

**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): May 22, 2020

**TELA Bio, Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

3841  
(Primary Standard Industrial  
Classification Code 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)

Securities registered pursuant to Section 12(b) of the Act:

| <u>Title of Each Class</u>                | <u>Trading Symbol</u> | <u>Name of Exchange on Which Registered</u> |
|---|-----------------------|---|
| Common Stock, par value \$0.001 per share | TELA                  | Nasdaq Global Market                        |

Securities registered pursuant to Section 12(g) of the Act:

None

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))

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 7.01 Regulation FD Disclosure.**

On May 22, 2020, 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.

The information furnished pursuant to Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

The following exhibits are being filed herewith:

| Exhibit<br>No.       | Document  |
|----------------------|---|
| <a href="#">99.1</a> | <a href="#">Corporate Slide Deck, dated May 22, 2020.</a> |

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**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: May 22, 2020

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# TELA Bio:

## Advancing Soft Tissue Reconstruction

May 2020



## 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: the impact to the Company's business of the ongoing COVID-19 pandemic, including 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](http://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 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



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

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

Complex, Moderate  
Ventral / Abdominal Wall  
Reconstruction

~\$350 million US market<sup>(1)</sup>  
~58,000 total procedures per year

Simple Ventral Hernia  
Repair

~\$500 million US market<sup>(1)</sup>  
~326,000 total procedures per year

Inguinal Hernia Repair

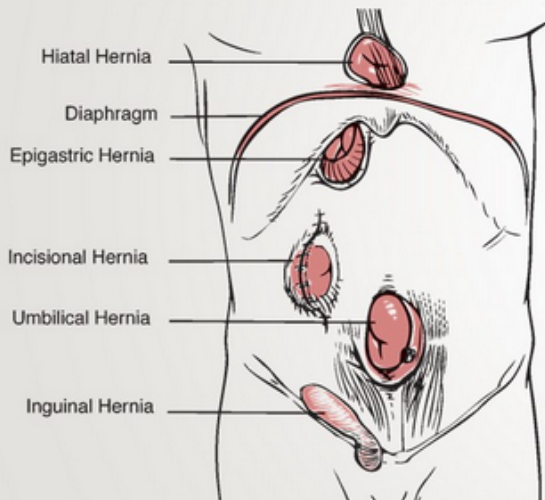
~\$650 million US market<sup>(1)</sup>  
~711,000 total procedures per year

Hiatal Hernia Repair

~\$40 million US market<sup>(1)</sup>  
~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

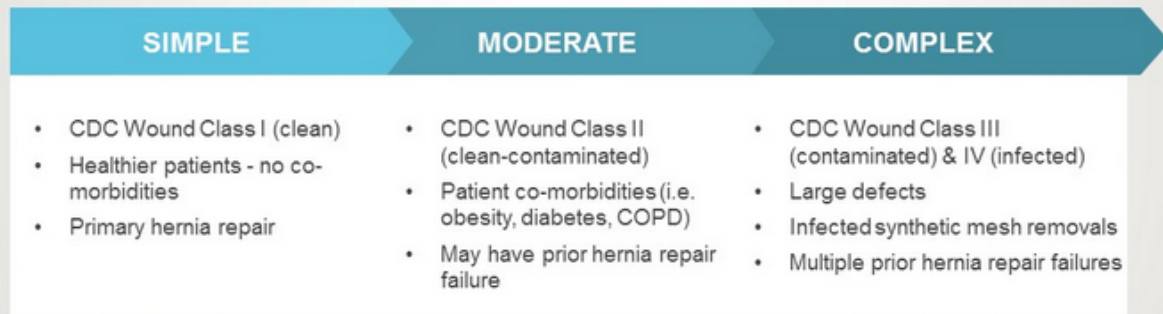
## Treating a hernia

- 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



**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

| PERMANENT SYNTHETIC MESH   |   | RESORBABLE SYNTHETIC MESH  | BIOLOGIC MESH  |  |
|--|---|--|--|--|
| <br><b>BARD</b><br>Ventralight™   | <br><b>Medtronic</b><br>ProGrip™             | <i>Natural Repair Products</i><br><br><b>BARD</b><br>PHASIX™ Mesh | <br><b>LifeCell</b><br>Stratattice™ | <br><b>ACell</b><br>Gentrix®  |
| <br><b>Medtronic</b><br>Parietex™ | <br><i>Johnson &amp; Johnson</i><br>PROCEED® | <br><b>GORE</b><br>BIO-A®   | <br>INTEGRA<br>SurgiMend®           | <br><b>BARD</b><br>XenMatrix™ |

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 years<sup>1</sup>**

## 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 18-months 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>**



1. Kokotovic, Bisgaard and Helgstrand, Long-dam: Recurrence and Complications Associated With Elective Incisional Hernia Repair. JAMA. 2016;315(15):1575-1582. doi:10.1001/jama.2016.15217 (on-line)  
2. Roth, JS et. al. (2017) "Prospective evaluation of poly-4-hydroxybutyrate mesh in CDC class I/high-risk ventral and incisional hernia repair: 18-month follow-up." Surgical Endoscopy.  
3. Itani, KMF et. al. (2012) "Prospective study of single-stage repair of contaminated hernias using a biologic porcine tissue matrix: The RICH Study" Surgery

# Our Solution: New Category of Tissue Reinforcement Materials

## Purposefully Designed Biologic & Polymer Solutions for Specific Clinical Needs

Biologic Tissue  
derived from sheep

Polymer Fibers

### Innovative Textile Engineering

Polymer fibers  
interwoven through  
layers of biologic  
material in unique  
embroidered patterns



Hernia & Ab Wall  
Reconstruction

Plastic  
Reconstruction

Surgeon Collaboration

# 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

## 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)
- 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

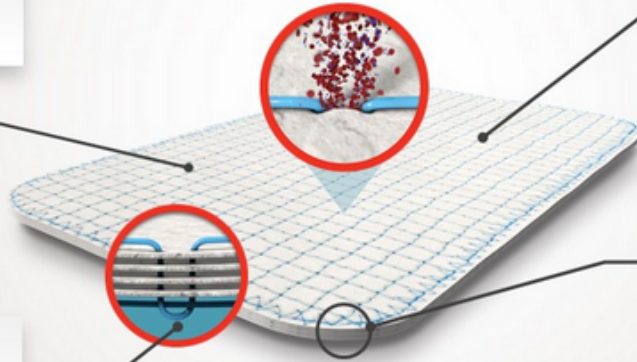
An innovative reinforced tissue matrix designed to reduce stretch compared to biologic matrices and long-term complications experienced with resorbable and permanent synthetic meshes

**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

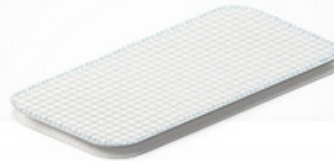
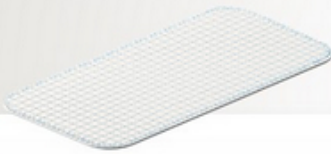
**Interwoven polymer** for added strength and improved handling

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



# 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.



CONFIGURATION

## 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

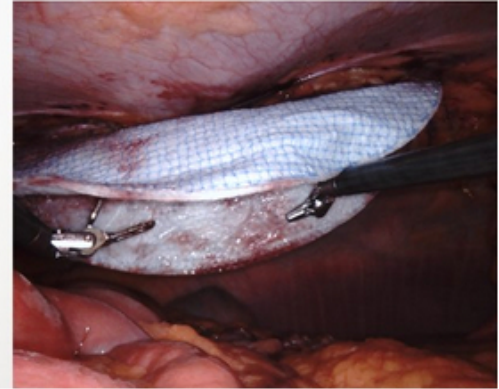


Images represent permanent polymer OviTex products. Resorbable polymer products have clear polymer.  
\* Biomechanical data on file.



## 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 simple-moderate ventral hernia patients



# Disruptive Technology Supported by a Compelling Body of Clinical Evidence



## 91 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

## 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

## 12 clinical publications

- Strong clinical efficacy and low complication rates in range of hernias

## Continue to build clinical evidence

- Additional BRAVO data over time
- 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   |
|---|---|---------|---|
| <ul style="list-style-type: none"><li>• 20-patients at 24-months</li><li>• 57-patients at 12-months</li><li>• 84-patients at 3-months</li></ul> | <ul style="list-style-type: none"><li>• ~75 patients at 12-months</li></ul> |         | <ul style="list-style-type: none"><li>• ~50-patients at 24-months</li></ul> |



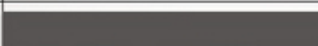


- Primary focus is hernia recurrence rate at each time point
  - Additional information on surgical site occurrence rate will also be analyzed
- Study design allows for robotic, laparoscopic and open implantation of OviTex 1S, allowing for sub-analyses by surgical technique
- Data will be submitted to 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 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% | 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> | Number of Patients who Completed Follow-up <sup>1</sup> | Follow-up 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                         |



<sup>1</sup>) 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).

## 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



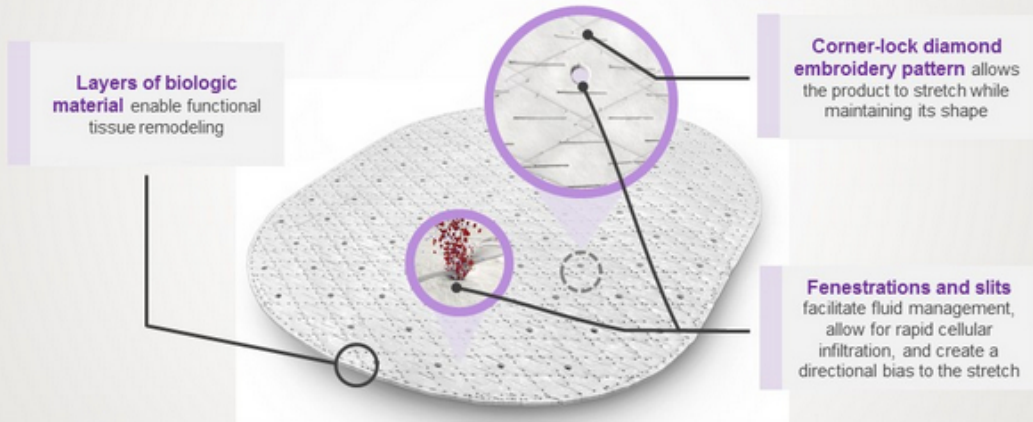
**~\$500 Million Annual  
U.S. Market Opportunity**

### 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



510(k) cleared April 2019; limited launch ongoing with plans to expand launch in 1H 2020

## Commercial Organization

Recognize need for integrated approach to account management to meet the needs of all stakeholders (surgeons, supply chain & OR / materials management)



- Single direct sales effort calling on General, Plastic Recon, Colorectal & Trauma surgeons
- Supplement high volume territories with Associate Account Managers
- Model is scaled at a regional level, with span-of-control for Regional Managers at ~6-8 Account Managers

## 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<sup>1</sup>



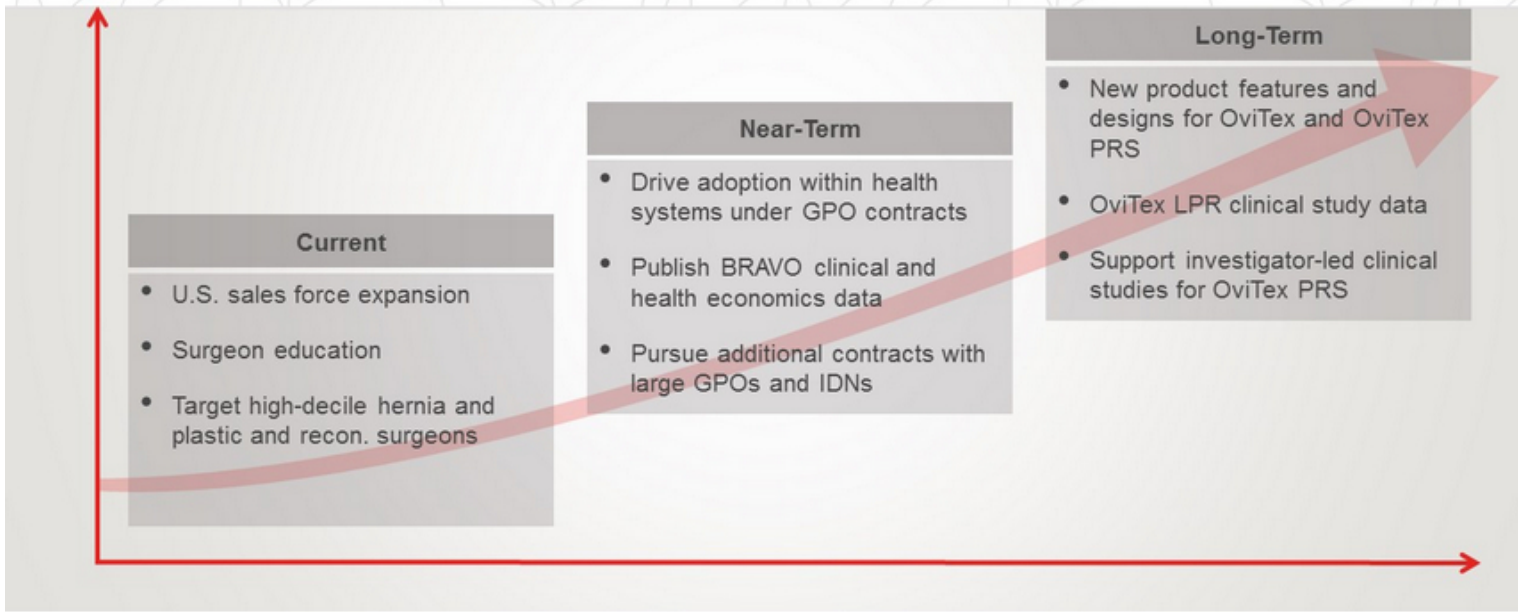
Data-driven, targeted implementation strategy



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



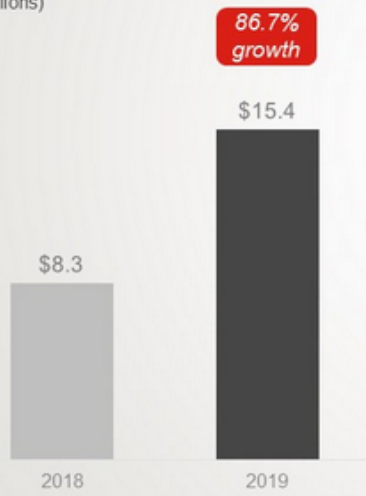
# Growth Strategy



# Revenue Growth

## Annual Results

(\$ millions)



## Quarterly Results

(\$ millions)



*Note: Q1 2020 revenue impacted by COVID-19 pandemic beginning mid-March*

## Statement of Operations

|                                   | Three months Ended March 31 |                |
|-----------------------------------|-----------------------------|----------------|
|                                   | 2020                        | 2019           |
| Revenue                           | \$3.7                       | \$3.3          |
| Cost of revenue                   | 1.5                         | 1.4            |
| Amortization of Intangible Assets | 0.1                         | 0.1            |
| <b>Gross profit</b>               | <b>\$2.2</b>                | <b>\$1.8</b>   |
| <i>Gross margin</i>               | <i>59%</i>                  | <i>54%</i>     |
| Operating expenses:               |                             |                |
| Selling and Marketing             | 5.3                         | 4.0            |
| General and Administrative        | 2.5                         | 1.3            |
| Research and Development          | 0.9                         | 1.7            |
| Gain on litigation settlement     | 0.0                         | 0.0            |
| Total operating expenses          | 8.7                         | 7.0            |
| <b>Loss from operations</b>       | <b>(\$6.5)</b>              | <b>(\$5.2)</b> |
| Other (expense) income, net       | (0.7)                       | (0.8)          |
| <b>Net loss</b>                   | <b>(\$7.2)</b>              | <b>(\$6.0)</b> |

# Managing Response to COVID-19 Pandemic

## Ensure Health & Safety

- Enabled employees to work remotely
- Limited non-essential travel
- Implemented increased sanitizing measures and protocols to promote physical distancing

## Maintain Operations

- Continue manufacturing at partner facility in New Zealand
- Provide uninterrupted customer support & order fulfillment
- Implement Virtual Selling Model to engage with and educate surgeon & hospital customers
- Launch virtual sales force education programs

## Manage Expenses

- Conserve cash of \$46.7 million
- Reduced consulting spend and temporary base salary reductions for all employees
- Implemented hiring freeze
- Deferred certain marketing and clinical activities

**Emerge from a position of strength to drive growth as surgical procedure volumes improve, leveraging the momentum experienced at the beginning of 2020**

## 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**