#### 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 7, 2024

#### TELA Bio, Inc.

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation) 001-39130 (Commission File Number) 45-5320061 (I.R.S. Employer Identification No.)

1 Great Valley Parkway, Suite 24 Malvern, Pennsylvania

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: (484) 320-2930

Not Applicable (Former name or former address, if changed since last report.)

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:

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:

<u>Title of each class</u> Common Stock, par value \$0.001 per share

Trading Symbol(s)
TELA

Name of each exchange on which registered 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.  $\Box$ 

#### Item 2.02 Results of Operations and Financial Condition.

On November 7, 2024, TELA Bio, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2024. 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 7, 2024, 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:

Exhibit No.	Document
99.1	Press Release of TELA Bio, Inc., dated November 7, 2024.
<u>99.2</u>	Corporate Slide Deck, dated November 7, 2024.
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:

Name: Title:

/s/ Antony Koblish
Antony Koblish
President, Chief Executive Officer and Director

Date: November 7, 2024



TELA Bio Reports Third Quarter 2024 Financial Results

Reiterates 2024 Revenue Guidance and Expects Recently Implemented Operational Efficiency Improvements to Reduce Operating Expenses in 2025

MALVERN, PA. November 7, 2024 -- TELA Bio, Inc. ("TELA Bio"), a commercial-stage medical technology company focused on providing innovative soft-tissue reconstruction solutions, today reported financial results for the third quarter ended September 30, 2024.

#### Recent Highlights

- Reported revenue of \$19.0 million in the third quarter, representing growth of 26% over the prior year period;
- Increased demand for OviTex® and OviTex PRS Reinforced Tissue Matrix products during the third quarter, resulting in a year-over-year growth in unit sales volume for each product of approximately 39% and 44%,
- Closed on an underwritten public offering yielding gross proceeds of approximately \$46.0 million before deducting underwriting discounts and commissions and other estimated offering expenses;
- Implemented certain operating efficiency improvements that are expected to reduce operating expenses in 2025 by between \$5.0 million to \$10.0 million from annualized first half of 2024 operating expenses; and
- Reiterated full year 2024 revenue guidance of \$74.5 million to \$76.5 million, representing 27% to 31% year-over-year growth. Impact from IV fluid shortages resulting from recent natural disasters may affect this projection but is currently unpredictable

"Third quarter revenue of \$19 million was the highest in TELA Bio's history and indicates a healthy demand for our products and a return to normalized growth across the OviTex portfolio following the second quarter's external market disruptions," said Antony Koblish, President and CEO of TELA Bio. "Our commercial leadership is prioritizing growth, and we are confident in our ability to demonstrate increased operating leverage going forward. With an additional \$43 million in net proceeds following the recent underwritten public offering, and actions already taken to reduce operating expenses for 2025, we believe that we are amply funded to attain profitability with current

#### Third Ouarter 2024 Financial Results

Revenue was \$19.0 million in the third quarter of 2024, an increase of 26% compared to the same period in 2023. The increase was primarily driven by an increase in unit sales of our products due to the addition of new customers and growing international sales. This growth was partially offset by a decrease in average selling prices caused by product mix as the share of smaller-sized units increased with the introduction of robotically compatible OviTex IHR and our increased focus in growing market share in high-volume minimally invasive and robotic procedures.

Gross profit was \$12.9 million in the third quarter of 2024, or 68% of revenue, compared to \$10.4 million, or 69% of revenue, in the same period in 2023. The decrease in gross margin was primarily due to a higher charge for excess and obsolete inventory as a percentage of revenue.

Operating expenses were \$22.2 million in the third quarter of 2024, compared to \$20.6 million in the same period in 2023. The increase was due to higher compensation costs, including increased severance costs and additional employee-related expenses, as well as increased travel and consulting.

Loss from operations was \$9.4 million in the third quarter of 2024, compared to a loss from operations of \$10.2 million in the same period in 2023.

Net loss was \$10.4 million in the third quarter of 2024, compared to a net loss of \$11.0 million in the same period in 2023.

Cash and cash equivalents on September 30, 2024 totaled \$17.3 million.

#### Conference Call

TELA Bio will host a conference call at 4:30 p.m. Eastern Time on Thursday, November 7, 2024, to discuss its third quarter 2024 financial results. Investors interested in listening to the conference call should register online. Participants are required to register a day in advance or at minimum 15 minutes before the start of the call. A live webcast and replay can be accessed via the Events & Presentations page of the investor section of TELA's website.

#### About TELA Bio, Inc.

TELA Bio, Inc. (NASDAQ: TELA) is a commercial-stage medical technology company focused on providing innovative technologies that optimize clinical outcomes by prioritizing the preservation and restoration of the patient's own anatomy. The Company is committed to providing surgeons with advanced, economically effective soft-tissue reconstruction solutions that leverage the patient's natural healing response while minimizing long-term exposure to permanent synthetic materials. For more information, visit <a href="https://www.telabio.com">www.telabio.com</a>.

TELA Bio intends to use the Investor Relations section of its website as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor TELA Bio's website in addition to following its press releases, SEC filings, public conference calls, presentations, and webcasts.

#### Caution Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Words such as "may," "might," "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 Bio's management. Such forward-looking statements include statements relating to our expected revenue and revenue growth for the full year 2024 and reduction in operating expenses through the full year 2025. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and other factors that could cause actual results and events to differ materially and adversely from those indicated by such forward-looking statements including, among others: the impact to our business from macroeconomic conditions, including any lingering effects of the COVID-19 pandemic and other public health crises, recessionary concerns, banking instability, increasing market interest rates, and inflationary pressures, potentially impacting our ability to market our products; the impact of cybersecurity events, external supply chain, or pricing pressures concerning our products or the procedures using our products; the impact of cybersecurity events, external supply chain disruptions, and natural disasters or extreme weather events affecting or disrupting hospital operations and procedural volumes; our ability to achieve or sustain profitability; our ability to gain market acceptance for our products and to accurately forecast and meet customer demand; our ability to compete successfully; that data from earlier studies related to our products and interim data from ongoing studies may not be replicated in later studies or indicative of future data; that data obtained from clinical studies using our product may not be indicative of future data; that data obtained fro

Investor Contact Louisa Smith ir@telabio.com

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

	September 30,		December 31,	
		2024		2023
Assets				
Current assets:				
Cash and cash equivalents	\$	17,301	\$	46,729
Accounts receivable, net of allowances of \$230 and \$416		11,222		9,737
Inventory		13,600		13,162
Prepaid expenses and other current assets		2,009		2,098
Total current assets		44,132		71,726
Property and equipment, net		2,423		1,984
Intangible assets, net		1,834		2,119
Right-of-use assets		1,796		1,954
Other long-term assets		2,566		_
Restricted cash		265		265
Total assets	\$	53,016	\$	78,048
Liabilities and stockholders' (deficit) equity				
Current liabilities:				
Accounts payable	\$	2,479	\$	1,667
Accrued expenses and other current liabilities		14,379		15,300
Total current liabilities		16,858		16,967
Long-term debt		40,970		40,515
Other long-term liabilities		1,460		1,685
Total liabilities		59,288		59,167
Stockholders' (deficit) equity:				
Stockholders (uchrel) 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; 24,717,193 and 24,494,675 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively		25		24
2023, tespectively Additional paid-in capital		343.076		339.655
Aduntona pate-in capital Accumulated other comprehensive income		343,076 149		91
Accumulated deficit				
		(349,522)		(320,889)
Total stockholders' (deficit) equity	_	(6,272)		18,881
Total liabilities and stockholders' (deficit) equity	\$	53,016	\$	78,048

## 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,				
		2024		2023		2024		2023
Revenue	\$	18,957	\$	15,052	\$	51,651	\$	41,455
Cost of revenue (excluding amortization of intangible assets)		6,004		4,568		16,099		12,682
Amortization of intangible assets		95		95		285		285
Gross profit		12,858		10,389		35,267		28,488
Operating expenses:								
Sales and marketing		16,472		14,474		50,691		42,517
General and administrative		3,683		3,728		11,133		10,834
Research and development		2,068		2,368		6,784		6,934
Total operating expenses		22,223		20,570		68,608		60,285
Other operating income:	·			<u> </u>				
Gain on sale of product line		_		_		7,580		_
Loss from operations		(9,365)		(10,181)		(25,761)		(31,797)
Other expense:								
Interest expense		(1,344)		(1,334)		(4,007)		(3,878)
Other income		337		558		1,135		1,901
Total other expense, net		(1,007)		(776)		(2,872)		(1,977)
Net loss	\$	(10,372)	\$	(10,957)	\$	(28,633)	\$	(33,774)
Net loss per common share, basic and diluted	\$	(0.42)	\$	(0.45)	\$	(1.16)	\$	(1.51)
Weighted average common shares outstanding, basic and diluted		24,703,578		24,483,664		24,648,933		22,322,256
Comprehensive loss:								
Net loss	\$	(10,372)	\$	(10,957)	\$	(28,633)	\$	(33,774)
Foreign currency translation adjustment		51		51		58		(15)
Comprehensive loss	\$	(10,321)	\$	(10,906)	\$	(28,575)	\$	(33,789)





### **INVESTOR PRESENTATION**

November 2024

## **Forward Looking Statements**

This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. All 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 the actual results, performance or achievements of TELA Bio, Inc. (the "Company") 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," "ainticipate," "could," "intend," "farget," "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 are beyond the Company's control, including, among others: the impact to our business from macroeconomic conditions, including any lingering effects of the CoVID-19 pandemic and other public health crises, recessionary concerns, banking instability, increasing market interest rates, and inflationary pressures, potentially impacting our ability to admit our products, demand for our products due to the deferral of elective pr

## **Our Mission**

We provide innovative soft-tissue reconstruction solutions that optimize clinical outcomes by prioritizing the **Preservation** and **Restoration** of the patient's own anatomy.



## **TELA Bio, Inc.**

- Advanced reinforced tissue matrix portfolio supported by compelling clinical evidence
- \$2.2B US market opportunity<sup>1</sup> still in early stages of growth
- Driving commercial adoption with targeted directsales 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 and robust GPO access
- Highly accomplished executive team with proven track record

Redefining soft tissue preservation and restoration with a differentiated categor of tissue reinforcement materials and supportive products





Management estimate, \$2.28 total includes \$1.58 hernia & abdominal wall reconstruction, \$0.78 plastic reconstructive surgery.



## US Hernia Surgery Market: ~\$1.5 Billion Annual **Opportunity**



Sources: Millennium Research Group Reports, IMS Health Data; iData Research MedSKU.
 Management estimate. Market size based on volume and weighted average selling price for OviTex.

## **OviTex Reinforced Tissue Matrix**

A more natural hernia repair

#### **OviTex Core**

4-layer device No smooth sides Robot Compatible<sup>1</sup>: Yes

OviTex Core is designed to reinforce primary hernia repairs where the will not come into contact with viscera.

#### OviTex 1S

6-layer device smooth side Robot Compatible<sup>1</sup>: Yes

OviTex 1S incorporates a smooth side that is designed to minimize tissue attachment and to reinforce primary hernia repairs where the device may come into contact with viscera (e.g. intraperitoneal).

#### OviTex 2S

8-layer device 2 smooth sides Robot Compatible: No

OviTex 2S incorporates eight layers of tissue for added strength. The two smooth sides make it suitable for intraperitoneal placement.

#### OviTex LPR

4-layer device Robot Compatible<sup>1</sup>: Yes

OviTex LPR is designed specifically for use in minimally invasive procedures. The design also incorporates a smooth side making it suitable for intraperitoneal placement.

#### OviTex IHR

4-layer and 3-layer device No smooth sides Robot Compatible<sup>2</sup>: Yes

OviTex IHR is designed specifically for use in inguinal hernia repair procedures. The design also incorporates an anatomical and rectangular shape to suit surgeon preference.

- 1. Robot compatibility based on use of 10mm trocar. Robot compatibility of UPR and OviTex Core include sizes 400 cm² or less. Robot compatibility of OviTex 1S includes sizes 200 cm² or less. 2. Robot compatibility based on use of 8mm trocar. Robot compatibility of OviTex IHR include sizes of 221 cm² or less.

## **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

3 of 4

Hernia patients want proactive control in their care<sup>2</sup>

~15,000

Product liability lawsuits relating to permanent synthetic hernia repair (as of November 2024)<sup>3</sup> Not inclusive of ~40,000 or more cases settled or dismissed within the past three years4

2019

FDA issued multiple 522 orders to manufacturers requiring pre-market approval prior to sale and distribution of transvaginal mesh for pelvic organ prolapse repair<sup>5</sup>

10

Steps surgeons must take in the U.K. as part of the Royal College of Surgeons guidance for Patient Consent Supported Decision Making following the 2015 Montgomery Ruling<sup>6</sup>

<sup>1.</sup> Hernis and Abdominal Surgeries Survey (Dct 2020). A group of 71 surgeons were surveyed regarding use of mesh in various bernis repair surgeries.

2. Figures derived from Company-sponsored online poll of approximately 1,100 potential patients for hernis procedures.

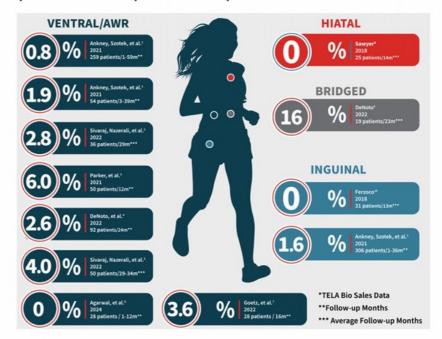
3. See Meditonic pic Form 10-C, filed with the SEC on Aug. 27, 2024; Atrium Medical Corp. C-Qur Mesh Products Liability Litigation (Case No: 16-md-2753 LM); In RE: Ethicon Physiomesh Flexible Composite Hernis Mesh Products Liability Litigation (Case No: 117-md-02782-RWS).

4. Reuten, "Bection Dickinson agrees to settle about 38,000 hernis mesh suits" (retrieved from https://www.reuters.com/legal/filigation/becton-dickinson-agrees-settle-about-38000-hernis-mesh-suits-2024-10-03/); Getinge Press Release, dated December 8, 2021; Johnson & Johnson Form 10-K, filed with the SEC on February 16, 2024 regarding settlement of Ethicon Physiomesh Flexible Composite Mesh Lobins).

5. U.S. Food and Drug Administration. (n.d.). FDA's activities: Urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh-implants/Has-activities-urogynecologic-surgical-mesh

## Consistently Low Recurrence Rates Backed by 8+ years of clinical experience and 43 published or presented works





Source: Refer to "Clinical References" in this presentation.
\* Indicates one or more surgeons are paid consultants of TELA Bio, Inc.

## Favorable Results of OviTex in Ventral Hernia Repair Comparisons to synthetic mesh and leading generation one biologics

	Park	er et al. <sup>3</sup>	Sivaraj et al.²						
Total enrolled patients	50 Ovi Tex	50 Polypropylene	36 Ovi Tex	51 Strattice	17 Permacol	37 Surgimend			
Length of follow-up	12 months	12 months	28.6 months (median)	34.6 months (median)	58.4 months (median)	37.5 months (median)			
mVHWG	32% grade 2 68% grade 3ª	94% grade 2 6% grade 3	33% grade 1 58% grade 2 8% grade 3	17% grade 1 79% grade 2 4% grade 3	18% grade 1 71% grade 2 12% grade 3	40% grade 1 51% grade 2 9% grade 3			
CDC wound class	70% CDC class	94% CDC class I	89% class I-II	86% class I-II	94% class I-II	91% class I-II			
Incidence of SSO	36%*	22%*	16.7%*	47.1%*	52.9%*	43.2%*			
Incidence of SSI		-	2.8%b	12.5%	11.8%	5.4%			
Recurrence rate	6%	12%	2.8% <sup>c</sup>	13.7% <sup>c</sup>	29.4%	24.3%			

Source: Refer to "Clinical References" in this presentation.

<sup>\*</sup>O verall complications including surgical site occurrences (SSOs) and surgical site infections (SSIs)
a – OvT ex patients were more complicated with a significantly higher mVHWG distribution and CDC wound dassification compared to polypropytene patients.
b – OvT ex patients experienced significantly less complications than patients receiving the other three biologics.
c – OvT ex and Strattice patients had a statistically lower recurrence rate than patients receiving the other two biologics.

## Positive 24-month BRAVO Results In Ventral Hernia

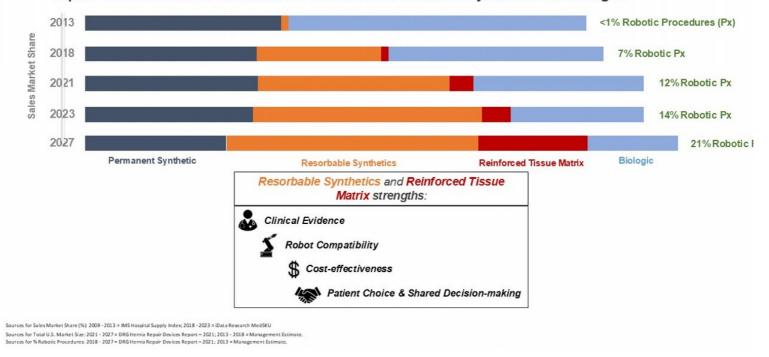
OviTex performance contextualized alongside contemporaneous publications for leading competitive products

competitive p	- Cuaroto				1
	DeNoto et al. (BRAVO) <sup>4</sup>	Harris et al	. (PRICE) <sup>11</sup>	Roth et al.12	Hope et al. (A TLAS) <sup>13</sup>
Total enrolled patients	92 Ovi Tex	82 Strattice	83 Ventralight ST or Bard Soft Mesh	121 Phasix	120 Phasix ST
Length of follow-up	24 months	26 m	onths	36 months	24 months
mVHWG	78% grade 2-3		-	-	-
CDC wound class	95% class I-II	90% class I-II	93% class I-II	100% class I	100% class I
Surgical technique	Open (65%) Laparoscopic (13%) Robotic (22%)	Open	Open	Open	Laparoscopic (55.8%) Robotic (44.2%)
Incidence of \$\$0	38% (includes SSI)	21% (excludes SSI)	22% (excludes SSI)		0.8% (includes SSI)
Incidence of SSI	20.7%	39%	34%	9%*	0%
Recurrence rate	2.6%*	40% (overall) 34% (class I wounds)	22% (overall) 28% (class I wounds)	17.9%*	31.7%* (overall) 18.6%* (defects < 7cm²)

Source: Refer to "Clinical References" in this presentation.

### **Hernia Market Evolution**

TELA Bio positioned to grow from a market shift towards resorbable and reinforced "natural repair" solutions as an alternative to traditional Permanent Synthetics or Biologics





# US Plastic and Reconstructive Surgery Market: ~\$700 Million Annual Opportunity



Surgeons use products to reinforce soft tissue during various reconstructive surgeries<sup>1</sup>, including:

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

Market dominated by human acellular dermal matrices (HADMs):

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

Cosmetic Plastic & Reconstructive Surgery



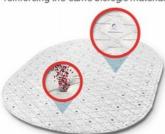
<sup>1.</sup> OviTexPRS is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The device is supplied sterile and is intended for one-time use. OviTexPRS has not been tested in breast surgical procedures.

Management estimate. Source: iData Research MedSKU, Q1 2024. Market size based on sales of current biologics.

## OviTex PRS: Specifically Designed for Plastic and

**Reconstructive Surgery** 

Available in both 2-layer resorbable (polyglycolic acid)
polymer, 3-layer permanent (polypropylene) polymer, or 3layer resorbable (polylactic-co-glycolic acid) polymer
reinforcing the same biologic material



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

#### **Product Features:**

- Layers composed of biologic building block retain biologically significant macromolecules for tissue regeneration<sup>1,2</sup>
- Diamond embroidery pattern and stents allow for directional flexibility; sawtooth embroidery pattern and slits allow for bidirectional stretch while providing stretch resistance
- Distinct permeability elements in various configurations e.g., micropores, macropores, and stents/slits – designed to facilitate fluid management

#### OviTex PRS compared to market leading human ADM3:

- Exhibited earlier host cell proliferation, collagen deposition and neovascularization
- Demonstrated tissue remodeling into mature, functional and organized collagen

1. Certain configurations available in two or three layers, see product catalog more information. 2. Lun S, Irvine S.M., Johnson K.D., Fisher N.J., Floden E. W., Negron L., Dempsey S.G., McLaughlin R.J., Vasudevamurthy M., Ward B.R., May B.C., A functional extracellular matrix biomaterial derived from ovine forestomach, Biomaterials 31(16) (2010) 4517-29.

3. ADM: Acellular Dermal Matrix. Overbeck N, Beierschmitt A, May B.C., Old, Koch J. In-Vivo Evaluation of a Reinforced Ovine Biologic for Plastic and Reconstructive Procedures in a Nonhuman Primate Model of 50t Tissue Repair. Epilasty. 2022 Sep 14;22:e43. PMID: 36160663; PMC1D: PMC3490677. Animal testing results may not be indicative of clinical performance.



### LIQUIFIX FIX8™ and LIQUIFIX Precision™

LIQUIFIX FIX8<sup>1</sup> is a complementary product addressing both open and laparoscopic groin hernia repair

### **Atraumatic liquid fixation devices**

- Reduce the need for penetrating mechanical fixation for inguinal and femoral hernia repair
- Provide precise, controlled adhesive application

#### Addresses an unmet need in the market, less damage to tissue

- Designed to minimize the risk of mechanical tissue trauma<sup>2</sup>
- Strong and secure mesh fixation<sup>2</sup>
- Pre-assembled device
- Adhesives polymerize in ~10 seconds
- Provides versatile liquid anchors at multiple angles

1. LIQUIFIX FIX8 is intended for use in laparoscopic surgical repair of groin (femoral and inguinal) hernias, achieved through the fixation of prosthetic polypropylene or polyester mesh to the abdominal wall and the approximation of the peritoneum; LIQUIFIX Precision is intended for use in open surgical repair of groin (inguinal and femoral) hernias, achieved through the fixation of prosthetic polypropylene or polyester mesh to the abdominal wall.
2. Data on file: Advanced Medical Solutions



## **Driving Revenue Growth**

#### Sales Force Size

2021: 40-45 reps / 5 TB Ltd.

2022: 61 reps / 6 TB

2023: 86 reps / 9 TB Ltd.

3Q24: 69 reps + 7 asst. reps / 10 TB Ltd.

#### Rep Productivity

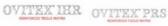
- Playbook90 training (new reps) & ongoing, intensive product training
- Avg. 6 mos. to breakeven
- Cadaver labs & other surgeon education and training programs
- Medical affairs support
- Industry & society meetings

#### Product Portfolio

OVITEX\*









**LIQUIFIX** Precision



**R&D** and BD



**GPO** 

Access

>1,600 hospitals



PREMIER

~4,400 hospitals



Third national GPO



More to come

Experience BRAVO 24-

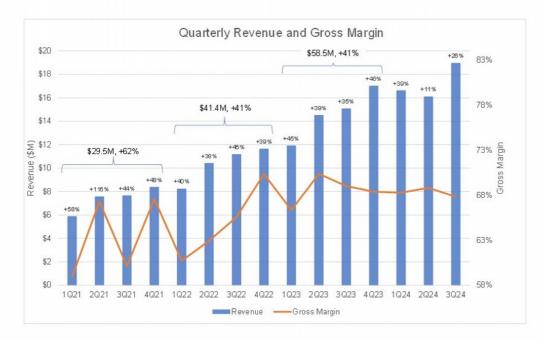
month data: 2.6% recurrence

Clinical

\$ales

- 43 published or presented works
- 50,000+ OviTex RTM implantations globally
- 10,000+ OviTex PRS implantations

## **Delivering Revenue Growth and Margin Improvement**



#### Q3 2024 Performance

- Record quarterly revenue of \$19.0M, growing 26% over corresponding period of 2023
- Cash and Cash Equivalents at September 30, 2024: \$17.3M
- Gross Margin: 68%
- The Company implemented costcutting measures in Q3, which are expected to result in reduced operating expenses in Q4 and beyond

#### Q4 2024 Fundraise

Net proceeds of \$43M from equity offering

### Clinical References

- 1. Ankney, C.; Banaschak, C.; Sowers, B.; Szotek, P. Minimizing Retained Foreign Body in Hernia Repair Using a Novel Technique: Reinforced Biologic Augmented Repair (ReBAR). J Clin Medical Res 2021, doi:10.37191/mapsci-2582-4333-3(4)-073.
- 3. Parker, M.J.; Kim, R.C.; Barrio, M.; Socas, J.; Reed, L.R.; Nakeeb, A.; House, M.G.; Ceppa, E.P. A Novel Biosynthetic Scaffold Mesh Reinforcement Affords the Lowest Hernia Recurrence in the Highest-Risk Patients. Surg Endosc 2021, 35, 5173–5178, doi:10.1007/s00464-020-08009-1.
- 4. DeNoto, G.; Ceppa, E.P.; Pacella, S.J.; Sawyer, M.; Slayden, G.; Takata, M.; Tuma, G.; Yunis, J. 24-Month Results of the BRAVO Study. A Prospective, Multi-Center Study Evaluating the Clinical Outcomes of a Ventral Hernia Cohort Treated with OviTex® 1S Permanent Reinforced Tissue Matrix. Ann Medicine Surg 2022, 83, 104745, doi:10.1016/j.amsu.2022.104745.
- 5. Sivaraj, D., Fischer, K. S., Kim, T. S., Chen, K., Tigchelaar, S. S., Trotsyuk, A. A., Gurtner, G. C., Lee, G. K., Henn, D., & Nazerali, R. S. (2022). Outcomes of Biosynthetic and Synthetic Mesh in Ventral Hernia Repair. Plastic and reconstructive surgery. Global open, 10(12), e4707. https://doi.org/10.1097/GOX.0000000000004707.
- 6. Agarwal, A. K.; Lake, S. P.; Deeken, C. R. (2024). Reinforced tissue matrix to strengthen the abdominal wall following reversal of temporary ostomies or to treat incisional hernias. World journal of gastrointestinal surgery, 16(3), 823–832. https://doi.org/10.4240/wjgs.v16.i3.823.
- Goetz, M.; Jurczyk, M.; Junger, J.; Schlitt, H.J.; Brunner, S.M.; Brennfleck, F.W. Semiresorbable biologic hybrid meshes for ventral abdominal hemia repair in potentially contaminated settings: lower risk of recurrence. Updates Surg. 2022; 74(6): 1995–2001. Published online 2022 Oct 12. doi: 10.1007/s13304-022-01378-3.
- 8. Sawyer, M.A.J. New Ovine Polymer-Reinforced Bioscaffold in Hiatal Hernia Repair. Jsls J Soc Laparoendosc Surg 2018, 22, e2018.00057, doi:10.4293/jsls.2018.00057
- 9. DeNoto, G. Bridged Repair of Large Ventral Hernia Defects Using an Ovine Reinforced Biologic: A Case Series. Ann Medicine Surg 75, 103446, doi:10.1016/j.amsu.2022.103446.
- 10. Ferzoco, S. (2018). Early Experience outcome of a reinforced Bioscaffold in inguinal hernia repair: A case series. International Journal of Surgery Open, 12. 9-11. https://doi.org/10.1016/j.ijso.2018.06.001.
- 11. Harris, H.W.; Primus, F.; Young, C.; Carter, J.T.; Lin, M.; Mukhtar, R.A.; Yeh, B.; Allen, I.E.; Freise, C.; Kim, E.; et al. Preventing Recurrence in Clean and Contaminated Hernias Using Biologic Versus Synthetic Mesh in Ventral Hernia Repair: The PRICE Randomized Clinical Trial. Ann Surg 2021, 273, 648–655, doi:10.1097/sla.0000000000000336.
- 12. Roth, J.S.; Anthone, G.J.; Selzer, D.J.; Poulose, B.K.; Pierce, R.A.; Bittner, J.G.; Hope, W.W.; Dunn, R.M.; Martindale, R.G.; Goldblatt, M.I.; et al. Prospective, Multicenter Study of P4HB (PhasixTM) Mesh for Hernia Repair in Cohort at Risk for Complications: 3-Year Follow-Up. Ann Medicine Surg 2021, 61, 1–7, doi:10.1016/j.amsu.2020.12.002.
- 13. Hope, W.W.; El-Ghazzawy, A.G.; Winterstein, B.A.; Blatnik, J.A.; Davis, S.S.; Greenberg, J.A.; Sanchez, N.C.; Pauli, E.M.; Tseng, D.M.; LeBlanc, K.A.; et al. A Prospective, Multicenter Trial of a Long-Term Bioabsorbable Mesh with Sepra Technology in Cohort of Challenging Laparoscopic Ventral or Incisional Hernia Repairs (ATLAS Trial). Ann Medicine Surg 2022, 73, 103156, doi:10.1016/j.amsu.2021.103156.