SOFT TISSUE RECONSTRUCTION

August 2020 Nasdaq: TELA





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## **TELA Bio Snapshot**

A commercial stage medical technology company marketing a new category of tissue reinforcement materials to address unmet needs in soft tissue reconstruction

- Differentiated portfolio of advanced reinforced tissue matrices addressing hernia repair, abdominal wall reconstruction and plastic and reconstructive surgery
- Headquartered: Malvern, Pennsylvania

~\$2B U.S Market Opportunity<sup>1</sup>

**Innovative Products** 

Improve Clinical Outcomes

Reduce Overall Costs of Care



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

Complex, Moderate
Ventral / Abdominal Wall
Reconstruction

Simple Ventral Hernia Repair

Inguinal Hernia Repair

Hiatal Hernia Repair

~\$350 million US market<sup>(1)</sup>

~58,000 total procedures per year

~\$500 million US market(1)

~326,000 total procedures per year

~\$650 million US market(1)

~711,000 total procedures per year

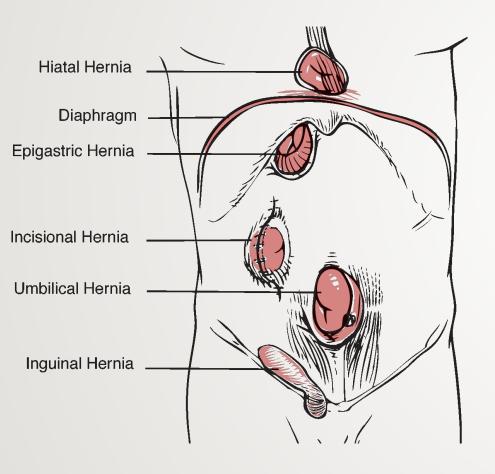
~\$40 million US market(1)

~40,000 total procedures per year

OviTex
~\$1.5 Billion TAM
Opportunity



## Hernias Occur Throughout the Abdomen



#### What is a hernia?

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

#### Treating a hernia

- Surgical repair of a hernia with a reinforcing material (mesh) is standard of care
- ~90% of hernia patients receive a mesh repair<sup>1</sup>
- Mesh intended to reinforce the defect and provide long-term support



## Ventral Hernia: Complex Patient Population

## **Ventral Hernia Complexity**

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

Objective is to give patient the best repair the first time to prevent the simple patient from becoming the complex



## Current Ventral Hernia Treatment Options: No Perfect Product



Simple Ventral Hernia
Inguinal Hernia

Complex, Moderate Ventral Repair / Abdominal Wall Reconstruction
Hiatal Hernia Repair



## Limitations of Reconstruction Materials Used in Hernia Repair

#### PERMANENT SYNTHETIC MESH

- Persistent inflammatory response
- Encapsulation of implant
- Chronic post operative pain
- Scar tissue / lack of remodeling
- Mesh infections
- Significant costs of re-operation
- Organ erosion or perforation
- 6.000 related U.S. lawsuits
- Danish Hernia Database: ~17% reintervention at five years¹

#### RESORBABLE SYNTHETIC MESH

- Inflammatory response until absorbed
- Encapsulation of implant or until absorbed
- Scar tissue / lack of remodeling
- Mesh infection until resorbed
- Organ erosion or perforation
- Lack of mid-term and long-term reinforcement
- Recurrence rate of 12% at 18months follow-up<sup>2</sup>

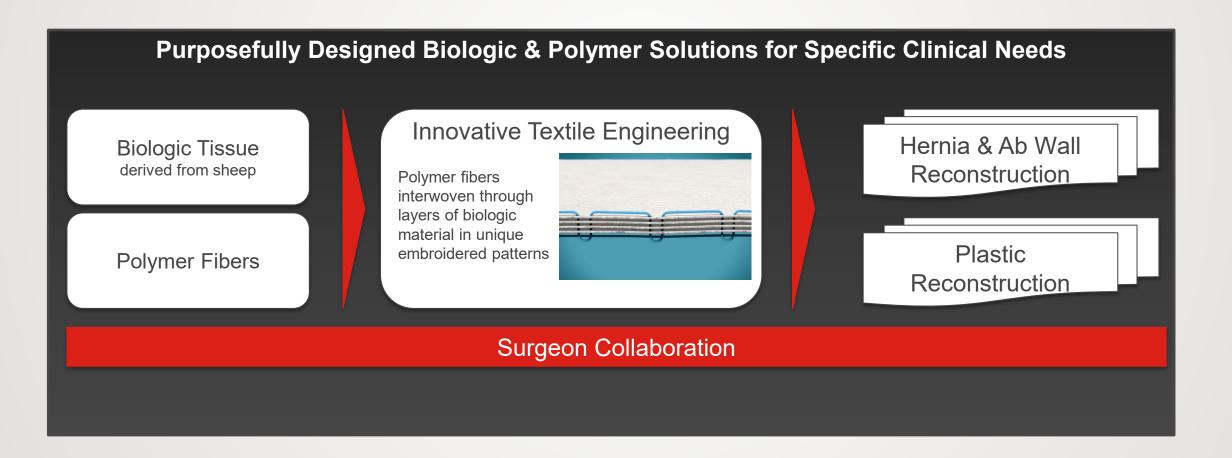
#### **BIOLOGIC MATRICES**

- Lack of strength or durability
- Prone to laxity and stretching
- Difficulty in surgeon handling
- Difficult using in robotic surgery / LAP
- High costs
- RICH study: recurrence rates of 22% and 33% at 12-months and 24-months follow-up, respectively<sup>3</sup>



<sup>2.</sup> Roth, JS et. al, (2017) "Prospective evaluation of poly-4-hydroybutyrate mesh in CDC class I/high-risk ventral and incisional hernia repair: 18-month follow-up." Surgical Endoscopy.

## Our Solution: New Category of Tissue Reinforcement Materials





## High Quality Biologic Material Drives Technology Platform

### TELA maintains a definitive license agreement with Aroa BioSurgery for the use of ovine rumen



- Aroa has two issued patents protecting the use of ovine rumen for use as a source of extracellular matrix
- Exclusive license in North America and Europe for hernia repair, abdominal wall and breast reconstruction
- Ovine rumen is high quality biologic source material, sourced from New Zealand and subject to strict quality controls
  - Plentiful supply ~27 million sheep in New Zealand
  - Low cost of goods
  - Homogenous, intact, minimally processed material lends itself to be a good building block for fabrication into medical devices
- Aroa recently completed its IPO and is listed on the ASX (ticker: ARX.AX)

#### **TELA**

- Product development, commercial strategy & execution and clinical data generation
- Revenue sharing agreement based on net sales;
   TELA retains 73% of net sales

#### **Aroa BioSurgery**

- Manufacturing and supply of product
- Aroa receives 27% of net sales



## Our Solution: A New Category of Soft Tissue Reinforcement Materials

Improve Performance Over Existing Reconstruction Materials

**Improved Biologic Response** 

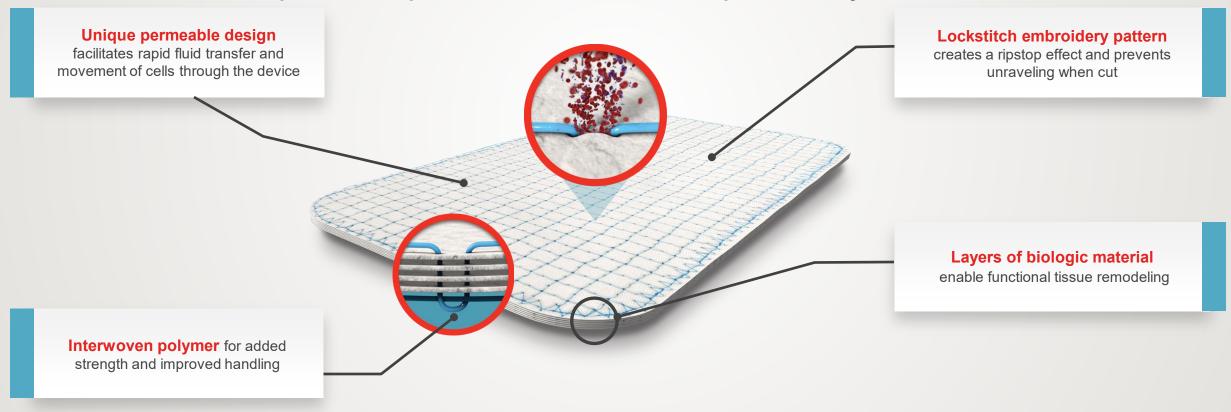
**Lower Upfront Costs** 

- Designed in close collaboration with more than 100 surgeons
- Products designed with over 95% biologic material (<5% polymer/synthetic content)</li>
- Benefits of both biologic materials and polymer materials
- Supports range of surgical techniques
- Reduced foreign body inflammatory response
- Improved outcomes of soft tissue reconstructions
- Enhanced remodeling of soft tissue and rate of healing
- Customers realize ~20% to 40% cost-savings over leading biologic materials and resorbable synthetic mesh
- Provides benefits of advanced biologic repair to more patients



# OviTex: a New Approach to Soft Tissue Reconstruction for Hernia Repair and Abdominal Wall Reconstruction

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

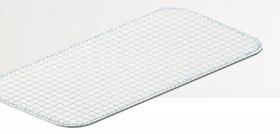




# CONFIGURATION

# Comprehensive Portfolio for a Range of Hernia Types & Surgical Techniques

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



#### **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

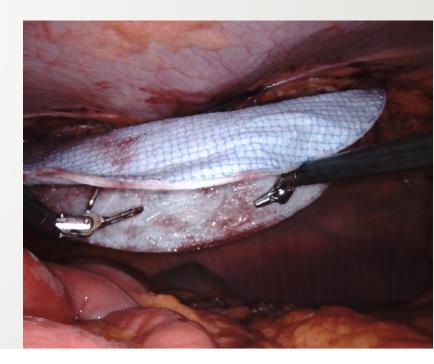
can be used for bridging



## OviTex LPR for Laparoscopic & Robotic-Assisted Repair

- OviTex LPR is specifically tailored for robotic-assisted hernia surgical repairs
  - Significant increase in robotic hernia repairs in last few years
  - Robotic-assisted hernia repair provides the benefits of laparoscopic repair
  - Designed for improved surgical handling, access, and primary closure of hernia
  - Designed for use with a trocar
- 4 total SKUs available, following commercial introduction of 3 additional SKUs in December 2019
- Products expected to be used most frequently in simplemoderate ventral hernia patients







## Disruptive Technology Supported by a Compelling Body of Clinical Evidence



#### 92 Adult Patient, Prospective, Single Arm, Multicenter BRAVO Study

- 0 (0%) hernia recurrence in first 20 patients at 24-months
- 1 (2%) hernia recurrence in first 57 patients at 12-months

#### 14 clinical publications

- Strong clinical efficacy and low complication rates in range of hernias
- Recent poster presentations at MISS conference highlighting use of OviTex products in robotic repair

#### More than 200 Non-Human Primates

 OviTex demonstrates more rapid tissue integration and revascularization compared to biologic matrices and lower inflammatory response and better functional tissue remodeling compared to permanent and resorbable synthetic mesh

#### Continue to build clinical evidence

Plan to initiate a post-market study of OviTex in robotic-assisted hernia repair surgery





## Multiple Future Analyses of BRAVO Data Planned for 2020

BRAVO Study is fully enrolled (n=91) and characterizes OviTex performance in moderate-to-complex ventral hernia patients

Q1 2020	Q2 2020	Q3 2020	Q4 2020
20-patients at 24-months			<ul> <li>~75 patients at 12-months</li> </ul>
• 57-patients at 12-months			<ul> <li>~50-patients at 24-months</li> </ul>
84-patients at 3-months			

- Primary focus is hernia recurrence rate at each time point
  - Additional information on surgical site occurrence rate will also be analyzed
- Study design allows for robotic, laparoscopic and open implantation of OviTex 1S, allowing for sub-analyses by surgical technique
- Data will be submitted to medical journals and for presentation at key medical conferences throughout the year



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

OviTex BRAVO Product Name	Study 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%	1	57	12
OviTex	Reinforced Tissue Matrix	0%	0	20	24

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

Product Name	Tissue Reinforcement Material	Hernia Recurrence Rate <sup>1</sup>	Number of Hernia Recurrence <sup>1</sup>	who Completed Follow-up <sup>1</sup>	Period in Months
Phasix	Resorbable Synthetic Mesh	5%	5	95	12
Phasix	Resorbable Synthetic Mesh	12%	11	95	18
Phasix	Resorbable Synthetic Mesh	23%	19	82	36
Strattice	Biologic Matrix	22%	15	69	12
Strattice	Biologic Matrix		33% 22	67	24



Number of Patients

Follow-up

# We believe Plastic and Reconstructive Surgery Represents a Significant Market Opportunity

- Use of biologic matrices validated by growing clinical literature
- Biologics provide the following clinical benefits:
  - Ability to define shape and position
  - Soft tissue reinforcement
  - Improvement of tissue quality
  - Aids in defining the pocket and allows for more immediate tissue expansion
  - Reduced inflammatory response
- Existing biologics are costly, prone to excessive stretch over time, and difficult for surgeons to handle

~\$500 Million Annual
U.S. Market Opportunity

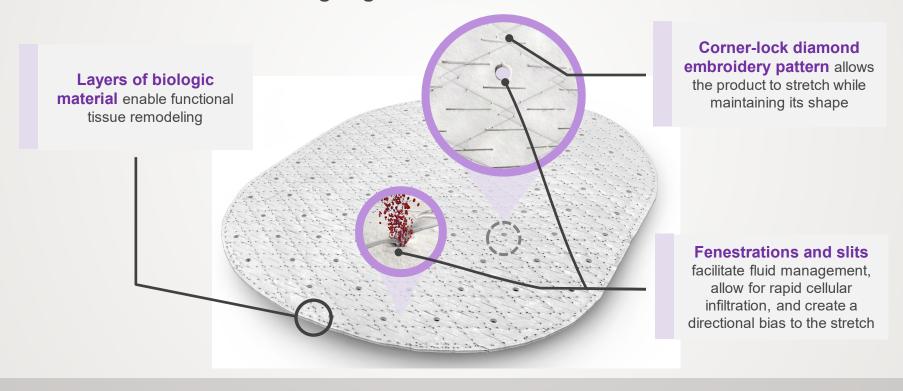
#### Uses

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



# 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

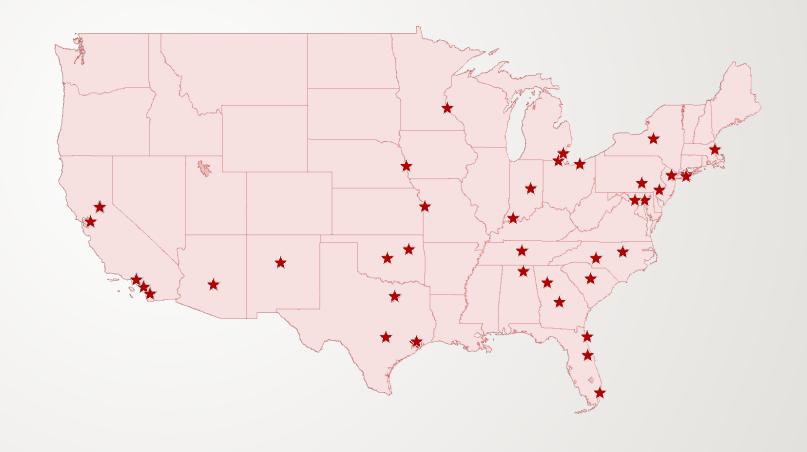


Expanded commercial launch in June 2020 following limited launch initiated in 2019



## **Commercial Organization**

- 41 sales territories at June 30, 2020
  - OR-based Account Managers call on General, Plastic Recon, Colorectal & Trauma surgeons
  - Carry full OviTex & OviTex PRS portfolio
- 6 sales regions
  - Plan to scale existing regions until each region has ~8 territories
- Territories supported by Clinical
   Development and Strategic Customer
   Relations teams





## Focused on Driving Utilization within Accessed Accounts



Contracts in place with multiple national and regional Group Purchasing Organizations (GPOs)



Current GPO contracts provide access to ~1,900 hospitals across the U.S., estimated to perform over ~135,000 addressable soft tissue reconstruction procedures per year<sup>1</sup>



Data-driven, targeted implementation strategy



Account Manager hiring for new territories focused on areas with high concentrations of accessed accounts



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## **Growth Strategy**

#### Current

- U.S. sales force expansion
- Surgeon education
- Target high-decile hernia and plastic and recon. surgeons

#### **Near-Term**

- Drive adoption within health systems under GPO contracts
- Publish BRAVO clinical and health economics data
- Pursue additional contracts with large GPOs and IDNs

## **Long-Term**

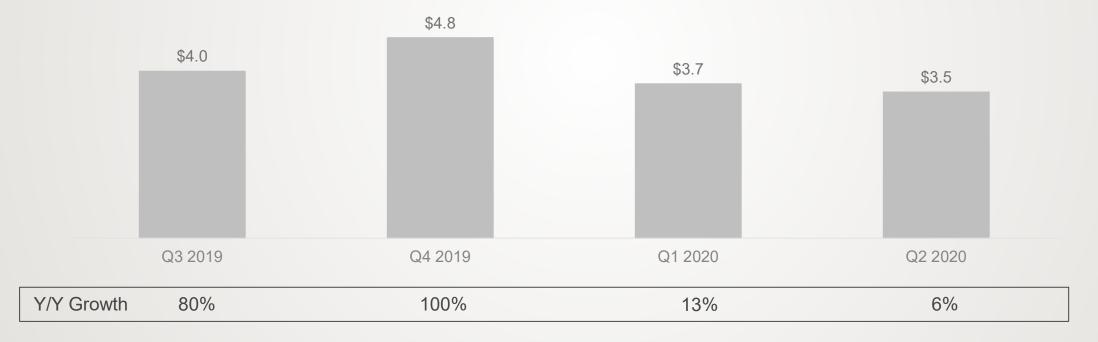
- New product features and designs for OviTex and OviTex PRS
- OviTex LPR clinical study data
- Support investigator-led clinical studies for OviTex PRS



## Revenue Growth

## **Quarterly Results**

(\$ millions)



Q1 2020 quarterly revenue impacted by COVID-19 pandemic beginning mid-March 2020 and continued throughout Q2 2020



## Statement of Operations

	Three months Ended	Three months Ended June 30	
	2020	2019	
Revenue	\$3.5	\$3.3	
Cost of revenue	1.3	1.3	
Amortization of Intangible Assets	0.1	0.1	
Gross profit	\$2.1	\$1.9	
Gross margin	59%	58%	
Operating expenses:			
Selling and Marketing	4.1	3.9	
General and Administrative	2.2	1.2	
Research and Development	1.0	1.1	
Total operating expenses	7.3	6.2	
Loss from operations	(\$5.2)	(\$4.3)	
Other (expense) income, net	(0.9)	(1.0)	
Net loss	(\$6.1)	(\$5.3)	

- Revenue increased 6% over prior year period
- Total cash and cash equivalents at June 30, 2020 were \$85.5 million

Q2 2020 revenue impacted by COVID-19 pandemic



## **Investment Highlights**



Advanced reinforced tissue matrix portfolio supported by compelling clinical evidence



Focused on ~\$2.0 billion annual U.S. total addressable markets



Well-defined high-decile surgeon customers targeted by growing direct sales force



Long-term supply agreement that provides pricing flexibility—cost savings to healthcare systems



**Established DRG-based reimbursement pathway for hernia repair** 



Recent product launches in growing categories: robotic hernia surgery + plastic and reconstructive surgery



**Broad intellectual property portfolio** 



Industry leading executive team with proven track record

