

**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): January 10, 2023

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)

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 7.01 Regulation FD Disclosure.

On January 10, 2023, 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 furnished herewith:

| Exhibit No. | Document |
|----------------------|--|
| 99.1 | Corporate Slide Deck, dated January 10, 2023. |
| 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: January 10, 2023



A Soft-Tissue Preservation and Restoration Company

INVESTOR PRESENTATION

January 2023

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, 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, that data from earlier studies related to the Company's 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 utilizing the Company's products may not be indicative of outcomes in other surgical settings, the Company's ability to enhance the Company's product offerings, development and manufacturing problems, capacity constraints or delays in production of the Company's products, maintenance of coverage and adequate reimbursement for procedures using the Company's products, product defects or failures. These and other risks and uncertainties are described more fully in the "Risk Factors" section and elsewhere in the Company's filings with the Securities and Exchange Commission and available at www.sec.gov. You should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in the Company's forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, the Company operates in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that the Company may face. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.



TELA Bio, Inc.

- Advanced reinforced tissue matrix portfolio supported by compelling clinical evidence
- \$2.2B US market opportunity¹ – still in early stages of growth
- 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 and robust GPO access
- Highly accomplished executive team with proven track record

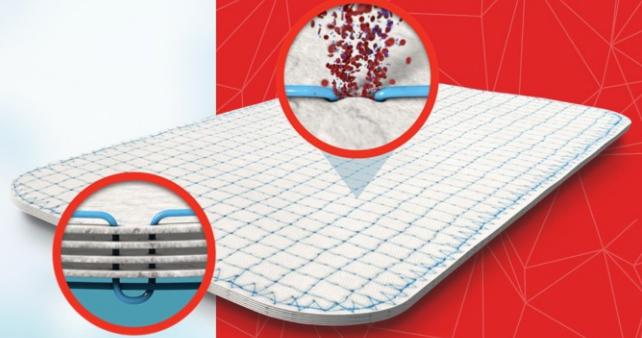
Redefining soft tissue preservation and restoration with a differentiated category of tissue reinforcement materials and supportive products

OVITEX®
REINFORCED TISSUE MATRIX

OVITEX® PRS
REINFORCED TISSUE MATRIX

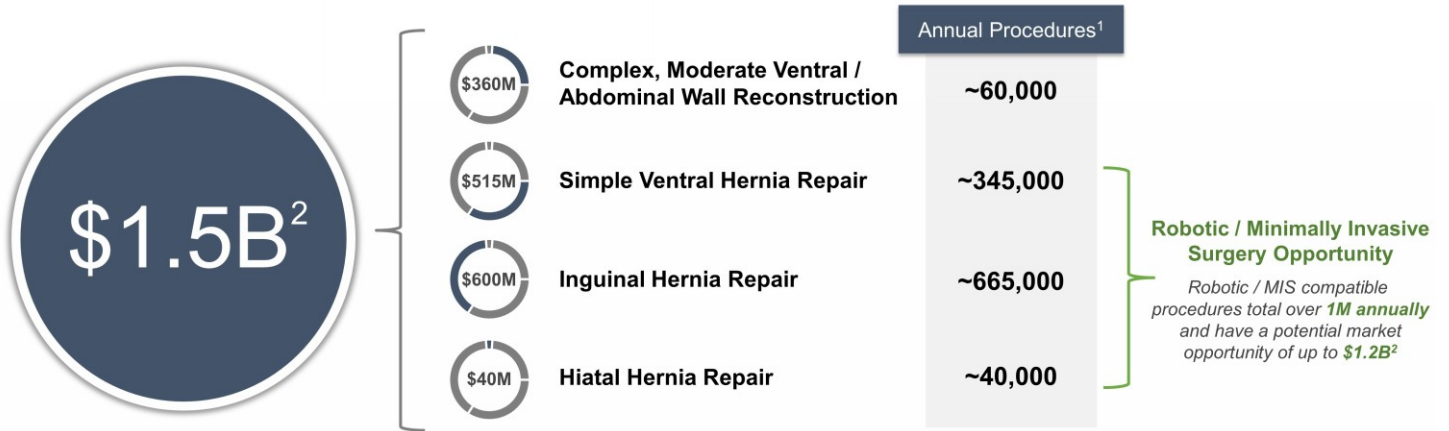
¹ Management estimate. \$2.2B total includes \$1.5B hernia & abdominal wall reconstruction, \$0.7B plastic reconstructive surgery.

OVITEX[®]
REINFORCED TISSUE MATRIX





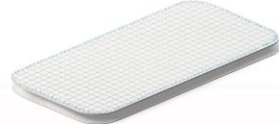















TELABIO[®]
SCIENCE. VALUE. INNOVATION.

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



¹Sources: Millennium Research Group Reports, IMS Health Data; iData Research MedSKU
²Management estimate. Market size based on volume and weighted average selling price for OviTex

OviTex Portfolio: Designed for a Range of Hernia Patients and Surgical Techniques

| |  |  |  |  |
|------------------------|--|---|---|---|
| CONFIGURATION | <p>OviTex LPR 4-layer device, with "smooth side" suitable for intraperitoneal placement</p> <p>Robot Compatible¹: Yes Strength²: + Viscera Contact²: Yes</p> | <p>OviTex 4-layer device, not intended for intraperitoneal placement</p> <p>Robot Compatible¹: Yes Strength²: + Viscera Contact²: Not recommended</p> | <p>OviTex 1S 6-layer device, with "smooth side" suitable for intraperitoneal placement</p> <p>Robot Compatible¹: Yes Strength²: ++ Viscera Contact²: Yes</p> | <p>OviTex 2S 8-layer device, with 2 "smooth sides" suitable for intraperitoneal placement</p> <p>Robot Compatible¹: No Strength²: +++ Viscera Contact²: Yes</p> |
| COMPETITIVE SET | <ul style="list-style-type: none"> Coated resorbable synthetic meshes <ul style="list-style-type: none">  BD Phasix ST Biologic meshes <ul style="list-style-type: none">  abbvie Strattice Laparoscopic | <ul style="list-style-type: none"> Resorbable synthetic meshes <ul style="list-style-type: none">  BD Phasix  GORE Bio-A Biologic meshes <ul style="list-style-type: none">  abbvie Strattice  INTEGRA SurgiMend  BD XenMatrix | <ul style="list-style-type: none"> Coated resorbable synthetic meshes <ul style="list-style-type: none">  BD Phasix ST Biologic meshes <ul style="list-style-type: none">  abbvie Strattice  INTEGRA SurgiMend  BD XenMatrix | <ul style="list-style-type: none"> Biologic meshes <ul style="list-style-type: none">  abbvie Strattice  INTEGRA SurgiMend  BD XenMatrix |

Images represent permanent polymer OviTex products. Resorbable polymer products have clear polymer. All trademarks and registered marks are property of their respective owners.

1. Robot compatibility based on use of 10mm trocar. Robot compatibility of LPR and OviTex include sizes 400 cm² or less. Robot compatibility of OviTex 1S includes sizes 200 cm² or less

2. Biomechanical data on file.

3. OviTex 1S and OviTex 2S were shown to not adhere in an animal model. Rabbit data on file. Correlation to results in humans has not been established.

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 care²

~30K

Lawsuits against permanent synthetic meshes estimated to be assembled across the U.S.³

1. Hernia and Abdominal Surgeries Survey (Oct 2020). A group of 71 surgeons were surveyed regarding use of mesh in various hernia repair surgeries.
2. Figures derived from Company-sponsored poll of approximately 1,100 potential patients for hernia procedures.
3. www.drugwatch.com (September 2021)

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

| | Parker et al. ³ | | Ankney et al. ⁵ | Sivaraj et al. ⁷ | | | |
|-------------------------|--|---------------------------|----------------------------|---|--|---|--|
| Total enrolled patients | 50 OviTex | 50 Polypropylene | 259 OviTex | 36 OviTex | 51 Strattice | 17 Permacol | 37 Surgimend |
| Length of follow-up | 12 months | 12 months | 1 – 59 months | 29 months (median) | 34.6 months (median) | 58.4 months (median) | 37.5 months (median) |
| mVHWG | 32% grade 2 68% grade 3^a | 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 II+^a | 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%* | 1.5% | 17%* | 47%* | 53%* | 43%* |
| Incidence of SSI | - | - | 0.8% | 2.8%^b | 12.5% | 11.8% | 5.4% |
| Recurrence rate | 6% | 12% | 0.8% | 2.8%^c | 13.7% ^c | 29.4% | 24.3% |

*Overall complications including SSI

a – OviTex patients were more complicated with a significantly higher mVHWG distribution and CDC wound classification compared to polypropylene patients

b – OviTex patients experienced significantly less complications than patients receiving the other three biologics

c - OviTex and Strattice patients had a statistically lower recurrence rate than patients receiving the other two biologics

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



Positive 24-month BRAVO results in ventral hernia: OviTex performance contextualized alongside recent publications for leading competitive products

| | DeNoto et al. (BRAVO) ⁸ | Harris et al. (PRICE) ¹⁰ | | Roth et al. ¹¹ | Hope et al. (ATLAS) ¹² |
|-------------------------|---|---------------------------------------|---------------------------------------|---------------------------|--|
| Total enrolled patients | 92 OviTex | 82 Strattice | 83 Ventralight ST or Bard Soft Mesh | 121 Phasix | 120 Phasix ST |
| Length of follow-up | 24 months | 26 months | | 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 SSO | 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 < 7cm ²) |

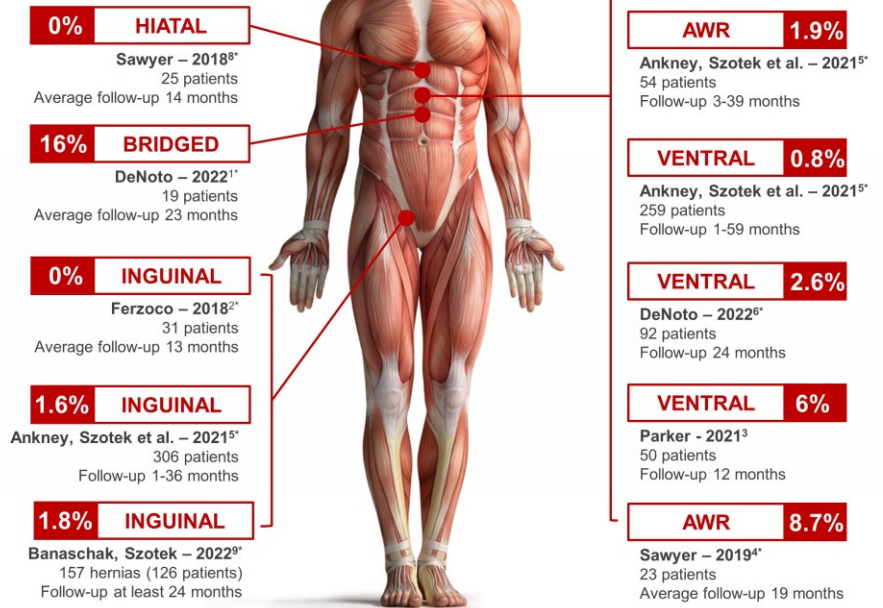
* Kaplan-Meier survival estimate

**No head-to-head clinical studies have been conducted. Due to differences in patient population, surgeons, surgical technique, and other variables, direct comparisons of results must be made with caution. For a comparative discussion of these studies, please see G. DeNoto, E.P. Ceppa, S.J. Pacella, M. Sawyer, G. Slayden, M. Takata, G. Tuma, J. Yunis, 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.

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



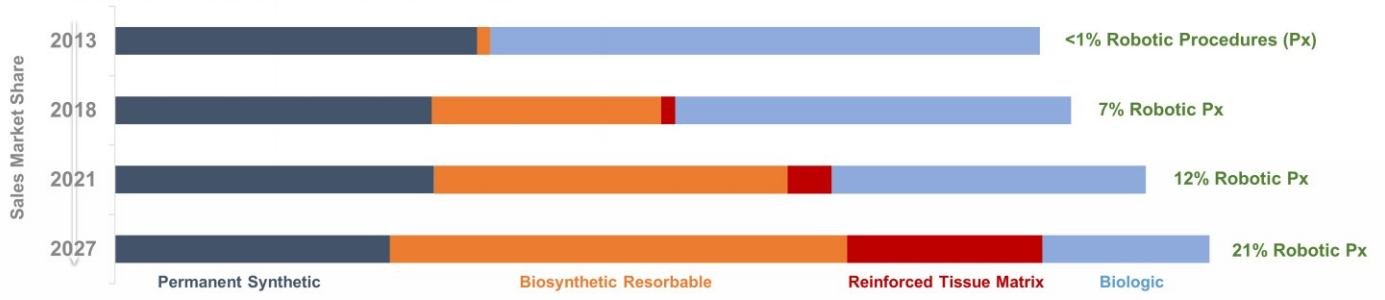
LOW RECURRENCE ALL APPLICATIONS WITH OVITEX



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

Hernia Market Evolution

TELA Bio is gaining from a market shift by providing our reinforced “natural repair” solutions as an alternative to traditional Permanent Synthetics or Biologics



Biosynthetic Resorbable and Reinforced Tissue Matrix strengths:

-  Clinical Evidence
-  Robot Compatibility
-  Cost-effectiveness
-  Patient Choice & Shared Decision-making

Sources for Sales Market Share (%): 2009 - 2013 = IMS Hospital Supply Index; 2018 - 2021 = iData Research MedSKU; 2027 = Management Estimate
 Sources for Total US Market Size: 2021 - 2027 = DRG Hernia Repair Devices Report – 2021; 2013 - 2018 = Management Estimate
 Sources for % Robotic Procedures (Px): 2018 - 2027 = DRG Hernia Repair Devices Report – 2021; 2013 = Management Estimate



OVITEX[®] PRS

REINFORCED TISSUE MATRIX



 **TELABIO[®]**
SCIENCE. VALUE. INNOVATION.

OviTex PRS: ~\$700 Million Annual U.S. Plastic and Reconstructive Surgery Market Opportunity



\$600M¹

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

- Head and neck surgery
- Chest wall reconstruction
- Pelvic reconstruction
- Extremities reconstruction
- Breast reconstruction²

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

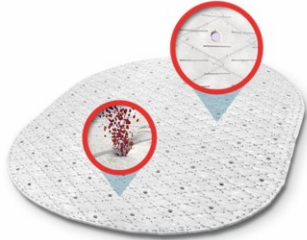


\$100M¹

¹Management estimate. Source: iData Research MedSKU, Q3 2021. Market size based on sales of current biologics
²OviTex PRS not indicated for breast reconstructions

OviTex PRS: Specifically Designed for Plastic and Reconstructive Surgery

Available in both **2-layer resorbable (polyglycolic acid) polymer** or **3-layer permanent (polypropylene) 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:

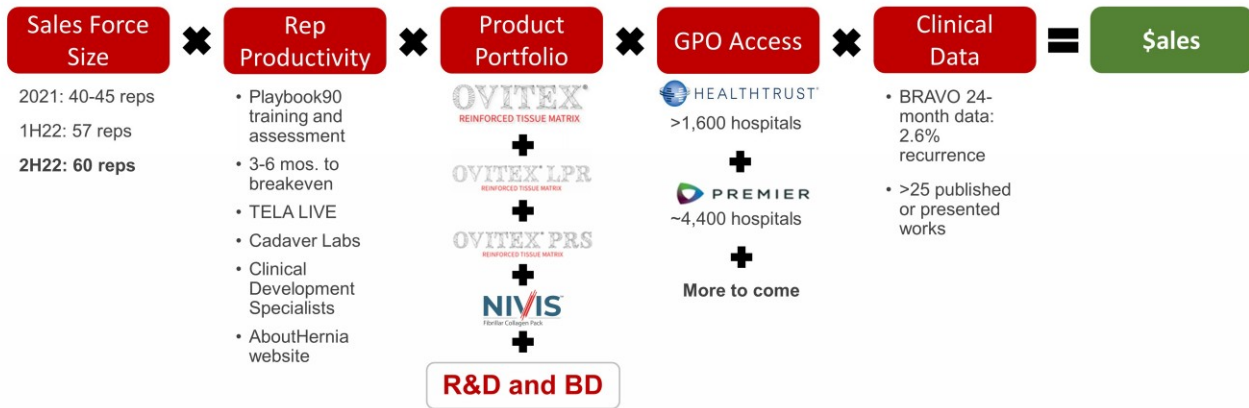
- Layers composed of biologic building block retain biologically significant macromolecules for tissue regeneration^{1,2}
- Diamond embroidery pattern and stents allow for directional flexibility
- Distinct permeability elements – micropores, macropores, and stents – designed to facilitate fluid management

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 BC, Qi S, Koch J. In-Vivo Evaluation of a Reinforced Ovine Biologic for Plastic and Reconstructive Procedures in a Non-human Primate Model of Soft Tissue Repair. *Eplasty*. 2022 Sep 14;22:e43. PMID: 36160663; PMCID: PMC9490877. Animal testing results may not be indicative of clinical performance.

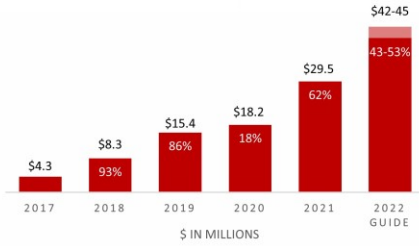
Driving Revenue Growth



TELA Bio is growing each factor that contributes to sales, providing for multi-year, long-term growth

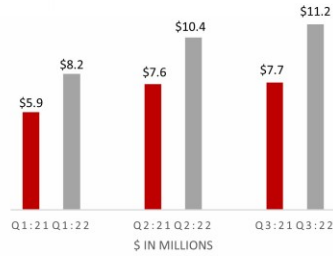
Delivering Revenue Growth

Annual Revenue



Quarter Revenue

YTD Revenue Growth: 41%



Q3 2022 Performance

- Revenue growth of 46% over corresponding period of 2021
- Cash and Cash equivalents (as of September 30, 2022): \$54.2M
- Closed equity offering resulting in net proceeds of \$34.4M
- Published 24-month BRAVO Study Results

CLINICAL REFERENCES

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2. Ferzoco, S. Available and Emerging Technologies for Assessing Intraoperative Tissue Perfusion during Complex Ventral Hernia Repair Procedures. *Open Access Surg* 2013, 1, doi:10.2147/oas.s55335.
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. Sawyer, M.A. Ovine Polymer-Reinforced BioScaffold in Abdominal Wall Reconstruction Poster Presented at: American Hernia Society (AHS) Annual Meeting 2019, Las Vegas, NV.
5. 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/maps-ci-2582-4333-3(4)-073.
6. 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.
7. Sivaraj, D.; Henn, D.; Fischer, K.S.; Kim, T.S.; Black, C.K.; Lin, J.Q.; Barrera, J.A.; Leeolou, M.C.; Makarewicz, N.S.; Chen, K.; et al. Reinforced Biologic Mesh Reduces Postoperative Complications Compared to Biologic Mesh after Ventral Hernia Repair. *Plastic Reconstr Surg - Global Open* 2022, 10, e4083, doi:10.1097/gox.0000000000004083.
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9. Banaschak, C.; Szotek, P. Robotic Reinforced Biologic Augmented Repair (ReBAR) of Over 150 Inguinal Hernias: 2 Year Outcomes. Presented at: 2022 American Hernia Society (AHS) Meeting, September 14-16, 2022, Charlotte, NC.
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11. Roth, J.S.; Anthonie, G.J.; Selzer, D.J.; Poulouse, 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 (Phasix™) 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.
12. 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.