

**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 10, 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 2.02 Results of Operations and Financial Condition.

On November 10, 2021, TELA Bio, Inc. (the “*Company*”) issued a press release announcing its financial results for the third quarter ended September 30, 2021. A copy of this press release is furnished as Exhibit 99.1 hereto.

The information furnished pursuant to this Item 2.02, 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 (the “*Securities Act*”), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 7.01 Regulation FD Disclosure.

On November 10, 2021, 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 99.2, and incorporated herein by reference.

The information furnished pursuant to Item 7.01, including Exhibit 99.2, shall not be deemed “filed” for purposes of Section 18 of 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 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 furnished herewith:

<u>Exhibit No.</u>	<u>Document</u>
<u>99.1</u>	<u>Press Release of TELA Bio, Inc., dated November 10, 2021.</u>
<u>99.2</u>	<u>Corporate Slide Deck, dated November 10, 2021.</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: November 10, 2021



TELA Bio Reports Strong Third Quarter 2021 Revenues Reflecting Continued Growth Driven by Increased Demand

MALVERN, Pa., November 10, 2021 (GLOBE NEWSWIRE) -- TELA Bio, Inc. ("TELA") (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 reported third quarter 2021 financial results.

Third Quarter 2021 Financial Results and Recent Business Highlights

- Reported revenue of \$7.7 million for the third quarter of 2021, increasing 44% year-over-year;
- Increased demand for OviTex® and OviTex PRS Reinforced Tissue Matrix products in the third quarter of 2021 resulting in a revenue increase of 34% and 101% year-over-year, respectively;
- Strong international sales during the third quarter of 2021;
- Entered into an exclusive distribution agreement with Next Science for its advanced anti-biofilm, no-rinse surgical wash; and
- Appointed Roberto Cuca as the Company's new Chief Operating Officer and Chief Financial Officer.

"Throughout the quarter, we continued our efforts towards gaining market share across our portfolio of OviTex products," said Antony Koblisch, co-founder, President and Chief Executive Officer of TELA Bio. "Although the market experienced some volatility due to the continued impact of COVID-19, we remained focused on building a foundation with strategic initiatives to increase brand awareness and commercial execution to drive organic growth. We anticipate that a market recovery is near and believe we remain well-positioned to capitalize on this as we look towards the end of 2021 and the ensuing quarters."

Third Quarter 2021 Financial Results

Revenue was \$7.7 million for the third quarter of 2021, an increase of 44% compared to the prior year period despite demand headwinds for our products in September due to the surge of new COVID-19 cases related to new variants, such as the delta variant. This increase was driven by the expansion of our commercial organization, increased penetration within existing customer accounts and stronger than anticipated international sales. Sequentially, third quarter revenue grew slightly.

Gross profit was \$4.6 million for the third quarter of 2021, or 60% of revenue, compared to \$3.3 million, or 62% of revenue, in the same period in 2020. The decrease in gross margin was primarily due to the increase in the reserve for excess and obsolete inventory as a percentage of revenue as compared to the prior year, driven by the growth of the Company's product inventory in the third quarter of 2021.

Operating expenses were \$11.8 million in the third quarter of 2021, compared to \$10.2 million in the same period in 2020. The increase was due to the expansion of our commercialization activities, higher professional, consulting and legal expenses, and increased research and development expenses.

Loss from operations was \$7.2 million in the third quarter of 2021, compared to a loss from operations of \$6.9 million in the same period in 2020.

Net loss was \$8.3 million in the third quarter of 2021, compared to a net loss of \$7.7 million in the same period in 2020.

Cash and Cash Equivalents at September 30, 2021 were \$53.6 million.

Financial Outlook

We continue to monitor and evaluate the impact the COVID-19 pandemic has had and will continue to have on our results of operations. Despite these challenges, for the full year 2021, TELA Bio is maintaining its expectation for revenue to be in the range of \$28.0 million to \$30.0 million, representing growth of 54% to 65% over the prior year period. As with previous guidance, continued uncertainty relating to the dynamic environment with the COVID-19 pandemic could materially impact this projection.

Conference Call and Webcast Details

The Company will host a live conference call and webcast to discuss these results and provide a corporate update on Wednesday, November 10, 2021, at 4:30 PM ET.

To participate in the call, please dial (855) 548-1219 (domestic) or (409) 217-8881 (international) and provide conference ID 8535689. The live webcast will be available on the Events & Presentations page of the Investors section of TELA's website.

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.

Caution Regarding Forward-Looking Statements

This press release may contain 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 our expected revenue and revenue growth for the full year 2021, our expected increase in market share throughout the remainder of 2021, and our expectations with respect to market stability in the near term. 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, 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.

Investor Contact

Greg Chodaczek
347-620-7010
ir@telabio.com

TELA Bio, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(Unaudited)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 53,636	\$ 74,394
Accounts receivable, net	3,573	2,683
Inventory	6,269	3,907
Prepaid expenses and other assets	2,061	2,241
Total current assets	65,539	83,225
Property and equipment, net	891	626
Intangible assets, net	2,379	2,607
Total assets	<u>\$ 68,809</u>	<u>\$ 86,458</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,334	\$ 652
Accrued expenses and other current liabilities	7,043	5,953
Total current liabilities	9,377	6,605
Long-term debt with related party	31,315	30,827
Other long-term liabilities	388	—
Total liabilities	<u>41,080</u>	<u>37,432</u>
Stockholders' equity:		
Preferred stock; \$0.001 par value: 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock; \$0.001 par value: 200,000,000 shares authorized; 14,503,582 and 14,437,289 shares issued and 14,503,518 and 14,437,107 shares outstanding at September 30, 2021 and December 31, 2020, respectively	15	14
Additional paid-in capital	249,067	245,736
Accumulated other comprehensive loss	(43)	(71)
Accumulated deficit	(221,310)	(196,653)
Total stockholders' equity	27,729	49,026
Total liabilities and stockholders' equity	<u>\$ 68,809</u>	<u>\$ 86,458</u>

TELA Bio, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenue	\$ 7,654	\$ 5,313	\$ 21,089	\$ 12,546
Cost of revenue (excluding amortization of intangible assets)	2,976	1,950	7,707	4,746
Amortization of intangible assets	76	76	228	228
Gross profit	4,602	3,287	13,154	7,572
Operating expenses:				
Sales and marketing	6,948	6,342	20,749	15,734
General and administrative	3,462	2,607	9,184	7,274
Research and development	1,409	1,201	5,018	3,092
Total operating expenses	11,819	10,150	34,951	26,100
Loss from operations	(7,217)	(6,863)	(21,797)	(18,528)
Other (expense) income:				
Interest expense	(922)	(898)	(2,675)	(2,661)
Other (expense) income	(127)	58	(185)	185
Total other expense	(1,049)	(840)	(2,860)	(2,476)
Net loss	\$ (8,266)	\$ (7,703)	\$ (24,657)	\$ (21,004)
Net loss per common share, basic and diluted	\$ (0.57)	\$ (0.53)	\$ (1.71)	\$ (1.69)
Weighted average common shares outstanding, basic and diluted	14,485,688	14,421,990	14,461,174	12,431,257
Comprehensive loss:				
Net loss	\$ (8,266)	\$ (7,703)	\$ (24,657)	\$ (21,004)
Foreign currency translation adjustment	38	(29)	28	2
Comprehensive loss	\$ (8,228)	\$ (7,732)	\$ (24,629)	\$ (21,002)



Advancing Soft Tissue Reconstruction

Investor Presentation

November 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: the impact to the Company's 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 the Company's ability to market its products, demand for the Company's products due to deferral of procedures using the Company's products, the labor and staffing environment in the healthcare industry, 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.



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

- ~\$2B U.S Market Opportunity¹
*in hernia repair, abdominal wall reconstruction and
plastic and reconstructive surgery*
- Innovative Products
- Compelling Clinical Evidence
- Products Offer Attractive Value
Proposition for Hospitals

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

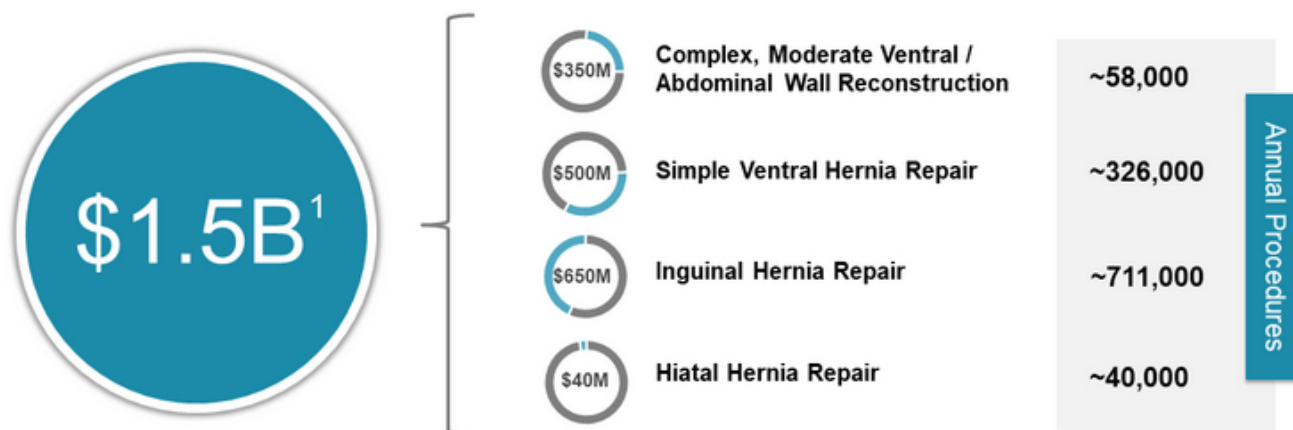


Hernia & Ab Wall
Reconstruction

Plastic
Reconstruction

Issued patents protect underlying biologic tissue and product design

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



Ventral Hernia Patients Range in Complexity

Ventral Hernia Complexity

SIMPLE	MODERATE	COMPLEX
<ul style="list-style-type: none">• CDC Wound Class I (clean)• Healthier patients - no co-morbidities• Primary hernia repair	<ul style="list-style-type: none">• CDC Wound Class II (clean-contaminated)• Patient co-morbidities (i.e., obesity, diabetes, COPD)• May have prior hernia repair failure	<ul style="list-style-type: none">• CDC Wound Class III (contaminated) & IV (infected)• Large defects• Infected synthetic mesh removals• Multiple prior hernia repair failures

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

Current Ventral Hernia Treatment Options: No Perfect Product

Natural Repair Products

	PERMANENT SYNTHETIC MESH	RESORBABLE SYNTHETIC MESH	BIOLOGIC MESH
	 BARD Parietex™  Medtronic ProGrip™ + Ventralight™  Johnson & Johnson PROCEED®	 BARD Phasix™ Mesh  GORE GORE® BIO-A®	 LifeCell Strattice™  INTEGRA SurgilMend®  ACell Gentrix®  BARD XenMatrix™
LIMITATIONS	<ul style="list-style-type: none"> ▫ 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 	<ul style="list-style-type: none"> ▫ Inflammatory response until absorbed ▫ Encapsulation of implant or contraction until absorbed ▫ Scar tissue / lack of remodeling ▫ Mesh infection until resorbed ▫ Organ erosion or perforation ▫ Lack of mid-term and long-term reinforcement 	<ul style="list-style-type: none"> ▫ Lack of strength or durability ▫ Prone to laxity and stretching ▫ Challenges to surgeon handling ▫ Difficult to use in laparoscopic or robotic surgery ▫ High costs
			
	Simple Ventral Hernia Inguinal Hernia	Complex, Moderate Ventral Repair / Abdominal Wall Reconstruction Hiatal Hernia Repair	

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 complications¹

1 in 5

Hernia patients have voiced concern over use of permanent synthetic mesh according to surgeons¹

~15K

Lawsuits against permanent synthetic meshes estimated to be assembled across the U.S.²



HERNIA MESH COMPLICATIONS INCLUDE: PAIN, INFECTION, RECURRENCE, ADHESION, OBSTRUCTION, & PERFORATION. THOSE AFFECTED MAY BE ELIGIBLE FOR COMPENSATION.



If you've been injured due to potentially defective hernia mesh, you may be entitled to financial compensation.

OviTex Reinforced Tissue Matrix: a More Natural Hernia Repair™

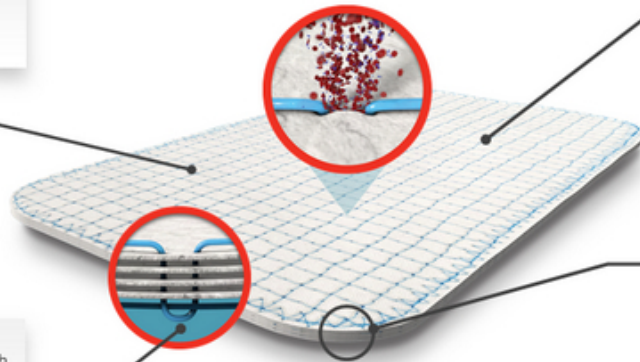
An innovative reinforced tissue matrix designed to reduce stretch compared to biologic matrices and long-term complications experienced with resorbable and permanent synthetic meshes

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



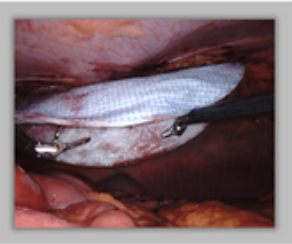
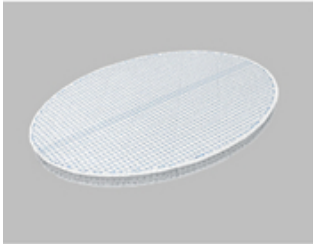
OviTex LPR for Laparoscopic & Robotic Hernia Repair

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



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 upon study completion by the end of 2021

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

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



\$500M¹

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

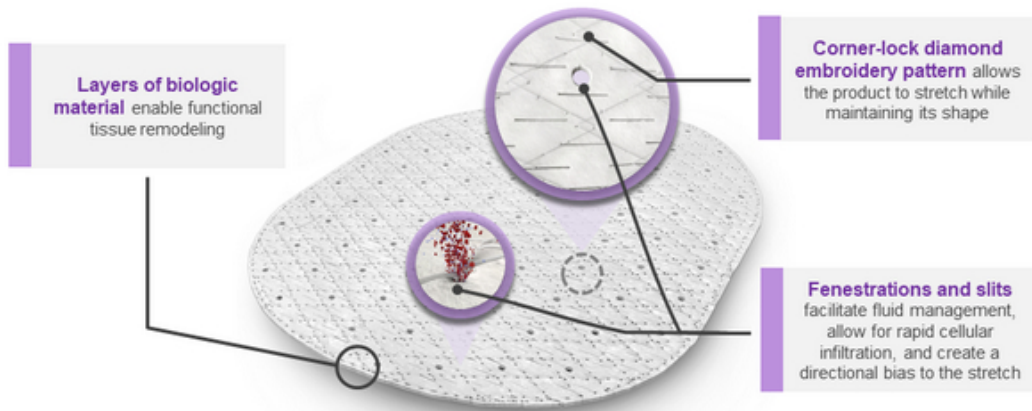
- Breast reconstruction
- Head and neck surgery
- Chest wall reconstruction
- Pelvic reconstruction
- Extremities reconstruction

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

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

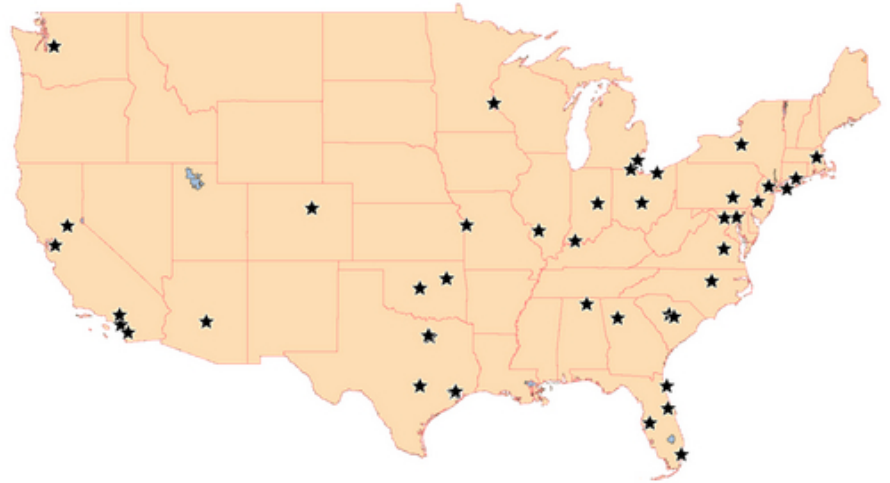
Commercial Organization

45 sales territories as of September 30, 2021

- 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

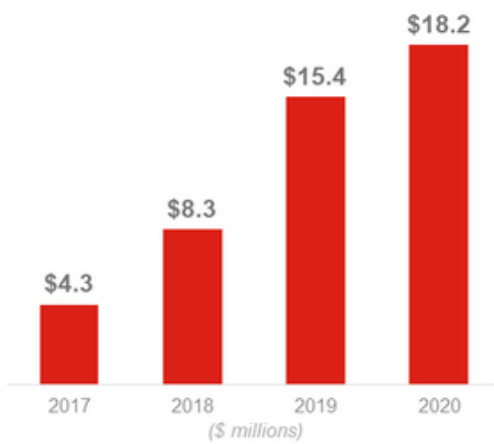
MARKET EXPANSION

- 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

Delivering Revenue Growth

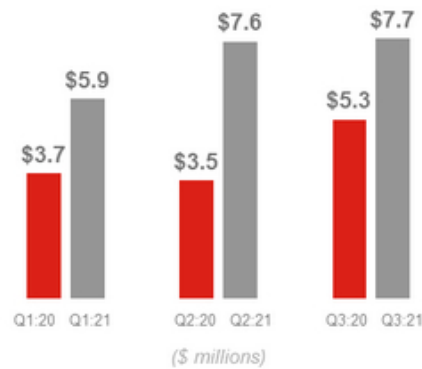
Annual Revenue

Revenue CAGR: 62%



Quarter Revenue

YTD Revenue Growth: 68%



Q3 2021 Performance

- Revenue growth of 44% year over year, up 1% from Q2:21
- Cash and Cash equivalents (as of September 30, 2021): \$53.6M

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**