

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2021

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 001-37526

**TELA Bio, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**45-5320061**  
(I.R.S. Employer  
Identification Number)

**1 Great Valley Parkway, Suite 24  
Malvern, Pennsylvania**  
(Address of principal executive offices)

**19355**  
(Zip Code)

**(484) 320-2930**

(Registrant's telephone number, including area code)

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

Title of each class:	Trading Symbol	Name of each exchange on which registered:
Common Stock, \$0.001 par value per share	TELA	The Nasdaq Global Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.  Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.  Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of June 30, 2021 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common stock held by non-affiliates was approximately \$153.5 million based on the closing price of the common stock as reported on the NASDAQ Global Market on June 30, 2021.

As of March 16, 2022, the registrant had 14,551,869 shares of Common Stock, \$0.001 par value per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement to be filed with the U.S. Securities and Exchange Commission (the "SEC") for TELA Bio's annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this Annual Report on Form 10-K that are not statements of historical or current facts, such as those under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements discuss our business, operations and financial performance and conditions, as well as our plans, objectives and expectations for our business operations and financial performance and condition. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “positioned,” “potential,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. In addition, statements that “we believe” or similar statements reflect our beliefs and opinions on the relevant subject. These forward-looking statements, which are subject to risks, uncertainties and assumptions about us, may include projections of our future financial performance, our anticipated growth strategies and anticipated trends in our business.

You should understand that the following important factors could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in our forward-looking statements:

- the full extent of the impact on our business from the pandemic resulting from the novel coronavirus and the disease it causes, including variants thereof, (“COVID-19”) is highly uncertain and difficult to predict and it may continue to impact our business, results of operations and financial condition, including our revenue (resulting from deferrals of elective procedures using our products), expenses, manufacturing capability, supply chain integrity, research and development activities, and employee-related matters, including compensation;
- any future developments around COVID-19 and the uncertainty of COVID-19, including new information that may emerge, changes in the rate of COVID-19 transmission and infection, the emergence of new variants of COVID-19, the availability of vaccinations for COVID-19, changes in the level of restrictions imposed by governmental authorities (and the resulting impact on the frequency of surgical procedures using our products), access to hospitals, labor and hospital staffing shortages, and other actions taken to contain or treat COVID-19, as well as the economic impact on regional, national and international customers and markets;
- estimates regarding future results of operations, financial position, research and development costs, capital requirements and our needs for additional financing;
- the commercial success and the degree of market acceptance of our products;
- our ability to expand, manage and maintain our direct sales and marketing organization and to market and sell our products in the U.S.;
- the performance of Aroa Biosurgery Ltd. (“Aroa”), in connection with the development and production of our products;
- our ability to maintain our supply chain integrity and expand our supply chain to manage increased demand of our products;
- our ability to compete successfully with larger competitors in our highly competitive industry;
- our ability to achieve and maintain adequate levels of coverage or reimbursement for our current products and any future products we may seek to commercialize;
- our ability to enhance our products, expand our indications and develop and commercialize additional products;
- the development, regulatory approval, efficacy and commercialization of competing products;
- our business model and strategic plans for our products, technologies and business, including our implementation thereof;
- the size of the markets for our current and future products;
- our ability to attract and retain senior management and other highly qualified personnel;
- our ability to obtain additional capital to finance our planned operations;
- our ability to commercialize or obtain regulatory approvals for our products, or the effect of delays in commercializing or obtaining regulatory approvals;
- regulatory developments in the U.S. and internationally;
- the volatility of capital markets and other macroeconomic factors, including due to geopolitical tensions or the outbreak of hostilities or war;

- our ability to develop and maintain our corporate infrastructure, including our internal controls;
- our ability to establish and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others;
- our expectations regarding the use of proceeds from our future public offerings of common stock, if any;
- the occurrence of adverse safety events, restrictions on use with our products or product liability claims; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

These forward-looking statements are based on management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management’s beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe the expectations reflected in the forward-looking statements are reasonable, the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements may not be achieved or occur at all. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Annual Report on Form 10-K or to reflect the occurrence of any unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

## SUMMARY RISK FACTORS

**We are providing the following summary of the risk factors contained in our Form 10-K to enhance the readability and accessibility of our risk factor disclosures. We encourage our stockholders to carefully review the full risk factors contained in this Annual Report on Form 10-K in their entirety for additional information regarding the risks and uncertainties that could cause our actual results to vary materially from recent results or from our anticipated future results.**

### **Risks Related to COVID-19**

- The ongoing COVID-19 pandemic is negatively impacting certain aspects of our business and, depending on the severity and duration beyond current experience, could have a material adverse effect on our business, results of operations and financial condition.

### **Risks Related to Achieving or Sustaining Profitability, Financial Position and Capital Requirements**

- We have incurred significant operating losses since inception, we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability.
- Our indebtedness may limit our flexibility in operating our business and adversely affect our financial health and competitive position.
- We may require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all.
- If we are unable to expand, manage and maintain our direct sales and marketing organizations, we may not be able to generate anticipated revenue.

### **Risks Related to the Commercialization of our Products**

- To date, the vast majority of our revenue has been generated from sales of our OviTex products, and we therefore are highly dependent on the commercial success of our OviTex product line.
- Even if we are able to attain significant market acceptance of our products, the commercial success of our products is not guaranteed.
- If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our OviTex, OviTex PRS or other products we may commercialize in the future, our commercial success may be hindered.
- In the future our products may become obsolete, which would negatively affect operations and financial condition.
- The commercial success of our products will largely depend upon attaining significant market acceptance.

### **Risks Related to Our Reliance on Third Parties**

- We are highly dependent upon Aroa as the exclusive manufacturer and supplier of our products.
- We, or our partners, may experience development or manufacturing problems, capacity constraints, or delays in the production of our products that could limit the potential growth of our revenue or increase our losses.
- Our supply of ovine rumen for use in manufacturing our products may be vulnerable to disruption due to natural disaster, disease or other events.

### **Risks Related to Intellectual Property Matters**

- We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.
- If we fail to comply with our obligations under any license, collaboration or other agreements, we could lose intellectual property rights that are necessary for developing and protecting our products.

- If we are unable to adequately protect our intellectual property rights, or if we are accused of infringing on the intellectual property rights of others, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.
- Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money, enter into license agreements for disputed intellectual property and could prevent us from selling our products.
- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

**Risks Related to Government Regulation**

- Our products and operations are subject to extensive government regulation and oversight both in the U.S. and internationally.
- We may not receive, or may be significantly delayed in receiving, the necessary clearances or approvals for our future products and modifications to our current products may require new 510(k) clearances or premarket approval (“PMA”), and may require us to cease marketing or recall the modified products until clearances or approvals are obtained.
- Although we have obtained regulatory clearance for our products, they will remain subject to extensive regulatory scrutiny.
- If guidelines for soft-tissue reconstruction surgery change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for our OviTex and OviTex PRS products or other products we may commercialize in the future.
- Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our business, financial condition and results of operations.

**Risks Related to Our Business and Products**

- Our financial results may fluctuate significantly and may not fully reflect the underlying performance of our business.
- We may be unable to renew existing or obtain additional contract positions with major group purchasing organizations (“GPOs”) and integrated delivery networks (“IDNs”) for our products, and even if we are able to do so, such contracts may not generate sufficient sales of our products.
- We have limited data and experience regarding the safety and efficacy of our products. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products.
- Interim or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

**Risks Related to Our Securities**

- The trading price of the shares of our common stock has been and could in the future be highly volatile.
- Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.
- We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.
- Provisions in our corporate charter documents and under Delaware law could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

## PART I

### ITEM 1. BUSINESS

#### Overview

We are a commercial-stage medical technology company focused on providing innovative soft-tissue reconstruction solutions that optimize clinical outcomes by prioritizing the preservation and restoration of the patient's own anatomy. Our growing product portfolio is purposefully designed to leverage the patient's natural healing response while minimizing long-term exposure to permanent synthetic materials. We are committed to delivering our advanced technologies with a strong economic value proposition to assist surgeons and institutions in providing next-generation soft-tissue repair solutions to more patients worldwide.

We are dedicated to building true partnerships with surgeons and healthcare providers to deliver solutions that provide both clinical and economic improvements. We believe that genuine collaboration with surgeons and healthcare providers results in the development of new solutions that empower patient care.

Our first portfolio of products, the OviTex Reinforced Tissue Matrix ("OviTex"), addresses unmet needs in hernia repair and abdominal wall reconstruction by combining the benefits of biologic matrices and polymer materials while minimizing their shortcomings, at a cost-effective price. Our OviTex products have received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") which clearance was obtained and is currently held by Aroa, our exclusive manufacturer and supplier. Interim results of our single arm, multicenter post-market clinical study, which we refer to as our BRAVO study, were recently published in the Journal of Clinical Medicine. The interim analysis of patients reaching 12-month follow-up suggests that OviTex is safe and clinically effective for treatment of ventral hernias. The recurrence rate was 2.7% at 12 months. Twenty-four month follow-up has been completed for all possible patients in our BRAVO study, and the recurrence rate remains below 5%. Final analysis is underway and full results will be presented in a future peer-reviewed publication. Our second portfolio of products, the OviTex PRS Reinforced Tissue Matrix ("OviTex PRS"), addresses unmet needs in plastic and reconstructive surgery. In April 2019, our OviTex PRS products received 510(k) clearance from the FDA, which clearance was obtained by Aroa and is currently held by us.

We began commercialization of our OviTex products in the U.S. in July 2016, primarily for hernia repair. Hernia repair is one of the most common surgeries performed in the U.S., representing approximately 1.1 million procedures annually. Our OviTex portfolio consists of multiple products that can be used for ventral hernia repair and abdominal wall reconstruction, inguinal hernia repair and hiatal hernia repair. In addition, to address the significant increase in the number of robotic-assisted hernia repairs over the last several years, we have designed an OviTex product specifically for use in laparoscopic and robotic-assisted surgery called OviTex LPR, which we began commercializing in November 2018.

OviTex PRS is indicated for use in implantation to reinforce soft-tissue where weakness exists in patients requiring soft-tissue repair or reinforcement in plastic and reconstructive surgery. Our OviTex PRS portfolio is supported by non-human primate data that demonstrated more rapid tissue integration and tissue remodeling compared to the market leading biologic matrix used in this indication. The current annual market for biologic matrices used for plastic and reconstructive surgery in the U.S. is approximately \$600 million. We commenced a limited launch in May 2019 and gathered clinical feedback from our initial surgeon users. Based on this feedback, we expanded our commercial launch in June 2020 and expect to continue to expand our access to surgeons. We have also engaged in discussions with the FDA regarding an Investigational Device Exemption ("IDE") protocol to study the safety and effectiveness of our OviTex PRS product for an indication in breast reconstruction surgery. The FDA has stated that a PMA, rather than 510(k) clearance will be required for such an indication.

We have a broad portfolio of intellectual property protecting our products that we believe, when combined with our proprietary manufacturing processes and know-how, provides significant barriers to entry. Our intellectual property applies to our differentiated product construction and materials. In addition, we believe our exclusive manufacturing and long-term supply and license agreement (the "Aroa License") with Aroa creates a competitive advantage by allowing us to secure an exclusive supply of ovine rumen at a low cost. Ovine rumen, the forestomach of a sheep, is the source of the

biologic material used in our products. In manufacturing the product, we use biologic material from ovine rumen because of its plentiful supply, optimal biomechanical profile and open collagen architecture that allows for rapid cellular infiltration. We purchase product from Aroa at a fixed cost equal to 27% of our net sales of licensed products.

We market our products through a single direct sales force, predominantly in the U.S., augmented by distributors in certain European countries. We have invested in our direct sales and marketing infrastructure to expand our presence and to promote awareness and adoption of our products. As of December 31, 2021, we had 46 sales territories in the U.S. As part of our commercial strategy, we plan to continue to invest in our commercial organization by hiring additional account managers, clinical development specialists and administrative support staff to support and service new accounts for soft-tissue reconstruction procedures. We believe we can enhance the productivity of our sales force by improving customer segmentation and targeting, leveraging digital channels to engage customers, and utilizing engagement analytics to support development. We plan to continue to contract with GPOs and IDNs to increase access to and penetration of hospital accounts. However, we will adjust our commercial expansion plan, as appropriate, as we continue to better understand the effects of the pandemic resulting from COVID-19 on our sales and marketing efforts.

Our business has been impacted by the ongoing COVID-19 pandemic and the development of variants of COVID-19. We believe our revenue was slightly impacted during the first quarter of 2021, mostly in January 2021, due to COVID-19 resurgences and the resulting lower surgical procedural volumes, though not at the levels seen in early 2020. This impact subsided throughout the remaining months of the first quarter and the second quarter of 2021. However, we believe our revenue was also impacted in September 2021 and December 2021 due to the surge of new COVID-19 cases relating to new variants and the impact of the surge on surgical procedural volumes. We are continuing to be impacted by postponements in non-emergent procedures in areas of the country where COVID-19 infections are rising or remain high, however, at a less drastic pace than early 2020. Our revenue for the years ended December 31, 2021 and 2020 was \$29.5 million and \$18.2 million, respectively, which represents an increase of \$11.3 million, or 62%. Our net loss for the same time periods was \$33.3 million and \$28.8 million, respectively, which represents an increase of \$4.5 million, or 16%. As of December 31, 2021, we had an accumulated deficit of \$229.9 million. The vast majority of our revenue to date has been generated from sales of our OviTex and OviTex PRS products in the U.S., with the remainder generated from sales of our OviTex products in Europe.

We announced, in November 2021, that we entered into a distribution agreement with Next Science Technologies Pty Limited (“Next Science”), a medical technology company, granting us the exclusive rights to sell and market Next Science’s proprietary antimicrobial surgical wash with XBIO® technology across the U.S. plastic reconstructive market. We will commence private label marketing of the solution for plastic surgery in 2022. Next Science’s XBIO Technology delivers an advanced option for surgical infection control by addressing the biofilms that make bacteria more resistant to traditional antimicrobial agents, disinfectants, and host immune defenses. We believe the infection control solution will expand our service offerings and diversify our supplier base as we continue to create a soft tissue restoration portfolio.

## **Market Opportunity**

### ***OviTex***

Hernia repair is one of the most common surgeries performed in the U.S. There are an estimated 1.1 million hernia repairs annually in the U.S. including recurrences, which we categorize as approximately (i) 60,000 complex/moderate ventral hernia repairs and abdominal wall reconstructions, (ii) 345,000 simple ventral hernia repairs and (iii) 665,000 inguinal hernia repairs. We estimate that there are approximately 40,000 hiatal hernia repairs annually in the U.S.

The healthcare burden of hernia disease to patients, insurers and employers is significant. For the patient, a hernia may cause an increasing level of pain when lifting, straining during urination or a bowel movement, or sitting or standing for long periods of time. Increased pain from the hernia is the most common reason that a patient who is deferring surgical hernia repair will ultimately elect repair surgery. Following surgical hernia repair, convalescence has a significant socioeconomic impact. Absence from work during this period can range from approximately five to 14 days according to one study. Pain is the most common cause of delay in returning to work, followed by wound problems. Long-term pain or discomfort at the hernia repair site is one of the most serious complications of hernia surgery and may, in some cases, persist for years.



Given the limitations of and lack of innovation in existing hernia repair products, we believe a significant market opportunity exists for our portfolio of OviTex products. Based on the volume weighted average selling price of our OviTex products, we estimate the annual U.S. total addressable market opportunity for our OviTex products to be approximately \$1.5 billion.

	Approximate Number of Annual U.S. Hernia Procedures Using Tissue Reinforcement Material	Estimated Annual U.S. Total Addressable Market Opportunity	Traditional Products Utilized
Complex/Moderate Ventral Repair /Abdominal Wall Reconstruction	60,000	\$ 360 million	Biologic Matrices and Resorbable Synthetic Mesh
Simple Ventral Hernia Repair	345,000	\$ 515 million	Permanent Synthetic Mesh
Inguinal Hernia Repair	665,000	\$ 600 million	Permanent Synthetic Mesh
Hiatal Hernia Repair	40,000	\$ 40 million	Biologic Matrices and Resorbable Synthetic Mesh
<b>Total</b>	<b>1,110,000</b>	<b>\$ 1.5 billion</b>	

**OviTex PRS**

Modern advances in tissue engineering have transformed the plastic and reconstructive surgeon’s management strategies across a wide variety of applications. Because biologic matrices incorporate into host tissues and enable revascularization and functional tissue remodeling, surgeons have realized multiple applications for their use, with techniques tailored to the specific requirements of the surgery. There is growing clinical literature validating the use of biologic matrices in head and neck surgery and reconstructions of the chest wall, pelvic region, extremities and breast.

In head and neck surgery, biologic matrices are used for both aesthetic and reconstructive purposes that include: surgery of the nose to change its shape or improve its function, referred to as rhinoplasty; lip augmentation; repair of perforations of the cartilage and thin bone separating the nostrils referred to as the nasal septum; complex reconstruction of the oral and oropharynx cavities after oncologic resection; cleft palate repair; upper and lower eyelid reconstruction; scalp defects and defects of the fibrous membrane covering the brain and spinal cord referred to as dura. In chest wall reconstruction, biologic matrices are used to repair defects from oncologic resections. In pelvic reconstruction, biologic matrices are utilized as an adjunct in the reconstruction of acquired pelvic defects caused by resections for colorectal, gynecologic and urologic malignancies. In extremities reconstruction, biologic matrices are used in the upper extremity for repair of the donor site following the harvest of a radial forearm free flap, a procedure used to harvest tissue and replace it in the head and neck after cancer has been resected. In breast reconstruction, biologic matrices are utilized for prosthetic based reconstruction following the removal of cancerous breast tissue.

Based on the current sales of biologic matrices in the U.S., we estimate the annual U.S. current addressable market opportunity for our OviTex PRS products to be approximately \$600 million. Given the limitations of and lack of innovation in existing biologic matrices for plastic and reconstructive surgical procedures, we believe a significant market opportunity exists for our OviTex PRS portfolio products.

**Current Materials Used in Hernia Repair and Abdominal Wall Reconstruction and Their Limitations**

***Hernia Repair and Abdominal Wall Reconstruction***

The vast majority of hernias are treated with surgical repair. Surgical hernia repair is performed either through open repair, which uses a single incision to open the abdomen or groin across the hernia, or minimally invasive repair, which involves laparoscopic or robotic-assisted techniques. Laparoscopic surgery is a minimally invasive surgical technique performed in the abdomen or groin through small incisions. Surgical instruments and devices, such as mesh products, are then delivered to the surgical site through a trocar, which is an access port to the patient’s abdomen or groin. Robotic-

assisted surgery is also performed using small incisions in the patient's abdomen or groin and a trocar, but the surgeon sits at a console in the operating room and operates the robotic instruments remotely.

At the advent of hernia repair, all procedures were performed using an open surgical technique in which an incision is made through the body to access and repair the hernia. Due to the amount of healthy soft-tissue disruption required for an open procedure, there is a high risk of wound-related complications and seroma formation. In the early 1990s, surgeons began using a laparoscopic approach for hernia repair because it provided the benefits of lower wound complication rates, lower patient morbidity and decreased length of stay for patients. Despite these benefits, laparoscopic surgery presents surgeons with challenges, primarily due to restricted instrument dexterity that makes it difficult to achieve primary closure of the hernia defect, in which the connective tissue layer is sutured close, and leads to a bridged repair. In a bridged repair, the tissue reinforcement material spans a portion of the hernia defect without any connective tissue layer above it to provide additional reinforcement. This leads to increased risk of bulging of the material or hernia recurrence. Robotic-assisted hernia repair addresses this issue while still providing the benefits of a laparoscopic repair. In robotic-assisted repair, the surgeon enjoys greater instrument dexterity and precision, and is able to achieve primary closure of the hernia defect. This has contributed to a significant increase in the number of robotic-assisted hernia repairs over the last several years.

It is estimated that about 90% of hernia repairs today use a form of reconstruction material to provide long-term support at the repair site. Reconstruction materials include synthetic mesh, which can be either permanent or resorbable, and biologic matrices made from tissue material.

In October 2020, we surveyed a group of 71 surgeons to better understand their receptivity to natural repair solutions, their technique preferences across their hernia practice and their views on the risks associated with plastic mesh. Feedback was gathered across inguinal hernia, simple ventral, moderate-to-complex ventral and hiatal hernia repair. Included in the group were 43 general surgeons (61%), 19 plastic reconstructive surgeons (27%) and the remainder were colorectal and trauma surgeons. These surgeons indicated they believe there is a role for natural repair products across all hernia segments and they expect to increase their usage of those products in the next 24 months. Almost 60% of surgeons stated that they are aware of the risks associated with plastic mesh and reported approximately 20% of their hernia patients have voiced concern about the use of plastic mesh within the past 12 months.

#### ***Permanent Synthetic Mesh***

Permanent synthetic mesh, the oldest category of hernia repair materials, is made of plastic materials that are also used in industrial and consumer products. These products have gained popularity with surgeons because they are relatively inert, can be readily sterilized, exhibit biomechanical strength and durability and are available at relatively low upfront cost. Limitations of permanent synthetic mesh products may include:

- significant persistent foreign body inflammatory response that can result in encapsulation of the implant by fibrotic tissue or contraction of the mesh;
- chronic post-operative pain;
- scar tissue formation and lack of regeneration of soft-tissue;
- permanent susceptibility to mesh infection;
- significant cost associated with subsequent repairs or failed and infected mesh;
- compromised abdominal wall anatomy due to damaged and eroded tissue rendering subsequent surgical repairs challenging; and
- migration of the permanent synthetic mesh which can result in organ erosion or perforation.

Many of these complications caused by permanent synthetic mesh require additional surgical intervention, including, explantation of the mesh or repair of hernia recurrence or of the abdominal wall. Based on longitudinal data from the Danish Hernia Database, in an analysis of approximately 2,900 patients who received a hernia repair using a permanent synthetic mesh, the observed rate of surgical intervention due to either recurrence or mesh-related complications at five years post operatively was approximately 17%. As a result of these complications and litigation involving these complications, the number of adverse events reported to the FDA for permanent synthetic mesh hernia repairs has risen from 1,484 in 2016, 3,220 in 2017, 9,887 in 2018 to 18,072 in 2019. Synthetic mesh products have been the subject of an increasing number of lawsuits with over 13,000 cases filed in the state of Rhode Island alone.

### ***Biologic Matrices***

The complications associated with permanent synthetic mesh prompted the development of biologic matrices as a second category of hernia repair materials. Biologic matrices are derived from human or animal dermis, pericardium or intestinal submucosa, which allows them to become replaced entirely by the patient's own tissue over time, a process known as remodeling. The goal behind these biologic materials was to lower the foreign body inflammatory response and biomechanical requirements of the repair, while providing a matrix upon which tissue remodeling could occur. Compared to permanent synthetic mesh, biologic matrices are less likely to induce this inflammatory response and become infected; however, they may have the following limitations:

- lack strength or durability as compared to synthetic mesh products;
- prone to laxity and stretching;
- difficult to handle, leading to longer operating times as compared to synthetic mesh products;
- inability to be placed in a patient through a trocar in laparoscopic or robotic-assisted surgery; and
- considerably more expensive upfront costs than permanent synthetic mesh, typically limiting their use to complex hernia repairs or abdominal wall reconstructions.

Though hernia recurrence occurs with the use of all types of soft-tissue reconstruction, biologic matrices have the highest rates of recurrence, partly due to common use in complex hernia repairs or abdominal wall reconstructions. The RICH study, a multicenter, prospective study sponsored by LifeCell Corporation ("LifeCell") that evaluated the performance of Strattice, the industry leader for biological tissue matrices in complex abdominal wall reconstruction, in open ventral incisional hernia repair in contaminated abdominal wall defects, demonstrated post-operative hernia recurrence rates of 19% and 28% at 12-months and 24-months follow-up, respectively.

### ***Resorbable Synthetic Mesh***

Resorbable synthetic mesh was introduced as a third category of hernia repair materials and as an alternative to permanent synthetic mesh and biologic matrices. Resorbable synthetic mesh was designed with the intended benefits of full degradation over several months, a moderately lower cost than biologic matrices and gradual transfer of strength from synthetic mesh to native tissue over time. Resorbable synthetic mesh is polymer-based and does not include biologic material to promote tissue remodeling and healing. Despite improvements compared to the use of permanent synthetic mesh or biologic matrices, limitations of resorbable synthetic mesh may include:

- significant foreign body inflammatory response that can result in encapsulation or contraction of the mesh until resorbed;
- scar tissue formation and lack of remodeling of soft-tissue;
- mesh infection until resorbed;

- migration of the mesh until resorbed which can result in organ erosion or perforation; and
- lack of mid-term and long-term soft-tissue reinforcement as resorption progresses.

Many of these complications can require additional surgical intervention including explantation of the resorbable synthetic mesh or repair of hernia recurrence or the abdominal wall. Data from a published, multicenter, prospective study sponsored by C.R. Bard, Inc. (now a subsidiary of Becton, Dickinson and Company) that evaluated the performance of Phasix, the current market-leading resorbable synthetic mesh, in CDC Class I, high risk ventral and incisional hernia repair, showed a post-operative hernia recurrence rate of 9% at 18-months follow-up and 18% at 36-month follow-up.

### **Current Materials Used in Plastic and Reconstructive Surgery and Their Limitations**

Biologic matrices are most commonly used in plastic and reconstructive surgery, including surgery of the nose to change its shape or improve its function, referred to as rhinoplasty, lip augmentation, repair of perforations of cartilage and thin bone separating the nostrils, complex reconstruction of the oral and oropharynx cavities after oncologic resection, cleft palate repair, upper and lower eyelid reconstruction, scalp defects, and defects of the fibrous membrane covering the brain and spinal cord, called the dura, because of their ability to define shape and position, improve tissue quality, reinforce existing soft-tissue and reduce the rate of complications associated with a foreign body inflammatory response, however they are prone to excessive stretching over time and difficult for surgeons to handle. These limitations may lead to undesirable results requiring additional surgical intervention. Additionally, biologic matrices are typically expensive to source.

### **Our Solution**

We have created a new category of tissue reinforcement materials that were purposefully designed in close collaboration with more than 100 surgeons to address the unmet clinical needs in soft-tissue reconstruction. Our portfolio of products, designed with over 95% biologic material, combines the benefits of both biologic and polymer materials while addressing their limitations by interweaving polymer fibers through layers of a minimally-processed biologic material. These products are priced competitively and designed for use with a range of surgical techniques, allowing the benefits of an advanced biologic repair to be available to more patients for use in accordance with the products' 510(k) clearances and instructions for use.

The biologic material serves as the natural building block from which we can fabricate devices that meet specific clinical and surgical handling requirements. This material consists of an intact, minimally-processed extracellular matrix derived from ovine rumen, which is the forestomach of a sheep. Polymer fibers are interwoven through the layers of biologic material in unique embroidered patterns and contribute to less than 5% of the overall device by mass. The interwoven polymer utilized can be either permanent, made from polypropylene, or resorbable, made from polyglycolic acid ("PGA"). The embroidering pattern varies between our OviTex and OviTex PRS portfolios to impart different biomechanical properties tailored for their respective intended clinical applications. Our OviTex products are designed with a lockstitch embroidery pattern that is sewn in a grid pattern to create a ripstop effect and minimize stretch. Our OviTex PRS products are designed with a patented corner-lock stitch pattern designed to resist deformation and to control the degree and direction of stretching of the product.

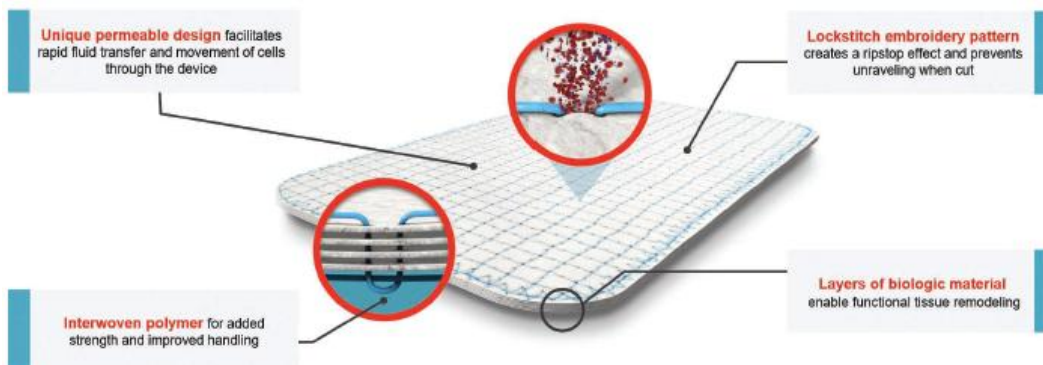
Our capabilities in polymer science, biologics, textile engineering and analytical testing enable us to quickly design, manufacture and develop innovative products. These competencies also allow our technical team to tailor the degree of stretch, direction of stretch, overall strength, handling properties, permeability, thickness, texture, size and shape of each reinforced tissue matrix to suit the needs of particular clinical applications and surgical techniques. This expertise has been utilized in the development of our OviTex and OviTex PRS products and is currently being leveraged in the development of our pipeline products.

Our reinforced tissue matrices are designed to improve the outcomes of soft-tissue reconstructions by reinforcing tissue while allowing rapid tissue integration, revascularization and biomechanical control. In addition to overall strength, a

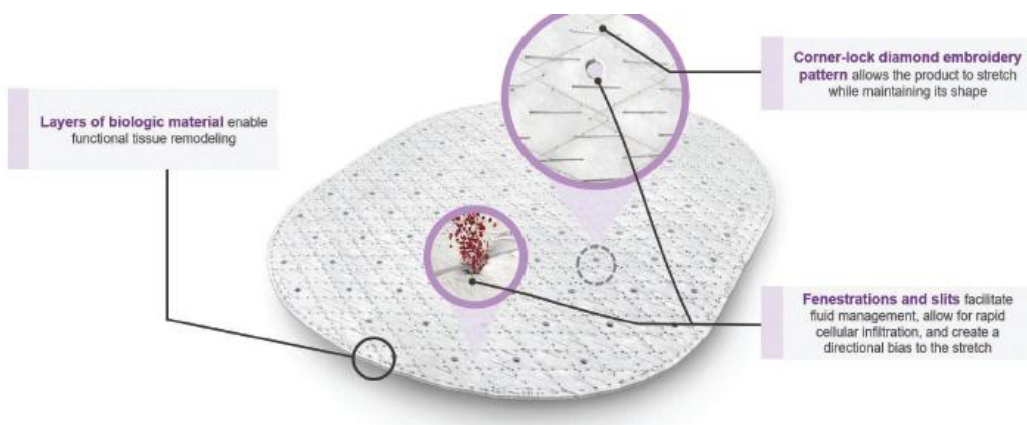
key property that we engineer into our products is the degree to which they stretch, known as compliance. Each of our products is designed to exhibit a degree of compliance appropriate for its intended clinical application.

The graphics below illustrate the key features of our OviTex and OviTex PRS products:

### OviTex



### OviTex PRS



We believe the principal benefits of our reinforced tissue matrices are:

- **Reduced foreign body inflammatory response.** The biologic material utilized in our reinforced tissue matrices acts to reduce the body's inflammatory response to the device. Our unique embroidered patterns create a macroporous grid within the biologic material. The biologic material largely surrounds the polymer and helps attenuate and localize inflammation to zones immediately surrounding the polymer. In our non-human primate comparative study in which we compared our OviTex products to several commercially available synthetic mesh and biologic matrix products, our OviTex products demonstrated a minimal

foreign body inflammatory response similar to that of biologic matrices, and less foreign body inflammatory response than all of the synthetic mesh tested at 24 weeks.

- **Enhanced remodeling of soft-tissue and rate of healing.** Our reinforced tissue matrices are constructed to provide increased surface area and permeability, allowing for rapid absorption of wound fluids and blood during implantation and enabling improved supply of oxygen, cellular infiltration, migration, and repopulation for revascularization and functional tissue remodeling during healing. In our non-human primate comparative study, at 24 weeks the pattern of collagen formation in our OviTex products resembled connective tissue as opposed to the random fibers typical of scar tissue that were seen adjacent to the synthetic mesh. By contrast, the synthetic mesh showed no signs of remodeling of soft-tissue and exhibited a high level of mesh contraction.
- **Ability to tolerate a contaminated wound environment.** Our reinforced tissue matrices are engineered to create hundreds of micro-channels to promote fluid exchange to allow host cells and new blood vessels to penetrate the reinforced tissue matrix. In our non-human primate comparative study, at four weeks our OviTex products had host cells between and within the layers of the reinforced tissue matrix. We believe this early cell infiltration may reduce the potential for bacterial colonization and the risk for infection, although we have not conducted comparative studies in humans.
- **Highly engineered biomechanical properties supported by clinical evidence.** Our reinforced tissue matrices are reinforced with interwoven polymer fibers to provide mid-term and long-term strength. The interwoven polymer increases the strength of our OviTex products by approximately 25% compared to the biologic material alone. When tensile forces are applied, this design allows for load sharing between the biologic material and the polymer during the remodeling process. Data from our strength testing demonstrated that our OviTex products meet or exceed that of published data from market-leading permanent and resorbable synthetic mesh. In our BRAVO study, there were two hernia recurrences in the 76 patients who reached one year follow-up, despite approximately 79% of these patients having one or more factors known to increase the risk of recurrence. Based on this data, we believe that this 2.7% recurrence rate is the lowest reported rate in any prospective study that includes either our biologic or resorbable synthetic mesh competitors. The addition of polymer to our reinforced tissue matrices allows each product to maintain its physiologic compliance properties, while resisting stretching and elongation. In our non-human primate comparative study, our OviTex devices best preserved their original shape, experiencing less contraction compared to biologic and synthetic mesh.
- **Enhanced surgeon handling and satisfaction.** Each of our embroidery patterns was designed specifically to allow the surgeon to trim and shape the product without the polymer unraveling. In addition, based upon our survey of approximately 50 surgeons, our OviTex products conform readily to the contours of surgical sites and are easy to handle, trim, suture and tack in all surgical approaches. In interim data presented from our BRAVO study, 29 of the 76 subjects reaching 12 months follow-up received minimally invasive surgery, 11 received laparoscopic repair and 18 received robotic repair. Of the subjects who received minimally invasive surgery, 26 had surgeon satisfaction scores, with 100% of those surgeons citing the product as being easy to place and the average surgeon satisfaction with the product was 9.7/10 at both 30 and 90 days. In May 2021, we also enrolled our first patient in the BRAVO II study, a prospective study evaluating the robotic repair of ventral hernias with OviTex. This study will utilize OviTex LPR, which has been purposefully designed for minimally invasive procedures, as well as OviTex Core Permanent and OviTex 1S Permanent.
- **Lower upfront cost products.** Our reinforced tissue matrices provide our customers with meaningful cost savings over leading competitive products across a range of clinical uses so that more patients can experience the benefits of an advanced biologic repair solution. We price our OviTex products competitively, and on average, our customers realize 20% to 40% cost savings over leading biologic matrices and resorbable synthetic mesh. Our OviTex PRS portfolio is priced below leading biologic matrices.

## Our Strengths

We are focused on developing and commercializing a new category of tissue reinforcement materials for surgeons and patients that aim to address the shortcomings of existing products. We believe the following strengths will allow us to build our business and potentially increase our market penetration:

- **Innovative and broad portfolio of products.** Our OviTex and OviTex PRS products are the only FDA-cleared products to incorporate polymer fibers interwoven through layers of biologic material in a lockstitch pattern creating an embroidered construction. The biologic matrix is derived from ovine rumen and utilizes a patented process to create a reinforced tissue matrix that is optimized for soft-tissue reconstruction. Our OviTex and OviTex PRS products are available in resorbable and permanent polymer versions in a variety of configurations and sizes. For example, our OviTex devices are currently available in sizes ranging from 4 × 8 cm to 25 × 40 cm, and our OviTex LPR devices are designed with specific thickness, handling properties and shapes optimized for use in laparoscopic and robotic-assisted surgery.
- **Disruptive technology supported by compelling pre-clinical and clinical evidence.** OviTex product technology is supported by extensive pre-clinical research, including bench testing, in vitro and in vivo studies. These studies have demonstrated appropriate physiologic strength for the repair, compliance within the physiologic range of the human abdominal wall, retention of extracellular matrix proteins which may aid in tissue remodeling and porosity and permeability to promote fluid transfer. Our in vivo non-human primate data demonstrated that use of our OviTex products resulted in more rapid tissue integration and revascularization compared to biologic matrices, as well as lower inflammatory response and better functional tissue remodeling compared to permanent and resorbable synthetic mesh. This preclinical data is supported by our compelling clinical evidence showing the safety and efficacy of our OviTex products in published data on over 1,000 hernia patients.
- **Long-term supply agreement that provides pricing flexibility.** Our Aroa License provides for the exclusive supply of ovine rumen and manufacture of our OviTex and OviTex PRS products, which gives us a low and fixed cost of raw materials. We purchase product from Aroa at a fixed cost equal to 27% of our net sales of licensed products.
- **Potential cost savings to healthcare systems and hospitals.** Our pricing flexibility allows us to sell our OviTex and OviTex PRS products to hospitals and healthcare systems at prices substantially below competitive products based on national average competitive pricing. Our OviTex products are sold at prices approximately 20% to 40% lower than other biologic matrices and resorbable synthetic mesh. We believe our pricing flexibility will drive greater adoption of our products. Our OviTex PRS products are priced below leading biologic matrices, and as we continue our launch of our OviTex PRS portfolio, we anticipate that our customers will realize cost savings over biologic matrices based on national average competitive pricing. We believe that the average selling prices across our products will provide financial benefits to our customers in addition to improving clinical outcomes.
- **Established reimbursement pathway for hernia repair.** The implantation of biologic matrices and synthetic mesh for hernia repair is coded using an established fixed procedure payment system known as a MS-DRG that consists of a lump sum payment rate that varies based on the degree of complications and comorbidities of each hernia. In addition, surgeons receive payment for their services depending on the coding associated with the procedure. The MS-DRG-based reimbursement system encourages hospitals to become more efficient in treating patients due to its fixed per-patient reimbursement nature.
- **Broad intellectual property portfolio.** Our products are covered by intellectual property that broadly covers changing a biologic matrix's biomechanical properties by interweaving a polymer thread through the biologic matrix. Specifically, our patents claim the ability to tailor stretch resistance. The ability to predictably control the biomechanical properties of a biologic matrix is the cornerstone of our product portfolio. Our intellectual property also covers the development of extracellular matrix scaffolds derived from ovine rumen, methods for isolating these scaffolds from ovine rumen, layering multiple sheets of

these ovine rumen scaffolds together, sewing in an anti-adhesive layer into a scaffold, and adding unique patterns sewn or embroidered into these scaffolds using different polymers to impart reinforcing strength. Through the Aroa License and our issued or allowed patents and patent applications, we have a broad portfolio of intellectual property that is leveraged in all of our reinforced tissue matrix products. In addition, we believe that the trade secrets developed with Aroa create additional barriers to entry.

- **Industry leading executive team with proven track record.** Our executive team consists of seasoned medical device professionals with deep industry experience, and a broad network of relationships within the industry and the medical community. Our executive team has led and managed companies through significant growth and introduction and commercialization of multiple new products, including driving surgeon adoption of biologic and biosurgery technologies. Members of our team have held leading positions with medical technology companies such as Orthovita Inc., Stryker Corporation, OraSure Technologies, Inc., LifeCell and Medtronic plc. We believe this team is well-positioned to lead us through the commercial expansion of our products and development and launch of future products.

### **Our Growth Strategy**

Our goal is to become the leading provider of soft-tissue reconstruction products. The key elements of our strategy include:

- **Expand our U.S. commercial organization to support our growth.** We sell our products through a single direct sales organization in the U.S. As of December 31, 2021, we had 46 sales territories in the U.S. which are supported by 84 employees in our U.S. based commercial organization. We plan to continue to invest in our commercial organization by adding account managers, clinical development specialists and administrative support staff in order to support and service new accounts for soft-tissue reconstruction procedures. We believe we can also enhance the productivity of our sales force by improving customer segmentation and targeting, leveraging digital channels to engage customers and utilizing engagement analytics to support development.
- **Promote awareness of our products to drive surgeon use.** We educate surgeons regarding the value proposition of our products through presentations and exhibits at industry conferences, medical education symposia, direct training and education, webinars and publishing additional clinical data demonstrating the benefits of our products and establishing online peer-to-peer communities. In response to the restrictions resulting from the ongoing COVID-19 pandemic, we developed a virtual marketing sales solution as well. Most of our sales professionals have used this solution, which includes virtual sales calls with physicians, peer-to-peer discussions with key opinion leaders, physician webinars and sales professional training, instead of in-person sales and marketing programs. We plan to continue to drive awareness of our products through these programs and continue to compliment the in-person visits with our virtual programs, while expanding their geographic reach and increasing the number of surgeon interactions. We will continue to increase our digital marketing efforts as well to build brand awareness with event marketing engagement, targeted ads and emails, various social media efforts and patient education and outreach efforts.
- **Drive utilization through existing GPO and IDN contracts and secure additional contracts.** We are focused on partnering with our existing GPO- and IDN-contracted customers to promote implementation of our contracts, increase our access to surgeon customers, broaden awareness of products and help drive utilization of our products within associated hospitals and healthcare systems. In addition, we continue to pursue contracts with additional GPOs and IDNs. GPO and IDN contracts enable greater access to geographies with high procedural volumes and provide prioritized status within hospital procurement systems.
- **Continue to build upon clinical evidence of the effectiveness and safety of our products.** We are committed to evidence-based medicine and investing in clinical data to support the use of our products. Our interim analysis of patients in the BRAVO study reaching 12-month follow-up was published in the



Journal of Clinical Medicine in 2021 and demonstrated a low recurrence rate of 2.7%. Twenty-four month follow-up has been completed for all possible patients in our BRAVO study, and the recurrence rate remains below 5%. We have begun our next post-market prospective study, BRAVO II, which evaluates OviTex LPR, OviTex Core Permanent and OviTex 1S Permanent in the robotic repair of ventral hernias over 24 months.

- ***Advance our portfolio of reinforced tissue matrices with the introduction of new product features and designs.*** We plan to continue to expand our product offerings and the treatment capabilities of our products to address a broader patient base within soft-tissue reconstruction. As we innovate and develop our products, the new features and improved surgical techniques expand the clinical applications for soft-tissue reinforcement. Areas of focus include enhanced surgical handling, increased permeability, and longer-acting resorbable polymers. Improving the surgical handling and implementation of our devices benefits both the clinician and patient. Increasing product permeability encourages a more-natural healing response. Longer-acting polymers can provide additional support for patients that need more time to heal. We believe these technology enhancements will continue to bolster our portfolio and expand the successful use of our products.

## **Our Products**

### ***Our Technology Platform***

Our advanced reinforced tissue matrix technology consists of multiple layers of minimally-processed, acellular extracellular matrix derived from ovine rumen with interwoven polymer fibers in a unique embroidered pattern. The extracellular matrix is the collagen component of the rumen that is retained following removal of the epithelium, muscle and cellular content, and has an optimal biomechanical profile and open collagen architecture that allows for rapid cellular infiltration. These thin, strong layers of ovine rumen are plentiful in supply and serve as building blocks from which we can construct multilayered devices to customize products to adapt to clinical needs and surgeon preferences. The layers of extracellular matrix provide a high degree of surface area for tissue remodeling. We strengthen these reinforced tissue matrix layers with interwoven polymers, that are either permanent, polypropylene, or resorbable, PGA. These polymers were selected because they are well characterized suture materials with a history of significant clinical use and recognized safety profiles. Polypropylene has a high tensile strength and a low inflammatory response in small quantities. PGA is the fastest resorbing polymer and within three months it tends to be fully absorbed into the body.

Our highly specialized and customizable textile engineering capability allows us to tailor the degree and direction of stretch, overall strength, handling properties, permeability, thickness, texture, size and shape of each reinforced tissue matrix to suit the needs of particular clinical applications and surgical techniques. Our textile engineering utilizes a computer-controlled fabrication method that is scalable, reproducible, efficient and customizable. This embroidery process uses steel gauge needles to interweave the polymer while also creating hundreds of micro-channels to allow the multi-directional passage of the patients' native cells and fluids throughout the product. The interwoven polymers are embroidered using a lockstitch pattern, which allows for the device to be trimmed without fraying, and we use a patented corner-lock pattern, which creates a stable polymer fabric within the biologic material. We manipulate the polymer thread patterns to control the degree and stretch of our products. Denser grid patterns increase the amount of reinforcement and less dense patterns of different geometry allow for greater stretch. We are also able to manufacture products with smooth external layers that minimize the amount of exposed polymer to allow for direct contact with patients' internal organs.

### ***OviTex Reinforced Tissue Matrix***

Our OviTex Reinforced Tissue Matrix has received 510(k) clearance from the FDA, which clearance was obtained and is currently held by Aroa and is intended for use as a surgical mesh to reinforce and/or repair soft-tissue where weakness exists. Indications for use include the repair of hernias and/or abdominal wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome. Our OviTex products can be used in a variety of hernia repairs, including simple and complex ventral, inguinal and hiatal hernias, as well as abdominal wall reconstructions.

Our OviTex products are sterile reinforced tissue matrices derived from ovine rumen with either polypropylene or PGA. The product is provided in a dry and hydratable form and packaged in a double pouched configuration. The product can be stored at room temperature and only needs five minutes of rehydration for use. To be used in surgery our OviTex product is placed in a sterile dish, rehydrated with sterile saline for five minutes, trimmed to fit the site, if needed, and then positioned to achieve maximum contact between the device and the surrounding tissue. The device may be sutured, stapled or tacked into place to avoid excess tension.





All of our OviTex products were designed to minimize the amount of polymer material implanted in patients. The synthetic material in our OviTex products comprise less than 5% of our final product. Depending on the configuration selected, the amount of polymer is approximately 75% less than the polymer content of the most widely implanted permanent synthetic mesh, thereby reducing the patient's foreign body inflammatory response to the polymer.

We market a variety of OviTex products in a range of sizes, thicknesses and degrees of reinforcement in order to suit surgeon preference and desired surgical technique. Our OviTex portfolio is designed to allow surgeons to select a device appropriate for any abdominal tissue plane. Generally, surgeons may place the reinforced tissue matrix in direct contact with internal organs, known as intraperitoneal placement, or away from these internal organs in a variety of tissue planes, known as pre-peritoneal placement. When selecting a product for intraperitoneal placement, surgeons require a surface that minimizes the risk of tissue attachment, whereas when selecting a product for pre-peritoneal placement, surgeons are able to use a product with polymer exposure on both sides. Surgeons may select the most appropriate product from our OviTex portfolio based on the size of the defect, necessity or surgeon preference for internal organ contact, use of a minimally invasive or open surgical technique and risk of infection.

#### ***OviTex Laparoscopic and Robotic Procedures***

Our OviTex for Laparoscopic and Robotic Procedures ("OviTex LPR") is a sterile reinforced tissue matrix derived from ovine rumen with polypropylene fiber intended to be used in laparoscopic and robotic-assisted hernia surgical repairs. OviTex LPR was designed for use with a trocar and requires the same rehydration and fixation as our other OviTex products. This product includes design elements to improve surgical handling, including two extra embroidered lines of blue colored polypropylene fibers to enhance endoscopic orientation and alignment. This product can be introduced into the patient's body through various sized trocar ports. Based on surgeon feedback, OviTex LPR was designed in an elliptical or circular shape to minimize trimming.

**OviTex Portfolio**

	OviTex	OviTex 1S	OviTex 2S	OviTex LPR
				
<b>Size and Shape</b>	4 × 8 cm to 25 × 40 cm* (Rectangle or Square)	4 × 8 cm to 25 × 40 cm* (Rectangle or Square)	4 × 8 cm to 25 × 40 cm* (Rectangle or Square)	12 × 18cm (Ellipse); 9 cm to 15 cm (Round)
<b>Strength</b>	+	++	+++	+
<b>Layers of Ovine Rumen</b>	Four	Six	Eight	Four
<b>Common Procedures</b>	Moderate ventral hernia (pre-peritoneal placement), inguinal hernia, hiatal hernia	Moderate to complex ventral hernia, can be placed intraperitoneally	Complex ventral hernia and abdominal wall reconstruction and can be used for bridging, can be placed intraperitoneally	Laparoscopic or Robotic-assisted surgery
<b>Polymer</b>	Resorbable (PGA) or Permanent (Polypropylene)	Resorbable (PGA) or Permanent (Polypropylene)	Resorbable (PGA) or Permanent (Polypropylene)	Permanent (Polypropylene)
<b>Shelf Life</b>	Resorbable-18 months Permanent-36 months	Resorbable-18 months Permanent-36 months	Resorbable-18 months Permanent-36 months	36 months
<b>Configuration</b>	Exposed polymer on both sides	Exposed polymer on one side, and one smooth side	Two smooth sides	Exposed polymer on one side, and one smooth side
<b>Commercial Availability</b>	· U.S. · Europe	· U.S. · Europe	· U.S. · Europe	· U.S. · Europe

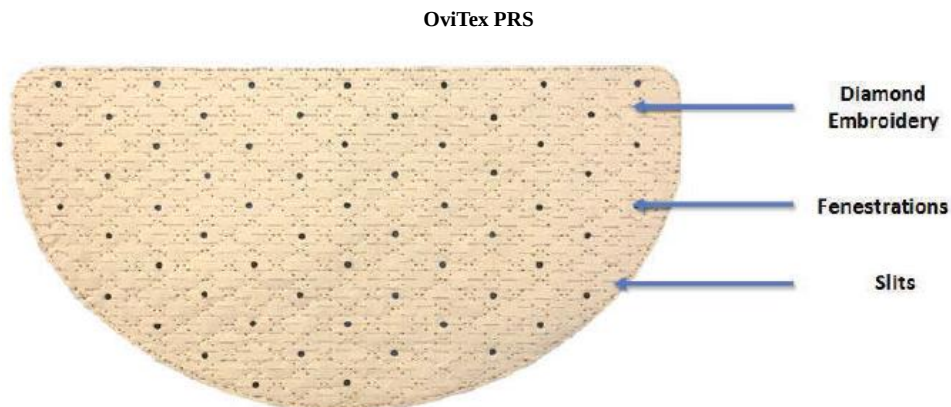
\* 25 x 30 cm and 25 x 40 cm sizes currently only available with permanent (polypropylene) polymer.

+ Denotes relative level of strength

**OviTex Plastic and Reconstructive Surgery — OviTex PRS**

OviTex PRS, has received 510(k) clearance from the FDA, which clearance was obtained by Aroa and is held by us, and is indicated for use in implantation to reinforce soft-tissue where weakness exists in patients requiring soft-tissue repair or reinforcement in plastic and reconstructive surgery. Our OviTex PRS product can be stored at room temperature and comes in the same packaging and requires the same rehydration and fixation as our OviTex products.

Our OviTex PRS product is a sterile reconstructive reinforced tissue matrix composed of three layers of ovine rumen joined by a patented corner-lock embroidered diamond patterned polymer (PGA or polypropylene) that allows the product to stretch while also maintaining its shape. Machine punched regularly spaced fenestrations, or holes, and die-cut slits in the product facilitate fluid management, allow for rapid cellular infiltration and create a directional bias to the stretch. Our OviTex PRS product is available in arced rectangle and half-moon shapes in a range of sizes (4 × 16 cm through 20 × 20 cm) to suit surgeon preference and nature of the soft-tissue repair in plastic and reconstructive surgery. The device may be trimmed to a desired shape to further accommodate individual anatomy. The current shelf life of permanent OviTex PRS is 36 months and the current shelf life of resorbable OviTex PRS is 12 months.



### **Product Pipeline and Research and Development**

We continue to advance our product pipeline to broaden our treatment capabilities for soft-tissue reinforcement. As we innovate and develop our products, the new features and improved surgical techniques expand the clinical applications for soft-tissue reinforcement. Areas of focus include enhanced surgical handling, increased permeability, and longer-acting resorbable polymers. Improving the surgical handling and implementation of our devices benefits both the clinician and patient. Increasing product permeability encourages a more-natural healing response. Longer-acting polymers can provide additional support for patients that need more time to heal. We believe these technology enhancements will continue to bolster our portfolio and expand the successful use of our products.

### **Scientific Evidence**

#### ***Overview of Preclinical and Clinical Programs***

One of our key strategies is to continuously obtain evidence to support the safety and effectiveness of our products, which we believe will differentiate us from our competitors. As part of our strategy to gather and analyze high-quality data, we seek to ensure rigorous and reliable data collection and reporting. The data from our preclinical and clinical studies strengthens our ability to raise surgeon awareness and drive adoption of our products as a new category of soft-tissue reconstruction products. We expect our clinical evidence will provide surgeons with safety and efficacy data on the appropriate use of our products and we plan to obtain further clinical evidence to support additional regulatory clearances or approvals of our reinforced tissue matrices for additional indications for use in the future.

#### ***Preclinical Program***

Our pre-clinical program is paramount in the design of our products. Our program starts with bench performance characterization to ensure proper strength and compliance for the indication, followed by in vitro and in vivo studies to ensure proper biological performance to help promote remodeling of the repair site. We have developed an extensive pre-clinical research library on our devices, as well as on competitor devices. We continue to evaluate new and existing technologies for safety and biocompatibility as part of our product development process.

We believe we have completed the largest non-human primate preclinical studies conducted in soft-tissue reconstruction surgery. In these studies, we compared our OviTex and OviTex PRS products to market leading competitive materials. The results showed our reinforced tissue matrices exhibited a minimal inflammatory response, rapid cellular infiltration and revascularization and demonstrated early and complete remodeling into functional tissue. The OviTex results have been published in the peer-reviewed journal *Hernia* (<https://doi.org/10.1007/s10029-019-02119-z>). We are currently in the process of preparing the OviTex PRS results for a future peer-reviewed publication.

### ***Clinical Program***

We are committed to obtaining evidence to support the safety and efficacy of our products across their indications. Clinical data has been published on over 1,000 patients treated with OviTex across four hernia types including ventral, inguinal, hiatal, and abdominal wall reconstruction. As part of our clinical research program, we have developed two post-market studies, BRAVO, a multi-center prospective study of ventral hernia repair and BRAVO II, a multi-center prospective study of robotic ventral hernia repair. This commitment to generating clinical data through controlled prospective studies with 24-month follow-up will allow us to understand the short- and long-term benefits of using OviTex in hernia repair.

Our BRAVO study concluded with the last patient completing their 24-month follow-up. We are currently in the process of preparing the BRAVO 24-month study data for a future peer-reviewed publication. The 12-month analysis was published in the Journal of Clinical Medicine. The study was fully enrolled at 92 patients. At 90 days post-operative, there were no recurrences among the 84 patients analyzed. There was one implant removal due to a bowel perforation. At 12 months post-operative, there were 76 patients analyzed, of whom twenty-six (34%) had a prior ventral hernia repair and sixty (79%) had factors known to increase the risk of recurrence. Twenty patients (26%) experienced a surgical site occurrence of whom ten (13%) required a procedural intervention such as wound debridement or percutaneous drainage. At 12 months, two patients (2.7%) experienced a recurrence, both adjacent to the original repair. The low recurrence rate observed in our subjects reaching 12-month follow-up continues to remain below 5% through 24-month follow-up.

Surgeons are beginning to utilize our OviTex PRS reinforced tissue matrices in their surgeries and we plan to collect, analyze and support the presentation of clinical data to characterize the performance of our reconstructive reinforced tissue matrices.

### ***Intellectual Property***

Our success depends in part on our ability to obtain, maintain, protect and enforce our proprietary technology and intellectual property rights, in particular, our patent and trademark rights, preserving the confidentiality of our trade secrets, and operating without infringing the valid and enforceable patents and other proprietary rights of third parties. We rely on a combination of patent, trademark, trade secret and other intellectual property rights and measures to protect the intellectual property rights that we consider important to our business. We also rely on know-how and continuing technological innovation to develop and maintain our competitive position.

### ***Aroa License***

In August 2012, we entered into the Aroa License, which was amended and restated in July 2015, pursuant to which we obtained an exclusive license to certain patents and know-how to develop, commercialize and sell bovine and ovine extracellular matrix products for hernia repair, abdominal wall and breast reconstruction in North America and Europe, which we refer to as the Licensed Territory. In addition, under the Aroa License, Aroa is our exclusive manufacturer and supplier for the development of our bovine and ovine extracellular matrix products.

Pursuant to the terms of the Aroa License, we made upfront payments to Aroa totaling \$2.3 million and granted Aroa 74,316 newly issued shares of our restricted common stock. We have made additional payments in the aggregate of \$2.0 million to Aroa following the achievement of certain regulatory and operational milestones, including FDA 510(k) clearance of our OviTex products, which clearance was obtained and is currently held by Aroa, for use in surgical soft-tissue reinforcement and the receipt of the first CE mark for sale of our products in the European Economic Area for use in abdominal wall reconstruction and hernia repair and our acceptance of certain supply quantities manufactured by Aroa for our commercial launch in Europe. In addition, we paid Aroa \$3.0 million in revenue-based milestone payments upon our achievement of certain net sales thresholds for sales of our products within the Licensed Territory. An additional \$1.0 million payment will be made to Aroa when cumulative product net sales of our products in the European territory reach certain amounts.

We are responsible for marketing the products manufactured for us by Aroa. We pay Aroa for the supply and manufacturing of our products through a revenue sharing agreement. Pursuant to the Aroa License, we retain 73% of the net sales of all of our products and pay Aroa the remaining 27%. If at any point during the term of the Aroa License we and Aroa determine that our anticipated product needs exceed Aroa's manufacturing capabilities, we and Aroa will mutually approve an expansion and equally share the cost of such expansion. Our share of such expansion costs may be offset by us against future revenue share payments.

The initial term of the Aroa License terminates on the later of (i) August 3, 2022, or (ii) the expiration of the last patent covering bovine and ovine products currently April 19, 2031, with an option to extend for an additional ten-year period. Either party may terminate the Aroa License upon the other party's material breach, subject to a ninety-day notice and cure period or upon thirty-days written notice in the event of bankruptcy. We may terminate manufacture and production of a specific product upon thirty-days prior written notice upon (i) a reasonable determination that such product infringes the intellectual property rights of a third party, (ii) an uncured supply failure by Aroa or (iii) such product proves unfeasible, and immediately upon written notice from a regulatory authority that such product must be withdrawn from the market. If we materially breach the Aroa License in one of the Licensed Territories, Aroa may terminate the Aroa License solely with respect to the Licensed Territory in which the breach occurred. Upon termination of the Aroa License, we have the right to purchase all or any part of the unsold portion of any completed products from Aroa and the right to continue to sell all products remaining in our inventory.

The Aroa License also contains customary representations and warranties, confidentiality, insurance, audit, indemnification and non-competition provisions.

### **Patents**

As of December 31, 2021, we exclusively license two issued U.S. patents that will expire in 2029 and 2031. We own twelve U.S. issued or allowed patents which will expire between 2035 and 2038 and eight pending U.S. patent applications, which subject to issuance, are projected to expire between 2035 and 2042, without taking into account potential patent term extensions or adjustments. In addition to our U.S. intellectual property, we also own three issued non-U.S. patents and four pending non-U.S. patent applications, which, subject to issuance, would be projected to expire between 2036 and 2037 and have exclusively licensed issued patents in Europe and Canada that will expire in 2029.

Our patents and patent applications cover, among other things, our corner-lock embroidery pattern, the use of adhesion barriers sewn into soft-tissue and compliance associated with stretching.

Although the term of individual patents varies depending upon the country in which they were granted, in most countries, including the U.S., the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the U.S., a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date.

We cannot be sure that our pending patent applications that we have filed or may file in the future will result in issued patents, and we can give no assurance that any patents that have issued or might issue in the future will protect our current or future products, will provide us with any competitive advantage, and will not be challenged, invalidated, or circumvented.

### **Trade Secrets**

We seek to protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to our proprietary information. However, trade secrets and proprietary information can be difficult to protect. While we have confidence in the measures we take to protect and preserve our trade secrets and proprietary information, such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets and proprietary information may otherwise become known or be independently discovered by competitors.

### **Trademarks**

We also rely on trademarks and trade designs to develop and maintain our competitive position. TELA Bio<sup>®</sup>, OviTex<sup>®</sup> and A More Natural Hernia Repair<sup>®</sup> are registered trademarks of ours in the U.S.

For more information regarding the risks related to our intellectual property, please see the section titled “Risk Factors — Risks Related to Intellectual Property Matters.”

### **Research and Development**

We invest in research and development to advance our reinforced tissue matrix products with the goal of improving upon and supplementing our existing product offerings. We believe our ability to rapidly develop, manufacture and obtain regulatory approval or clearance of our products is attributable to the dynamic product innovation process that we have implemented, the versatility and leveragability of our core technology and the management philosophy behind that process. We have recruited and retained engineers and scientists with significant experience in the development of polymer science, biologics, textile engineering and analytical testing. We have a number of design improvements for our reinforced tissue matrices in various stages of development that are expected to enhance our current products and increase surgeon adoption of our products. In addition, we have engaged in discussions with the FDA regarding an IDE protocol to study the safety and effectiveness of our OviTex PRS portfolio for an indication in breast reconstruction surgery. The FDA has stated that a PMA, rather than 510(k) clearance, will be required for such an indication. Our research and development efforts are based at our facility in Malvern, Pennsylvania.

### **Commercial Strategy**

Our commercial efforts are predominantly focused on the U.S. market where we have established strong relationships with key constituencies, including hospitals, ambulatory surgery centers, GPOs, IDN, third-party payors and other key clinical and economic decision makers by offering a unique high quality, cost-effective product. As part of our overall commercial strategy, we intend to contract with GPOs and IDNs to increase access and penetration with hospital accounts. We have invested in our direct sales and marketing infrastructure in order to expand our presence to promote awareness and adoption of our products.

We market our products to hospitals, ambulatory surgery centers, surgeons, GPOs, IDNs and medical device supply chain participants primarily through our direct sales force. Our sales representatives and sales managers have substantial medical device experience. As of December 31, 2021, we had 84 employees in our U.S. based commercial organization in 46 sales territories, which includes account managers and administrative support staff. We plan to continue to invest in our commercial organization by adding account managers, clinical development specialists and administrative support staff in order to cover the highest potential of accounts for soft-tissue reconstruction procedures.

### **Manufacturing**

All our raw materials are sourced through and manufactured by Aroa in their Auckland, New Zealand facility under the terms of the Aroa License. Aroa’s facility is approximately 25,000 square feet of which approximately 10,000 square feet is dedicated to manufacturing. Aroa is in the process of expanding manufacturing capacity, with approximately 15,000 square feet of additional manufacturing space being constructed in a neighboring facility, which we expect to be available in 2022. The Auckland facility is FDA registered and ISO 13485 certified. We believe that Aroa will be capable of providing sufficient quantities of our products to meet anticipated customer demands. In the event of an uncured supply failure by Aroa, we have the right to, directly or through a third-party, step in and operate the Aroa Auckland facility to manufacture our products on behalf of Aroa.

The proprietary ovine rumen used in the manufacturing of our products is obtained from sheep raised for human consumption in New Zealand and is currently sourced by Aroa from two abattoirs, or slaughterhouses. Although only two abattoirs are currently used, there are more than 30 additional abattoirs in New Zealand that could be used to source the ovine rumen. New Zealand cattle and sheep are considered by the USDA to be free of prion disease (progressive neurodegenerative disorders, including scrapie). The sheep receive veterinary inspection prior to slaughter and then each

carcass is inspected post-mortem for the presence of disease according to USDA approved standards. Only sheep which pass full inspection can be used as a raw tissue source for our products and all the ovine rumen is processed in compliance with the FDA's regulations for Medical Devices Containing Materials Derived from Animal Sources. Once the ovine rumen is procured, our reinforced tissue matrix products are then manufactured by Aroa at its facility in Auckland, New Zealand.

### **Distribution**

The majority of our products are shipped directly from Auckland, New Zealand to our headquarters in Malvern, Pennsylvania. We sell our products directly to our customers, which are hospitals and ambulatory surgery centers. Except for our stocking distributors in Europe, we do not use distributors to sell our products.

### **Competition**

The medical device industry is intensely competitive, subject to change and significantly affected by new product introductions and other market activities of industry participants.

In the hernia repair market our primary competitors are Bard, a subsidiary of Becton, Dickinson and Company, which produces Phasix and Ventralight ST, and LifeCell, a subsidiary of AbbVie, which produces Strattice. In the plastic and reconstructive surgery market, our primary competitor is LifeCell, a subsidiary of AbbVie, which produces AlloDerm.

Many of these competitors are large, well-capitalized companies with significantly greater market share and resources than we have. As a consequence, they are able to spend more on product development, marketing, sales and other product initiatives than we can. We also compete with smaller medical device companies that have single products or a limited range of products. Some of our competitors have:

- significantly greater name recognition;
- broader or deeper relations with healthcare professionals, customers and third-party payors;
- more established distribution networks;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- greater financial and human resources for product development, sales and marketing and patent prosecution.

We believe that our continued ability to compete favorably depends on:

- successfully expanding our commercial operations;
- continuing to innovate and maintain scientifically-advanced technology;
- attracting and retaining skilled personnel;
- maintaining and obtaining intellectual property protection for our products; and
- conducting clinical studies and obtaining and maintaining regulatory approvals.



## **Government Regulation**

Our products and operations are subject to extensive and rigorous regulation by the FDA and other federal, state and local authorities, as well as foreign regulatory authorities. The FDA regulates, among other things, the research, development, testing, design, manufacturing, approval, labeling, storage, recordkeeping, advertising, promotion and marketing, distribution, post-approval monitoring and reporting and import and export of medical devices in the U.S. to assure the safety and effectiveness of medical products for their intended use. The Federal Trade Commission also regulates the advertising of our products in the U.S. Further, we are subject to laws directed at preventing fraud and abuse, which subject our sales and marketing, training and other practices to government scrutiny.

### ***Regulatory System for Medical Devices in the U.S.***

All of our medical devices sold in the U.S. are subject to the Federal Food, Drug, and Cosmetic Act (“FDCA”) as implemented and enforced by the FDA.

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the U.S. will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA also referred to as a 510(k) clearance, or approval from the FDA of a PMA application. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

### ***Device Classification***

Under the FDCA, medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the General Controls for Medical Devices, which require compliance with the applicable portions of the Quality Systems Regulations, or QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent to a medical device cleared through the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and special controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA’s satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, preclinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA’s satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

### **510(k) Clearance Pathway**

Our current products are subject to premarket notification and clearance under section 510(k) of the FDCA.

When a 510(k) clearance is required, we must submit a pre-market notification to the FDA demonstrating that our proposed device is substantially equivalent to a predicate device, which is a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. By regulation, a pre-market notification must be submitted to the FDA at least 90 days before we intend to distribute a device. As a practical matter, clearance often takes nine to twelve months, but may take significantly longer. To demonstrate substantial equivalence, the manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or different technological characteristics and the information in the pre-market notification demonstrates that the device is equally safe and effective and does not raise different questions of safety and effectiveness. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is “not substantially equivalent” to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the *de novo* classification procedure, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, a *de novo* classification or PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer’s determination.

Many minor modifications today are accomplished by a manufacturer documenting the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for every change. The FDA can always review these letters-to-file in an inspection. If the FDA disagrees with a manufacturer’s determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

The FDA has undertaken efforts to modernize the 510(k) clearance process. In January 2019, the agency finalized guidance outlining the framework for the Safety and Performance Based Pathway. This option for 510(k) clearance will allow manufacturers to use objective performance criteria established or recognized by the FDA to facilitate demonstration of substantial equivalence of their new products to legally marketed devices. This new pathway will ensure that the performance characteristics of new devices are evaluated against a set of objective, transparent and well-validated safety and performance metrics. Devices using this pathway will still have to meet current standards for reasonable assurance of safety and effectiveness before they can be marketed.

### **De Novo Classification**

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997, or FDAMA, established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the “Request for Evaluation of Automatic Class III Designation,” or the *de novo* classification procedure.

This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk,

rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, a medical device could only be eligible for *de novo* classification if the manufacturer first submitted a 510(k) pre-market notification and received a determination from the FDA that the device was not substantially equivalent to a predicate device. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the *de novo* application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would support a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

### ***The PMA Approval Process***

Class III devices require PMA approval before they can be marketed although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. While our current products are subject to the 510(k) clearance pathway, any future products or modifications to our existing products that we plan to develop for a breast reconstruction indication would be subject to the PMA approval process.

Following receipt of a PMA application, the FDA determines whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA has 180 days to review a filed PMA application, although the review of an application can occur over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided, or the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (e.g., a major deficiency letter) within 360 days. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s).

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The FDA may condition PMA approval on some form of post-market

surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

New PMA applications or PMA supplements are required for changes to an approved device, such as modifications to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require extensive technical or clinical data or the convening of an advisory committee, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also require post-market surveillance for certain devices cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use.

### ***The Investigational Device Process***

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Some types of studies deemed to present a "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed and Institutional Review Board, or IRB approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by an appropriate IRB. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA good clinical practice regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product.

***Pervasive and Continuing FDA Regulation***

After the FDA permits a device to enter commercial distribution, numerous and pervasive regulatory requirements continue to apply to our business operations, products and technologies. These include:

- the FDA's Quality Systems Regulations ("QSR"), which requires manufacturers, including third party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling and marketing regulations which require that promotion is truthful, not misleading, fairly balanced and provides adequate directions for use and that all claims are substantiated;
- complying with new requirements for Unique Device Identifiers on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database;
- advertising and promotion requirements, including FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses and FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- restrictions on sale, distribution or use of a device;
- device establishment, registration and listing requirements and annual reporting requirements;
- approval or clearance of modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- post-market surveillance activities and regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The FDA has broad post-market and regulatory enforcement powers. Medical device manufacturers are subject to unannounced inspections by the FDA and other state, local and foreign regulatory authorities to assess compliance with the QSR and other applicable regulations, and these inspections may include the manufacturing facilities of any suppliers.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, untitled letters, Form 483s, fines, injunctions, consent decrees and civil penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;
- the FDA's refusal of requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- the FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

#### ***Regulatory System for Medical Devices in Europe***

The European Union ("EU") and the European Economic Area ("EEA") (which is comprised of the 27 Member States of the EU plus Norway, Liechtenstein and Iceland and, until 2021, the United Kingdom) has a coordinated system for the authorization of medical devices. The European Union Medical Devices Directive ("MDD") sets out the basic regulatory framework for medical devices in the EU. This directive has been separately enacted in more detail in the national legislation of the individual member states of the EU.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745) ("MDR"), which repeals and replaces the MDD and the Active Implantable Medical Devices Directive. The MDR went into effect on May 26, 2021, and it:

- strengthens the rules on placing devices on the market and reinforces surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- sets up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthens rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

Under both the MDD and the MDR, the system of regulating medical devices operates by way of a certification for each medical device. Each certificated device is marked with a CE mark which shows that the device has a Certificat de Conformité, also referred to as a Certificate of Conformance. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the MDD (and now the MDR) within their jurisdiction. The means for achieving the requirements for CE mark varies according to the nature of the device. Devices are classified in accordance with their perceived risks, similarly to the U.S. system. The class of a product determines the requirements to be fulfilled before a CE mark can be placed on a product, known as a conformity assessment. Conformity assessments for products are carried out as required by the MDD (and now the MDR). Except for low-risk medical devices (Class I

non-sterile, non-measuring devices), where the manufacturer can self-certify compliance with the MDD (and now the MDR) based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a member state of the EEA to conduct conformity assessments, or a Notified Body. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the EU without further conformance tests being required in other member states.

Under transitional provisions provided in the MDR, medical devices that had valid CE Certificates of Conformity issued under the MDD prior to May 26, 2021 may, provided related obligations are respected, continue to be placed on the EEA market for the remaining validity of the certificate, and until May 27, 2024 at the latest. After the expiry of any applicable transitional period, only devices that have been CE marked on the basis of the MDR may be placed on the market in the EEA.

Post-Brexit, the MDR does not apply in the United Kingdom (except for Northern Ireland, which under the Northern Irish Protocol is bound by certain E.U. laws). The medical device legislative framework in the United Kingdom is set out in the Medical Devices Regulations 2002. These Regulations are based on the previous medical device directives of the E.U. but have been amended so that they function properly now the United Kingdom is no longer part of the E.U. The Medical Devices Regulations 2002 have introduced several changes including (but not limited to) replacing the CE mark with a UKCA marking (although E.U. CE marks will be recognized until June 30, 2023), requiring manufacturers outside of the United Kingdom to appoint a “UK Responsible Person” if they place devices on the market in the United Kingdom and more wide-ranging device registration requirements.

### ***Privacy and Security Laws***

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information, including health information. Among others, the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations (collectively referred to as “HIPAA”) establish privacy and security standards that limit the use and disclosure of protected health information, or PHI, and require covered entities and business associates to implement administrative, physical, and technical safeguards to ensure the confidentiality, integrity and availability of individually identifiable health information in electronic form, among other requirements.

Violations of HIPAA may result in civil and criminal penalties. Companies subject to HIPAA must also comply with HIPAA’s breach notification rule which requires notification of affected patients and the U.S. Department of Health and Human Services (“HHS”) and in certain cases of media outlets, in the case of a breach of unsecured PHI. The regulations also require business associates of covered entities to notify the covered entity of breaches by the business associate. State attorneys general also have the right to prosecute HIPAA violations committed against residents of their states, and HIPAA standards have been used as the basis for the duty of care in state civil suits, such as those for negligence or recklessness in misusing personal information. In addition, HIPAA mandates that HHS conduct periodic compliance audits of HIPAA covered entities and their business associates for compliance.

Many states have laws that protect the privacy and security of sensitive and personal information, including health information, to which we are subject. These laws may be similar to or even more protective than HIPAA and other federal privacy laws. For example, California enacted the California Consumer Privacy Act (“CCPA”) which creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA went into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA has been amended from time to time, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. And the CPRA, which will take effect in most material respects on January 1, 2023, modifies the CCPA significantly, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses to comply.

We may be subject to other state and federal privacy laws, including laws that prohibit unfair privacy and security practices and deceptive statements about privacy and security, laws that place specific requirements on certain types of

activities, such as data security and texting, and laws requiring holders of personal information to maintain safeguards and to take certain actions in response to a data breach.

Foreign data protection laws, including the General Data Protection Regulation, (“GDPR”) may also apply to health-related and other personal information belonging to individuals who reside outside of the U.S. The GDPR went into effect in the European Union in May 2018 and introduced strict requirements for processing the personal data of data subjects residing in the European Economic Area. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates cross-border transfers of personal data and requires transferee countries to have protections equivalent to protections available in the EU. Because of the uncertainty created by the Court of Justice of the European Union’s decision invalidating the EU/US Privacy Shield (the primary mechanism to effectuate the flow of data from the EU to the United States), there continues to be uncertainty as to appropriate transfer mechanism for the transfer of data from the EU to the United States.

Further, the United Kingdom’s exit from the European Union, referred to as Brexit, has created uncertainty regarding data protection regulation in the United Kingdom. The United Kingdom has transposed the GDPR into domestic law with a United Kingdom version of the GDPR that took effect in January 2021 (“UK GDPR”). The UK GDPR could expose us or our collaborators to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for violations.

European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised.

#### ***Anti-Kickback Statutes***

The federal Anti-Kickback Statute prohibits persons from (among other things) knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce the referral of an individual, or the recommending, furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid.

Courts have interpreted the Anti-Kickback Statute quite broadly, holding that the statute will be violated if even one purpose of a payment — though not its sole or primary purpose — is to induce an act prohibited by the statute with a willful intent to act improperly. The statute prohibits many arrangements and practices that are otherwise lawful in businesses outside of the healthcare industry. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Prosecutors may infer intent from the surrounding circumstances and, because courts have interpreted the statute to be violated if even one purpose of a payment is to induce the purchase of items or services paid for by federal healthcare programs, prosecutors have broad discretion in choosing arrangements to prosecute under the statute. There are statutory exceptions and regulatory “safe harbors” available to protect certain appropriately structured arrangements that otherwise would implicate the Anti-Kickback Statute and those who structure their business arrangements to satisfy all of the criteria of a safe harbor are protected from liability under the statute. Our business is subject to these laws.

Many states have adopted anti-kickback and self-referral laws similar to the Anti-Kickback Statute; however, some of these state prohibitions are broader in scope and apply to arrangements involving healthcare items or services reimbursed by any source, and not only by Medicare, Medicaid or another federal healthcare program. These state laws do not always have the same exceptions or safe harbors as the federal Anti-Kickback Statute.

#### ***False Claims Laws***

The federal False Claims Act imposes liability on any individual or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam or “whistleblower” provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal



government alleging that the defendant has violated the False Claims Act and to share in any monetary recovery. In recent years, the number of lawsuits brought against healthcare industry participants by private individuals has increased dramatically.

There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government, but also may arise when an entity knowingly makes a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the federal government. Various states have also enacted false claims and insurance fraud laws that are analogous to the federal False Claims Act. Many of these state laws apply to claims submitted to any third-party payor and are not limited to claims submitted to a federal healthcare program. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. A determination of liability under such laws could result in fines and penalties and restrictions on a company's ability to operate in these jurisdictions.

#### ***Transparency Laws***

The federal Physician Payment Sunshine Act ("Sunshine Act") which was enacted as part of the Patient Protection and Affordable Care Act ("PPACA") generally requires certain manufacturers of a drug, device, biologic or other medical supply that is covered by Medicare, Medicaid or the Children's Health Insurance Program and applicable GPOs to report on an annual basis: (i) certain payments and other transfers of value given to certain healthcare professionals and teaching hospitals and (ii) any ownership or investment interest that certain healthcare professionals, or their immediate family members, have in their company. The payments required to be reported include the cost of meals provided to a healthcare professional, travel reimbursements and other transfers of value, including those provided as part of contracted services such as speaker programs, advisory boards, consultation services and clinical trial services. Under the statute, the federal government makes reported information available to the public. Failure to comply with the reporting requirements can result in significant civil monetary penalties or criminal penalties if an entity intentionally makes false statements in the reports.

There has been a recent trend of separate state regulation of payments and transfers of value by manufacturers of medical devices to healthcare professionals and entities, however, and some state transparency laws apply more broadly than the federal Sunshine Act. There are also an increasing number of analogous state laws that require manufacturers to file reports with states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. For example, several states have enacted legislation requiring manufacturers to, among other things, establish and implement commercial compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities and/or register their sales representatives. Certain state laws also regulate manufacturers' use of physician and patient identifiable data. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities. All of our activities are also potentially subject to federal and state consumer protection and unfair competition.

#### ***Other Federal Healthcare Fraud and Abuse Laws***

We may also be subject to other federal healthcare fraud and abuse laws, including provisions of HIPAA, which imposes criminal liability and amends provisions on the reporting, investigation, enforcement, and penalizing of civil liability for, among other things, knowingly and recklessly executing a scheme or artifice to defraud any healthcare benefit program, including private payors, as well as knowingly and willfully falsifying, concealing or covering up a material fact by any trick, scheme or device or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government-sponsored programs. As with the federal Anti-Kickback Statute, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

### ***Foreign Corrupt Practices Act***

The Foreign Corrupt Practices Act (“FCPA”) prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us to maintain books and records, which in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the corporation, including international subsidiaries, if any, and to devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements. Our industry is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. Violations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Enforcement actions may be brought by the Department of Justice or the SEC, and recent enacted legislation has expanded the SEC’s power to seek disgorgement in all FCPA cases filed in federal court and extended the statute of limitations in SEC enforcement actions in intent-based claims such as those under the FCPA from five years to ten years.

### ***International Laws***

In Europe, and throughout the world, other countries have enacted anti-bribery laws and/or regulations similar to the FCPA. Violations of any of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation.

There are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

### ***U.S. Healthcare Reform***

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The U.S. government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls and restrictions on reimbursement.

In the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the healthcare industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms.

There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate. Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select

Committee did not achieve its targeted deficit reduction of an amount greater than \$1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. Subsequent litigation extended the 2% reduction, on average, to 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, which was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 to December 31, 2021. The sequester will remain in place through 2030. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Affordable Care Act has been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions.

Further changes to and under the Affordable Care Act remain possible, but it is unknown what form any such changes or any law proposed to replace or revise the Affordable Care Act would take, and how or whether it may affect our business in the future.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control healthcare costs, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

### **Pricing and Reimbursement**

In the U.S. and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third party payors. Third party payors include government health administrative authorities, managed care providers, private health insurers, and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and there are continuing legislative and regulatory efforts by the federal government and the states to reduce the cost of medical products and services overall. We may need to conduct expensive studies in order to demonstrate the cost-effectiveness of our products. Our product candidates may not be considered cost-effective. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. One third-party payor's decision to cover a particular product or procedure using the product does not ensure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate revenue levels. Future legislation could limit payments for medical devices, including our products and our future products.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of less costly products. Adoption of government controls and measures,

and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for our products. The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the U.S. has increased and will continue to increase the pressure on medical product and service pricing.

### **Corporate Information**

We were incorporated on April 17, 2012.

Our primary executive offices are located at 1 Great Valley Parkway, Suite 24, Malvern, Pennsylvania 19355 and our telephone number is (484) 320-2930. Our website address is [www.telabio.com](http://www.telabio.com). The information contained in, or that can be accessed through, our website is not part of this Annual Report.

### **Human Capital Resources**

As of December 31, 2021, we had 123 employees worldwide. None of our employees are represented by a collective bargaining agreement and we have never experienced a work stoppage. We believe we have good relationships with our employees.

The success of our business is fundamentally connected to the well-being of our employees. Accordingly, we are committed to their health, safety and wellness. We provide our employees and their families with access to a variety of flexible and convenient health and wellness programs, including benefits that provide protection and security so they can have peace of mind concerning events that may require time away from work or that impact their financial well-being; that support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors; and that offer choice where possible so they can customize their benefits to meet their needs and the needs of their families. In response to the ongoing COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, and which comply with government regulations.

We strive to provide a competitive mix of pay, benefits and services that help meet the needs of our employees. In addition to salaries, these programs include variable incentive compensation plans, potential annual discretionary bonuses, stock awards, a 401(k) Plan, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, and flexible work schedules, among others. In addition to our broad-based equity award programs, we have used targeted equity-based grants with vesting conditions to enhance retention of personnel.

## ITEM 1A. RISK FACTORS

*You should carefully consider the following risks described below, together with all of the other information in this Annual Report, including our consolidated financial statements and related notes. While we believe that the risks and uncertainties described below are the material risks facing our business, additional risks that we do not know of or that we currently think are immaterial may also arise and materially affect our business. The realization of any of these risks could have a material adverse effect on our business, financial condition, results of operations, and our ability to accomplish our strategic objectives.*

### **Risks Related to COVID-19**

***The ongoing COVID-19 pandemic is negatively impacting certain aspects of our business and, depending on the severity and duration of the pandemic, could have a material adverse effect on our business, results of operations and financial condition.***

The ongoing COVID-19 pandemic has negatively impacted our business, results of operations and financial condition, and we expect the pandemic to continue to negatively impact our business, results of operations and financial condition. Extraordinary actions have been taken by federal, state and local governmental authorities to combat the spread of COVID-19, including issuance of “stay-at-home” directives and similar mandates for many individuals to substantially restrict daily activities and for many businesses to curtail or cease normal operations. However, while many restrictions have since eased with COVID-19 vaccines now widely available, the elective surgery market faced additional pandemic-related challenges in 2021 due to regional surges in COVID-19 Delta variant cases, staffing shortages and fatigue from care teams addressing significant procedure backlogs. In December 2021, the COVID-19 Omicron variant prompted some government restrictions on elective procedures and surgical staffing challenges which began to ease in January 2022. While these challenges have recently begun to subside, it is unknown how long it will take the elective surgery market to normalize, or if restrictions on elective procedures will recur due to COVID-19 variant strains or otherwise. We do not know if, and how, future restrictions may affect the surgical communities’ return to, or redefining of, normal operations, whether due to governmental restrictions, institutional, patient or clinical decisions or general economic conditions. New or prolonged suspensions of elective surgeries by governmental restrictions or action would cause net sales of our products to decrease.

The health of our workforce is our top concern and we have implemented safety protocols in an effort to maintain the health and safety of our employees. Similar to many other employers in the U.S., we have and may continue to require employees to work remotely. Remote work arrangements could increase operational risk, including, but not limited to, cybersecurity risks. Increased levels of remote access may create additional opportunities for cybercriminals to attempt to exploit vulnerabilities, and our employees may be more susceptible to phishing and social engineering attempts.

Hospitals have reduced and diverted staffing and diverted resources to patients suffering from COVID-19 and have limited hospital access for non-patients, including our sales professionals. In addition, travel restrictions due to COVID-19 have impacted our sales professionals’ ability to travel to customers. These circumstances have negatively impacted our sales professionals’ efforts to market to physicians in person and caused us to develop virtual marketing and sales solutions. If our sales professionals’ efforts to market to physicians in person continue to be negatively impacted, or our virtual marketing and sales solutions prove to be of limited utility or unsuccessful, the sales and market penetration of our OviTex and OviTex PRS products could be negatively impacted.

In addition, the spread of COVID-19 has had, and may continue to have, an impact on the number of patients seeking and receiving hernia repair, abdominal wall reconstruction or plastic and reconstructive surgeries, as hospitals cancel elective surgeries and patients postpone these procedures due to COVID-19 concerns, which may reduce demand for our OviTex and OviTex PRS products and negatively impact our sales and results of operations. Even after the pandemic has subsided and/or governmental orders no longer prohibit or recommend against performing such procedures, patients may continue to defer such procedures out of concern of being exposed to COVID-19 or for other reasons.

COVID-19 has and may continue to have an impact on ports and trade globally. We currently rely on Aroa, which is headquartered in New Zealand, for supply of our products. While there have been minimal disruptions to our supply chain,

there is a risk that in the future supplies of our products may be significantly delayed or may become unavailable as a result of COVID-19 and the resulting impact on Aroa's labor force and operations, including as a result of governmental restrictions on business operations and the movement of people and goods in an effort to curtail the spread of the virus. There can be no assurance that we would be able to timely implement any mitigation plans relating to our supply chain. Disruptions in our supply chain, whether as a result of restricted travel, quarantine requirements or otherwise, could negatively impact our ability to supply and sell our products.

The continued spread of COVID-19 has led to periods of severe disruption and volatility in the global credit or financial markets, and may cause such periods of disruption and volatility in the future, which could result in a decline in our stock price, high inflation, increase our cost of capital and adversely affect our ability to access the capital markets in the future even after local conditions improve. In addition, trading prices on the public stock market have experienced periods of high volatility as a result of the ongoing COVID-19 pandemic.

The full extent to which the ongoing COVID-19 pandemic will further, directly or indirectly, impact our business, results of operations and financial condition, including our sales, expenses, manufacturing capability, supply chain integrity, research and development activities, and employee-related matters, including compensation, will depend on future developments that are highly uncertain, including, variant strains of the virus and the degree of their vaccine resistance and as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related effects.

Information pertaining to the impact of the ongoing COVID-19 pandemic and associated economic disruptions on our operations to date can be found in "Management's Discussion and Analysis of Financial Position and Results of Operations" in this Annual Report on Form 10-K.

### **Risks Related to Achieving or Sustaining Profitability, Financial Position and Capital Requirements**

***We have incurred significant operating losses since inception, we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability.***

We have incurred net losses since our incorporation on April 17, 2012. For the years ended December 31, 2021, 2020 and 2019, we had net losses of \$33.3 million, \$28.8 million and \$22.4 million, respectively. As of December 31, 2021, we had an accumulated deficit of \$229.9 million.

We expect to continue to incur significant sales and marketing, research and clinical development, regulatory and other expenses as we expand our sales and marketing efforts to increase adoption of our products, expand existing relationships with our customers, obtain regulatory clearances or approvals for our planned or future products, conduct clinical trials on our existing and planned or future products and develop new products or add new features to our existing products. As a result, we expect to continue to incur operating losses for the foreseeable future and may never achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations and may cause the market price of our common stock to decline.

***Our indebtedness may limit our flexibility in operating our business and adversely affect our financial health and competitive position.***

As of December 31, 2021, we had \$30.0 million of indebtedness outstanding under our credit facility with OrbiMed Royalty Opportunities II, LP ("OrbiMed") that matures in November 2023.

To service this indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory, and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from operations or that future

borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness, our ability to plan for, or react to, changes in our business, industry and the economy generally will be limited.

In addition, the OrbiMed credit facility contains certain covenants that limit our ability to engage in certain transactions that may be in our long-term best interests. Subject to certain limited exceptions, these covenants limit our ability to, among other things:

- create, incur, assume or permit to exist any additional indebtedness, or create, incur, allow or permit to exist any additional liens;
- enter into any amendment, supplement, waiver or other modification of, or enter into any forbearance from exercising any rights with respect to, the terms or provisions contained in certain agreements without consent;
- effect certain changes in our business, fiscal year, management, entity name, business locations;
- liquidate or dissolve, merge with or into, consolidate with, or acquire all or substantially all of the capital stock or assets of, any other company;
- pay cash dividends on, make any other distributions in respect of, or redeem, retire or repurchase, any shares of our capital stock;
- make certain investments; and
- enter into transactions with our affiliates.

We have not previously breached and are not currently in breach of these or any of the other covenants; however, there can be no guarantee that we will not breach these covenants in the future. In the event that we breach one or more covenants, our lender may choose to declare an event of default and require that we immediately repay all amounts outstanding, terminate any commitment to extend further credit and foreclose on the collateral granted to it to collateralize such indebtedness. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

***We may require substantial additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all.***

If needed, any future funding requirements will depend on many factors, including:

- surgeon and market acceptance of our products;
- the cost of our research and development activities;
- the cost and timing of obtaining regulatory clearances or approvals;
- the cost and timing of establishing additional sales and marketing capabilities;
- the cost and timing of clinical trials that we are currently conducting or may conduct in the future;
- costs associated with any product recall that may occur;
- the effect of competing products in our markets or competing technologies;

- the extent to which we acquire or invest in products, technologies and businesses, although we currently have no commitments or agreements relating to any of these types of transactions;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent or other intellectual property rights; and
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patents or other intellectual property rights.

Any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. In addition, any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. If we raise additional funds through collaboration and licensing arrangements with third-parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us.

Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third-parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our business, financial condition and results of operations.

***If we are unable to expand, manage and maintain our direct sales and marketing organizations, we may not be able to generate anticipated revenue.***

Building the requisite sales, marketing and distribution capabilities to successfully market and sell our products continues to be expensive and time-consuming and requires significant attention from our leadership team to manage. Any failure or delay in the expansion of our sales, marketing or distribution capabilities would adversely impact the commercialization of our products. Additionally, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties on the commercialization of our products. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our products.

As of December 31, 2021, our commercial organization consisted of 84 employees in the U.S. and 7 employees in Europe. To generate future revenue growth, we plan to expand the size and geographic scope of our direct sales organization. This growth may require us to split or adjust existing sales territories, which may adversely affect our ability to retain customers in those territories. Additionally, our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled sales and marketing personnel with significant industry experience and technical knowledge of medical devices and related products. The competition for talented individuals experienced in selling and marketing medical device products is intense, and we cannot assure you that we can assemble or maintain an effective team. We cannot assure you that we will be able to hire and retain additional personnel on favorable or commercially reasonable terms, if at all. Our operating results are directly dependent upon the sales and marketing efforts of our employees. Failure to hire or retain qualified sales and marketing personnel would prevent us from expanding our business and generating revenue. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our products, which could have an adverse effect on our business, financial condition and results of operations.

#### **Risks Related to the Commercialization of our Products**

***To date, the vast majority of our revenue has been generated from sales of our OviTex products, and we therefore are highly dependent on the commercial success of OviTex product line.***

Sales of our OviTex products accounted for 78%, 83% and 91% of total revenue for the years ended December 31, 2021, 2020 and 2019, respectively. We first commercialized OviTex products in the U.S. in 2016 and have introduced our larger sized OviTex products, our OviTex LPR product for use in laparoscopic and robotic-assisted hernia surgical



repairs and OviTex PRS products for use in surgery for soft-tissue repair or reinforcement in plastic and reconstructive procedures. We expect that sales of our OviTex products and our OviTex PRS products, will account for all of our revenue for the foreseeable future. Our failure to successfully increase sales of these products or any other event impeding our ability to sell these products would result in a material adverse effect on our business, financial condition and results of operations.

***The commercial success of our products will largely depend upon attaining significant market acceptance.***

Our ability to execute our growth strategy, achieve commercial success and become profitable will depend upon the adoption by inpatient and outpatient hospitals, surgeons, and medical device supply chain participants of our reinforced tissue matrix products. We cannot predict how quickly, if at all, surgeons will accept our products or, if accepted, how frequently they will be used. Our products and planned or future products we may develop or market may never gain broad market acceptance among surgeons and the medical community for some or all of our indications. Some surgeons may have prior history with or a preference for other soft-tissue reinforcement products, such as permanent synthetic mesh, resorbable synthetic mesh, or other biologic matrices, or may be reluctant to alter their practice patterns to treat patients with our reinforced tissue matrix products. The degree of market acceptance of any of our products will depend on a number of factors, including:

- whether surgeons and others in the medical community consider our products to be safe, effective and cost effective;
- the potential and perceived advantages of our products over alternative products;
- the effectiveness of our sales and marketing efforts for our products;
- the prevalence and severity of any complications associated with using our products;
- the convenience and ease of use of our products relative to competing products;
- product labeling or product insert requirements by regulatory authorities;
- the competitive pricing of our products;
- the quality of our products meeting patient and surgeon expectations;
- the results of clinical trials and post-market clinical studies relating to the use of our products;
- pricing pressure, including from GPOs and government payors;
- the availability of coverage and adequate reimbursement for procedures using our products from third-party payors, including government authorities;
- the willingness of patients to pay out-of-pocket for our products in the absence of coverage and adequate reimbursement by third-party payors, including government authorities; and
- our ability to provide incremental clinical and economic data that show the safety, clinical efficacy and cost effectiveness, and patient benefits from, our products.

Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products or technologies, which are more cost effective or received more favorably, are introduced. Failure to achieve or maintain market acceptance and/or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations.

***Even if we are able to attain significant market acceptance of our products, the commercial success of our products is not guaranteed.***

Our future financial success will depend substantially on our ability to effectively and profitably market and sell our products. Even if we are able to attain significant market acceptance of our products, the commercial success of our products and any of our planned or future products is dependent on a number of additional factors, including the results of clinical trials relating to the use of our products and our ability to obtain and maintain regulatory approval or clearance to market our products and maintain compliance with applicable regulatory requirements. Successful growth of our sales and marketing efforts will depend on the strength of our marketing and distribution infrastructure and the effectiveness of our marketing and sales efforts, including our efforts to expand our direct sales force, while our ability to satisfy demand for our products driven by our sales and marketing efforts will be largely dependent on the ability of Aroa to maintain a commercially viable manufacturing process that is compliant with regulatory standards. If we fail to successfully market and sell our products, we will not be able to achieve profitability, which will have a material adverse effect on our business, financial condition and results of operations.

Our ability to grow our revenue in future periods will depend on our ability to increase sales of our OviTex and OviTex PRS products and any new product or product indications that we introduce, which will, in turn, depend in part on our success in expanding our customer base and driving increased use of our products. New products or product indications may also need to be approved or cleared by the FDA and comparable non-U.S. regulatory agencies to drive revenue growth. If we cannot achieve revenue growth, it could have a material adverse effect on our business, financial condition and results of operations.

***The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of our products for these uses.***

Surgeons and other medical professionals may misuse our reinforced tissue matrix products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance. In addition, any of the events described above could harm our business.

The products we commercialize have been cleared by the FDA and other regulatory authorities for specific indications. Our OviTex products are reinforced tissue matrices designed for use as a surgical mesh to reinforce and/or repair soft-tissue where weakness exists and indications for use of our OviTex products include the repair of hernia and/or abdominal wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. Our OviTex PRS products are reconstructive reinforced tissue matrices designed for implantation to reinforce soft-tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. In connection with the March 2019 meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee, the FDA stated that no surgical mesh device, including OviTex PRS, has been cleared or approved for use in breast surgery, and that to obtain such indication, the product sponsor must obtain an approved PMA. Our OviTex PRS products are not cleared or approved for breast reconstruction surgery and thus we are prohibited from marketing them for that use. OviTex PRS or any other product we may develop for use in breast reconstruction surgery will need to be approved specifically for that indication and there can be no guarantee that it will be approved. We have engaged in discussions with the FDA regarding an IDE protocol to study the safety and effectiveness of our OviTex PRS product for an indication in breast reconstruction surgery. There can be no assurance that we will be able to secure an IDE in a timely manner, or at all. Any marketing for OviTex PRS or any other product for a use in breast reconstruction surgery would be deemed off-label promotion of that product if it has been cleared for a general indication of use to reinforce or repair soft-tissue and has not received an approval specifically for use in breast surgery. We train our marketing personnel and direct sales force to not promote our OviTex or OviTex PRS products for uses outside of the FDA-cleared indications for use, known as "off-label uses." We cannot, however, prevent a surgeon or medical professional from using our OviTex or OviTex PRS products or other products we may commercialize in the future for off-label uses.

Although we train our direct sales force not to promote our products for off-label uses, and our instructions for use in all markets specify that our products are not intended for use outside of those indications cleared or approved for use, the FDA or another regulatory authority could conclude that we have engaged in off-label promotion. If the FDA determines that our promotional or training materials constitute promotion of an off-label use, or make claims that are not supported by the available clinical data, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions. It is also possible that other federal, state or non-U.S. enforcement authorities might take action under other regulatory authority if they consider our business activities to constitute promotion of an off-label use, or are otherwise objectionable, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

Even if surgeons or medical professionals use our OviTex products only for their approved indications, a failure by such surgeons and medical professionals to use our products in accordance with the processes and procedures established to properly utilize our OviTex products could result in product liability lawsuits, costly investigations and potentially affect our ability to achieve sufficient market penetration for our OviTex products. In those possible events, our reputation could be damaged and adoption of the products would be impaired. We may also be required to reassess the training, written instructions and product warnings or other labeling information we provide our customers. This process could require us to expend significant time and capital and could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business.

***If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our OviTex, OviTex PRS or other products we may commercialize in the future, our commercial success may be hindered.***

Our ability to successfully commercialize and achieve market acceptance of our products depends, in significant part, on the availability of adequate financial coverage and reimbursement from third-party payors, including governmental payors (such as the Medicare and Medicaid programs in the U.S.), managed care organizations and private health insurers. The primary customers for our products are hospitals and ambulatory surgery centers who will then seek reimbursement from third-party payors for the procedures performed using our products. While some third-party payors currently cover and provide reimbursement for procedures using our currently cleared or approved products, we can give no assurance that these third-party payors will continue to provide coverage and adequate reimbursement for the procedures using our products, to permit hospitals and surgeons to offer procedures using our products to patients requiring treatment, or that current reimbursement levels for procedures using our products will continue. Additionally, no uniform policy for coverage and reimbursement exists in the U.S. and coverage and reimbursement can differ significantly from payor to payor. If third-party payors reverse or limit their coverage for the procedures using our currently cleared or approved products in the future, this could have a material adverse effect on our business. If we are forced to lower the price we charge for our products, this could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business.

Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives. Third-party payors, whether U.S. or non-U.S., or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs, including examining the cost effectiveness of procedures, in addition to their safety and efficacy, when making coverage and payment decisions. Payors continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage or alter pre-authorization requirements for new or existing procedures. We cannot provide assurance that we will be successful in any efforts we may potentially undertake to reverse such non-coverage decisions. If we are not successful in reversing non-coverage policies, or if third-party payors that currently cover or reimburse certain procedures reverse or limit their coverage of such procedures in the future, or if other third-party payors issue similar policies, our business could be adversely impacted.

***Our long-term growth depends on our ability to enhance our product offerings.***

It is important to our business that we continue to enhance our OviTex and OviTex PRS products and develop and introduce new reinforced tissue matrix products. Developing products is expensive and time-consuming and could divert management's attention away from other aspects of our business. The success of any new reinforced tissue matrix

product offering or product enhancements to our OviTex and OviTex PRS products will depend on several factors, including our ability to:

- properly identify and anticipate surgeon and patient needs;
- develop and introduce new products and product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- ensure the quality, manufacture and supply of new products by Aroa;
- demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials;
- obtain the necessary regulatory clearances or approvals for expanded indications, new products or product modifications;
- be fully FDA-compliant with marketing of new devices or products;
- provide adequate training to potential users of our new products;
- receive adequate coverage and reimbursement for procedures performed with our new products; and
- develop an effective and dedicated sales and marketing team.

If we are not successful in introducing new product indications and developing and commercializing new products and product enhancements, our ability to increase our revenue may be impaired, which could have a material adverse effect on our business, financial condition and results of operations.

***In the future our products may become obsolete, which would negatively affect operations and financial condition.***

The medical device industry is characterized by rapid and significant change. There can be no assurance that other companies will not succeed in developing or marketing devices and products that are more effective than our reinforced tissue matrix products or that would render our reinforced tissue matrix products obsolete or noncompetitive. Additionally, new surgical procedures, medications and other therapies could be developed that replace or reduce the importance of our products. Accordingly, our success will depend in part on our ability to respond quickly to medical and other changes through the development and introduction of new products. Our reinforced tissue matrix products have a limited shelf life and will expire if not timely used. Product development involves a high degree of risk, and there can be no assurance that our new product development efforts will result in any commercially successful products.

***To successfully market and sell our products in markets outside of the U.S., we must address many international business risks with which we have limited experience.***

Approximately 5%, 4% and 2% of our revenue for the years ended December 31, 2021, 2020 and 2019, respectively, came from sales in markets outside of the U.S. Part of our sales strategy is to maintain our European presence. European sales are subject to a number of risks, including:

- difficulties in staffing and managing international operations;
- increased competition as a result of more products and procedures receiving regulatory approval in international markets;
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable;

- fluctuations in currency exchange rates;
- non-U.S. certification and regulatory clearance or approval requirements;
- difficulties in developing effective marketing campaigns in unfamiliar non-U.S. countries;
- the impact of the exit of the United Kingdom from the European Union;
- customs clearance and shipping delays;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- political, social, and economic instability abroad, terrorist attacks, and security concerns in general;
- the global impact of the ongoing COVID-19 pandemic;
- natural disasters and global pandemics like COVID-19, which result in lock-downs, travel restrictions and other restrictions on our ability to operate internationally;
- preference for locally produced products;
- potentially adverse tax consequences, including the complexities of non-U.S. value-added tax systems, tax inefficiencies related to our corporate structure, and restrictions on the repatriation of earnings;
- the burdens of complying with a wide variety of non-U.S. laws and different legal standards; and
- increased financial accounting and reporting burdens and complexities.

If one or more of these risks are realized, our business, financial condition and results of operations could be adversely affected.

#### **Risks Related to Our Reliance on Third Parties**

***We are highly dependent upon Aroa, as the exclusive manufacturer and supplier of our products.***

In August 2012, we entered into our Aroa License which was amended and restated in July 2015. The Aroa License grants us an exclusive license in North America, the EU, United Kingdom, Norway, Switzerland, Russia and former Soviet satellite countries to certain intellectual property rights, including patents relating to the use of bovine and ovine rumen as a source of extracellular matrix. Under the Aroa License, Aroa is our exclusive manufacturer and supplier of our products.

We are reliant upon the intellectual property we license from Aroa for the development and commercialization of our products. Under the Aroa License, we hold an exclusive license to certain intellectual and technology rights to develop, commercialize and sell certain endoform regenerative template products derived from cows and sheep. The Aroa License also provides for cooperative development of our products utilizing the licensed intellectual property and all of our products rely on intellectual property owned by Aroa and licensed to us under the Aroa License. The Aroa License imposes various developmental and regulatory requirements upon us along with requiring us to make milestone payments upon the achievement of certain commercial and regulatory milestones. If we fail to comply with our obligations under the Aroa License, Aroa will have the right to terminate the Aroa License, in which event we would not be able to develop and market our products. We are obligated to pay Aroa up to an aggregate of \$4.0 million in revenue-based milestone payments upon our achievement of certain net sales thresholds for sales of our products within the specified licensed territory, of which we have already paid \$3.0 million.

Aroa is required under the Aroa License to manufacture all of our products at its manufacturing and warehousing facility in Auckland, New Zealand. The production of all of our products in a single location exposes us to the risk of Aroa's facility being harmed or rendered inoperable by natural or man-made disasters or pandemics, which may render it difficult or impossible for Aroa to perform its manufacturing and assembly activities for some time. Although we and Aroa intend to establish redundant production facilities to lessen the risk of production disruptions, we will need to ensure that any manufacturing facility complies with our quality expectations and applicable regulatory requirements. If we are unable to establish redundant manufacturing facilities in a timely manner, any disruption in the manufacture of our products at Aroa's manufacturing and warehouse facility, the continued commercialization of our products, the supply of our products to customers and the development of any new reinforced tissue matrix products will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition and results of operations.

Under the Aroa License, Aroa provides all of the raw materials and components used in the manufacture and assembly of our products. If Aroa is unable to supply the raw materials and components or to manufacture and assemble our products reliably and at the levels we anticipate or that are required by the market, we may be unable to acquire a substitute supply of raw materials and components on a timely basis, if at all. Under the Aroa License Aroa also holds the FDA clearances under which we commercialize our products, and maintains ultimate responsibility for all regulatory interactions with FDA relating to our products and decisions made with respect to changing or updating those clearances. If Aroa fails to comply with all applicable regulatory requirements and maintain the FDA clearances related to our products, we may be unable to commercialize our products on a timely basis, or at all. Our ability to supply our products commercially and to develop any future products depends, in part, on our ability to obtain these materials, components and products in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. While Aroa has historically met our demand for its products and services on a timely basis in the past, we cannot guarantee that it will always be able to meet our demand for its products. If Aroa fails to meet demand or notifies us that it believes it will fail to meet demand for our products, we are required under the Aroa License to work with Aroa to cure its supply failure and may, only in certain circumstances and on a temporary basis, engage a replacement contract manufacturer to mitigate a failure by Aroa to meet demand for our products. As such, we are highly dependent upon Aroa's continued ability to supply our products at the levels we require and any production shortfall that impairs the supply of our products could have a material adverse effect on our business, financial condition and results of operations and adversely affect our ability to satisfy demand for our products, which could adversely affect our product sales and operating results materially.

***We, or our partners, may experience development or manufacturing problems, capacity constraints, or delays in the production of our products that could limit the potential growth of our revenue or increase our losses.***

We may encounter unforeseen situations in Aroa's manufacturing and assembly of our products that would result in delays or shortfalls in its production. For example, Aroa was unable to supply us with our products from September 2017 to December 2017 due to a quality testing process failure identified by Aroa. Personnel shortages and reduced manufacturing capacity due to the ongoing COVID-19 pandemic may also result in a disruption in production.

Based upon our current planned market adoption we believe we will reach our capacity limitations in the Aroa facility. Aroa is in the process of expanding manufacturing capacity, with approximately 15,000 square feet of additional manufacturing space being constructed in a neighboring facility, available in 2022. However, there can be no assurance that the new manufacturing facility will be completed on time or at all. If we are unable to successfully expand capacity, we may not be able to meet the demand for our products. In addition, Aroa's production processes and assembly methods may have to change in order to accommodate any significant future expansion of its manufacturing capacity, which may increase our manufacturing costs, delay production of our products and adversely impact our business. Conversely, if demand for our products shifts such that Aroa's manufacturing facility is operated below its capacity for an extended period, it may adjust its manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.

If Aroa's manufacturing activities are adversely impacted or if it is otherwise unable to keep up with demand for our products by successfully manufacturing, assembling, testing and shipping our products in a timely manner, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead

purchase our competitors' products, which would have a material adverse effect on our business, financial condition and results of operations.

***Our products contain materials derived from animal sources and may become subject to additional regulation.***

Our products are manufactured using ovine rumen. Products that contain materials derived from animal sources are increasingly subject to scrutiny in the media and by regulatory authorities. Regulatory authorities are concerned about the potential for the transmission of disease, particularly progressive neurodegenerative disorders, from animals to humans via those materials. In addition, the ongoing COVID-19 pandemic has heightened public awareness of animals and animal products as a disease vector. Products that contain materials derived from animals, including our products, may become subject to additional regulation, or even be banned in certain countries, because of concern over the potential for the transmission of infectious agents. Significant new regulation, or a ban of our products, could impair our current business or our ability to expand our business, and in the case of a ban or suspension, could have a material adverse effect on our business, financial condition and results of operations.

***Our supply of ovine rumen for use in manufacturing our products may be vulnerable to disruption due to natural disaster, disease or other events.***

The ovine rumen used in the manufacturing of our products is sourced through Aroa in New Zealand. Although Aroa obtains its supply of ovine rumen from jurisdictions with sheep that are not currently known to carry any prion disease (progressive neurodegenerative disorders, including scrapie disease), there can be no assurance that these flocks will remain prion disease-free or that a future outbreak or presence of other unintended and potentially hazardous agents would not adversely affect our products or patients that may receive them. The geographic concentration of our supply chain increases our vulnerability to disruption due to natural disasters, disease or other events. If there is a disruption in the supply of ovine rumen to our manufacturer and supplier, we may be unable to fulfill customer orders or delay the commercialization of new products.

We may also be prohibited from importing our products into the U.S. in the event of disease outbreak or other event impacting the sheep population in New Zealand. Any disruption in our supply lines could have a material adverse effect on our business, financial condition and results of operations.

***Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our products on a timely basis.***

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our OviTex and OviTex PRS products (and would rely heavily on such providers for any other products we may commercialize and ship in the future) to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any of our products, it would be costly to replace such products in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our OviTex and OviTex PRS products (or any other products we commercialize in the future) and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters, disease or other service interruptions affecting delivery services we use would adversely affect our ability to deliver our OviTex and OviTex PRS products (or any other products we commercialize in the future) on a timely basis. For example, disruptions to transportation infrastructure as a result of the ongoing COVID-19 pandemic may impact our ability to provide our products to our customers.

**Risks Related to Intellectual Property Matters**

***We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.***

We may need to obtain licenses from third parties to advance our research or allow commercialization of our products, and we cannot provide any assurances that third-party patents do not exist which might be enforced against our products

in the absence of such a license. The licensing and acquisition of third-party intellectual property rights is a competitive practice and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our products. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected products, which would have a material adverse effect on our business.

***If we fail to comply with our obligations under any license, collaboration or other agreements, we could lose intellectual property rights that are necessary for developing and protecting our products.***

We have licensed certain intellectual property rights covering our current products from third parties, including Aroa. We are heavily dependent on our agreements with such third parties for our current products. If, for any reason, one or more of our agreements is terminated or we otherwise lose those rights, it could harm our business. Our license and other agreements impose, and any future collaboration agreements or license agreements we enter into are likely to impose various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology, having to negotiate new or reinstated licenses on less favorable terms, or enabling a competitor to gain access to the licensed technology.

***If we are unable to adequately protect our intellectual property rights, or if we are accused of infringing on the intellectual property rights of others, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.***

Our commercial success will depend in part on our success in obtaining and maintaining issued patents, trademarks and other intellectual property rights in the U.S. and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We own twelve issued or allowed U.S. patents and have eight pending U.S. patent applications. As of December 31, 2021, we had rights, whether through ownership or licensing, to fourteen issued or allowed U.S. patents, eight pending U.S. patent applications, five issued non-U.S. patents and four pending non-U.S. patent applications. Our issued U.S. patents will expire between 2035 and 2038. The licensed patents will expire between 2029 and 2031.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We cannot provide any assurances that any of our patents, or patents to which we have ownership rights through licensing



agreements, have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our OviTex and OviTex PRS products, any additional features we develop for our OviTex and OviTex PRS products or any new products we seek to develop in the future. Other parties may have developed technologies that may be related or competitive to our OviTex or OviTex PRS products, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal, scientific and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own, or to which we have ownership rights through licensing agreements, may not provide any protection against competitors. Furthermore, an adverse decision in a judicial or administrative proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products.

***Patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. or abroad.***

Although an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors could purchase our OviTex or OviTex PRS products and attempt to replicate the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around the relevant patents, or develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some non-U.S. countries do not protect our proprietary rights to the same extent as the laws of the U.S., and we may encounter significant problems in protecting our proprietary rights in these countries.

In addition, proceedings to enforce or defend our patents, or patents to which we have ownership rights through licensing agreements, could put those patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of those patents are invalid or otherwise unenforceable. If any of the patents covering our OviTex or OviTex PRS products are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

***Third parties may assert ownership or commercial rights to inventions we develop.***

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in such intellectual property. Either outcome could harm our business and competitive position.

***Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money, enter into license agreements for disputed intellectual property and could prevent us from selling our products.***

Our commercial success will depend in part on not infringing the patents or violating other proprietary rights of others. Significant litigation regarding patent rights occurs in our industry. Our competitors may have applied for or obtained, or

may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of patents issued to third parties. In addition, patent applications in the U.S. and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. Patent applications in the U.S., the EU and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to develop and market our products. Third parties may assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from nonpracticing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect.

As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, we expect competitors may claim that one or more of our products infringe their intellectual property rights as a strategy to impede our commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved, and the uncertainty of litigation may increase the risk of business resources and management's attention being diverted to patent litigation. We have received, and we may in the future receive, letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents.

Moreover, we may become party to adversarial proceedings regarding our or third-party patent portfolios. Such proceedings could include supplemental examination or contested post-grant proceedings such as review, reexamination, inter partes review, interference or derivation proceedings before the U.S. Patent and Trademark Office ("USPTO") and challenges in U.S. District Courts. Patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. We may also occasionally use these proceedings to challenge the patent rights of others. We cannot be certain that any particular challenge will be successful in limiting or eliminating the challenged patent rights of the third party.

Any lawsuits resulting from such allegations could subject us to significant liability for damages and/ or invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments;
- incur significant legal expenses, including, in some cases, the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- pay substantial damages (possibly treble damages) or royalties to the party whose intellectual property rights on which we may be found to be infringing;
- redesign products that contain the allegedly infringing intellectual property; and
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay

substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. In addition, we may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give any competitors access to the same technology or intellectual property rights license to us. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a technically feasible way that would not infringe the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain a required license, the holders of any such patents may be able to block us, our licenses or our collaborators from marketing products based on the disputed technology until such patents expire, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations.

Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, importing, marketing or otherwise commercializing our products, services and technology. In addition, if the breadth or strength of protection provided the patents and patent applications we own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products. In addition, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected.

In addition, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.***

We also rely upon copyright and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome of any such claim is unpredictable. Trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed or reverse engineered by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest.***

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our target markets and our business may be adversely affected. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity, possibly leading to market confusion and potentially requiring us to pursue legal action. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. If we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

***We may be unable to enforce our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents covering our products in all countries throughout the world would be prohibitively expensive, and the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Additionally, in the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks, and we may not have adequate resources to enforce our trademarks.

Proceedings to enforce our patent or trademark rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

***Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.***

We employ individuals who previously worked with other companies, including our competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property or personal data, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***Recent changes in U.S. patent laws may limit our ability to obtain, defend and/or enforce our patents.***

The U.S. has recently enacted and implemented wide ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the U.S. federal courts, and the USPTO, the

laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

The USPTO and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and other patent agencies over the lifetime of the patent. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by additional payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance with such provisions will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our product or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, it can create opportunities for competitors to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our products.

***Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.***

The term of any individual patent depends on applicable law in the country where the patent is granted. In the U.S., provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we or our licensors obtain patents covering our products, when the terms of all patents covering a product expire, our business may become subject to competition from products identical or similar to ours. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***We may be unable to patent term extension in the U.S. under the Hatch-Waxman Act and in foreign countries under similar legislation.***

In the U.S., a patent that covers a drug product or medical device approved by the FDA may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our products, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. In the European Union, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

***Intellectual property rights do not necessarily address all potential threats.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our products that is in the public domain;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we may not be able to successfully commercialize our products before our relevant patents we may have, or to which we have ownership rights through licensing agreements, expire;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

**Risks Related to Government Regulation**

***Our products and operations are subject to extensive government regulation and oversight both in the U.S. and internationally.***

Our products are regulated as medical devices. We and our products are subject to extensive regulation in the U.S. and internationally including by the FDA and European Medicines Agency (“EMA”). The FDA, EMA and other foreign equivalents regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; establishment registration and device listing; marketing, sales and distribution; pre-market clearance and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including

reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export.

The regulations to which we are subject are complex, have become more stringent over time and are subject to further change. There is additional uncertainty in light of the new Presidential administration in the U.S. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; untitled letters; Form 483s; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of current approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

***We may not receive, or may be significantly delayed in receiving, the necessary clearances or approvals for our future products and modifications to our current products may require new 510(k) clearances or PMA approvals, and may require us to cease marketing or recall the modified products until clearances or approvals are obtained.***

An element of our strategy is to continue to add new features and expand the indications and uses for our current products. In the U.S., before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the FDCA or approval of a PMA from the FDA, unless an exemption applies. Our products are cleared with the FDA, through clearances obtained and, with the exception of the clearances relating to our OviTex PRS products, held by Aroa, under Section 510(k) of the FDCA, which permits marketing of a device if it is “substantially equivalent” to an already legally-marketed “predicate” device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (preamendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later downclassified, or a 510(k)-exempt device. To be “substantially equivalent,” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. To date, our products have been the subject of cleared 510(k)s, obtained and, with the exception of the clearances relating to our OviTex PRS products, held by Aroa. For more information regarding the regulation of our products, see “Business — Government Regulation.”

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA’s 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, we cannot assure you that any particular device will be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business.

In the U.S., Aroa has obtained and holds 510(k) clearances from the FDA to market our OviTex products and obtained the 501(k) clearances from the FDA held by us for our OviTex PRS products. An element of our strategy is to continue to upgrade our reinforced tissue matrix products. We expect that any such modifications may require new 510(k) clearances; however, future modifications may be subject to the substantially more costly, time-consuming and uncertain PMA process. The FDA will require a PMA, rather than a 510(k) clearance for the use if OviTex PRS in breast surgery. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could cause our sales to decline.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that the product or modification is substantially equivalent to the proposed predicate device or safe and effective for its intended use;
- the data from our preclinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our future products under development. For example, in January 2019, the agency finalized guidance outlining the framework for the Safety and Performance Based Pathway. This option for 510(k) clearance will allow manufacturers to use objective performance criteria established or recognized by the FDA to facilitate demonstration of substantial equivalence of their new products to legally marketed devices. This new pathway will ensure that the performance characteristics of new devices are evaluated against a set of objective, transparent and well-validated safety and performance metrics. Devices using this pathway will still have to meet current standards for reasonable assurance of safety and effectiveness before they can be marketed.

Even after we have obtained the proper regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations. The failure to comply with applicable regulations could jeopardize our ability to sell our reinforced tissue matrix products and result in enforcement actions such as:

- warning letters, untitled letters or Form 483s;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and harm our reputation, business, financial condition and results of operations.

In addition, regulators may determine that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study. Principal investigators for our clinical trials may serve as speakers or consultants to us from time to time and receive compensation in connection with



such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authority. The FDA or other regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or other regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our future products.

To sell our products in member countries of the EEA our products must comply with the essential requirements of the EU Medical Devices Regulation (Regulation 2017/745) (“MDR”), which was passed by the EU Parliament on April 5, 2017, and became effective on May 26, 2021. The MDR repeals and replaces the former Medical Devices Directive (Council Directive 93/42/EEC) and the Active Implantable Medical Devices Directive (Council Directive 90/385/EEC). Compliance with the new MDR requirements is a prerequisite to be able to affix the Conformité Européenne, or CE, mark to our products, without which they cannot be sold or marketed in the EEA. In the EEA, we have obtained the CE mark for our OviTex products. For more information regarding regulation of our products, see “Business—Government Regulation.”

An element of our strategy is to continue to add new features and expand the indications and uses for our current products. Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer’s decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. Such modifications can be expensive and uncertain in time and outcome. We may not be able to obtain additional 510(k) clearances or PMAs for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our products in the past and expect to make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for these modifications, we may be required to recall and to stop selling or marketing such products as modified until we obtain clearance or approval, which could harm our operating results and require us to redesign such products. In these circumstances, we may be subject to significant enforcement actions, including significant fines or penalties.

International regulatory approval processes may take more or less time than the FDA clearance or approval process. If we fail to comply with applicable FDA and comparable non-U.S. regulatory requirements, we may not receive regulatory clearances or approvals or may be subject to FDA or comparable non-U.S. enforcement actions.

We may be unable to obtain future regulatory clearance or approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. A failure or delay in obtaining necessary regulatory clearances or approvals would materially adversely affect our business, financial condition and results of operations.

***Although we have obtained regulatory clearance for our products, they will remain subject to extensive regulatory scrutiny.***

We are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacturing, marketing, advertising, medical device reporting, selling and promoting our products. For example, we must submit periodic reports to the FDA as a condition of our clearance under Section 510(k). These reports include safety and effectiveness information about the device after its clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA.

Even after we have obtained the proper regulatory approval to market our products, they will be subject to ongoing regulatory requirements for design, development, manufacturing, testing, labeling, packaging, storage, advertising,

promotion, sampling, record-keeping, recalls and field safety corrective actions, conduct of post-marketing studies and submission of safety, effectiveness and other post-market information, including both federal and state requirements in the U.S. and requirements of comparable non-U.S. regulatory authorities. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, EMA and applicable state regulatory authorities, which may include any of the following sanctions:

- issue warning or untitled letters that would result in adverse publicity or may require corrective advertising;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our products;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future clearances under Section 510(k) or pre-market approvals or EU regulatory approvals of new products, new intended uses, or modifications to existing products;
- withdrawal or suspension of regulatory clearances or approvals;
- FDA refusal to issue certificates to non-U.S. governments needed to export products for sale in other countries; and
- criminal prosecution.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition and results of operations.

***Our products must be manufactured in accordance with federal and state regulations, and we could be forced to recall our products or terminate production if we fail to comply with these regulations.***

The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's QSR which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, Aroa must maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various EU laws and regulations governing manufacturing.

Aroa may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. For example, following an inspection in March 2017, Aroa received an FDA Form 483 that contained multiple observations related to its manufacturing processes and procedures. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: untitled letters or warning letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us or our employees.

Any of these actions could significantly and negatively affect supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs.

***If guidelines for soft-tissue reconstruction surgery change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for our OviTex and OviTex PRS products or other products we may commercialize in the future.***

If guidelines for soft-tissue reconstruction surgery change or the standard of care for reconstructing tissue evolves, we may need to redesign the applicable product and seek new approvals from the FDA. Our clearances under Section 510(k) of the FDCA are based on current soft-tissue reconstruction surgery guidelines. If the guidelines change so that different surgeries or products become desirable, the clinical utility of one or more of our OviTex and OviTex PRS products or other products we may commercialize in the future could be diminished and our business could be adversely affected.

If any of our products cause or contribute to a death, serious injury, or other adverse medical events, or malfunction in certain ways, we will be required to report these events to FDA and other comparable regulatory authorities under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. If we fail to comply with our reporting obligations, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar EU and other foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including untitled letters, warning letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of related approvals, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory agencies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. For example, in April 2018, Aroa, as the product manufacturer, issued a voluntary recall of our resorbable OviTex products due to a reduction in the labeled shelf life of such products from 24 months to 18 months. The recall included a total of 1,974 units from 48 manufacturing lots and was ultimately terminated in April 2019. A government-mandated or voluntary recall by us could also occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

***Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained.***

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices, or the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our future products under development. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance of or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. There is additional uncertainty in light of the new Presidential administration. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i.e., without the need for adoption of EEA member state laws implementing them, in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The Medical Devices Regulation is intended to, among other things, establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

The MDR became fully effective on May 26, 2021. It includes new regulations which, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- establish a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and

- strengthen rules for the assessment of certain high-risk devices, which may have to undergo an additional check by experts before they are placed on the market.

Failure to comply with these regulations may harm our business.

***Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. There is additional uncertainty in light of the new Presidential administration.

Disruptions at the FDA and other agencies may also slow the time necessary for new devices to be reviewed and/or approved or cleared by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***Our relationships with surgeons, patients and payors in the U.S. are subject to applicable anti-kickback, fraud and abuse laws and regulations.***

Our current and future operations with respect to the commercialization of our products are subject to various U.S. federal and state healthcare laws and regulations. These laws impact, among other things, our proposed sales, marketing, support and education programs and constrain our business and financial arrangements and relationships with third-party payors, surgeons and other healthcare professionals. The laws are described in greater detail in the section below under “Business — Government Regulation,” and include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims laws, including the civil False Claims Act (which can be enforced through “qui tam,” or whistleblower actions, by private citizens on behalf of the federal government), which prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a

person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the Centers for Medicare and Medicare Services, or CMS, information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- state laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug and device manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare or medical device company may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. Certain physicians who influence the ordering or use of our products in procedures they perform have ownership interests in us and/or receive compensation for consulting services provided to us. It is possible that governmental authorities will conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance.

To enforce compliance with healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may also have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlements could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting requirements if we become subject to a corporate integrity agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to the same criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

***We are subject to anti-bribery, anti-corruption, and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act, in which violations of these laws could result in substantial penalties and prosecution.***

We are exposed to trade and economic sanctions and other restrictions imposed by the U.S. and other governments and organizations. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the U.S. Foreign Corrupt Practices Act, or the

FCPA, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control. In addition, the U.K. Bribery Act of 2010 (“Bribery Act”), prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that “fails to prevent bribery” by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented “adequate procedures” to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations.

***We face risks related to our collection and use of data, which could result in investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices.***

Our business processes personal data, including some data related to health. When conducting clinical trials, we face risks associated with collecting trial participants’ data, especially health data, in a manner consistent with applicable laws and regulations. We also face risks inherent in handling large volumes of data and in protecting the security of such data. We could be subject to attacks on our systems by outside parties or fraudulent or inappropriate behavior by our service providers or employees. Third parties may also gain access to users’ accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and may use such access to obtain users’ personal data or prevent use of their accounts. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, California enacted the CCPA on June 28, 2018, which took effect on January 1, 2020. The CCPA created individual privacy rights for California consumers and increased the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches in certain instances that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Additionally, a new privacy law, the California Privacy Rights Act, or the CPRA, was approved by California voters in the election of November 3, 2020. The CPRA, which will take effect in most material respects on January 1, 2023, modifies the CCPA significantly, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses to comply. A failure to comply with these current or future federal and state laws and regulations and industry standards relating to data privacy and security could lead to investigatory or regulatory action, private litigation or class actions that could result in exposure to civil or criminal penalties, monetary or statutory damages, attorney fee awards and/or exposure to adverse publicity that could negatively affect our operating results and business.

This risk is enhanced in certain jurisdictions as we expand our operations internationally. The EU’s GDPR became effective in May 2018. The GDPR applies extraterritorially and imposes several stringent requirements for controllers and processors of personal data, of data subjects residing in the European Economic Area. For example, the GDPR imposes higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of personal data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. This risk is increased because the GDPR provides that EU member states may make their own laws and regulations limiting the processing of personal data, including special categories of data

(e.g., racial or ethnic origin, political opinions, religious or philosophical beliefs) and profiling and automated individual decision-making of individuals, which could limit our ability to use and share personal data or other data and could cause our compliance costs and liability risks to increase, harming our business and financial condition.

The GDPR also regulates cross-border transfers of personal data and requires transferee countries to have protections equivalent to protections available in the EU. Because of the uncertainty created by the Court of Justice of the European Union's decision invalidating the EU/US Privacy Shield (the primary mechanism to effectuate the flow of data from the EU to the United States), there continues to be uncertainty as to appropriate transfer mechanism for the transfer of data from the EU to the United States. Further, the United Kingdom's exit from the European Union, referred to as Brexit, has created uncertainty regarding data protection regulation in the United Kingdom. The United Kingdom has transposed the GDPR into domestic law with a United Kingdom version of the GDPR that took effect in January 2021 (UK GDPR). The UK GDPR could expose us or our collaborators to two parallel regimes, each of which potentially authorizes similar fines and other potentially divergent enforcement actions for violations. In addition, uncertainties related to compliance with the GDPR exist with respect to the UK GDPR. Non-compliance with GDPR is subject to significant penalties, including fines of up to €20.0 million or 4% of total worldwide revenue, whichever is greater. The implementation and enforcement of the GDPR may subject us to enforcement risk and requirements to change certain of our data collection, processing and other policies and practices. We could incur significant costs investigating and defending such claims and, if we are found liable, significant damages. If any of these events were to occur, our business and financial results could be adversely affected. Other jurisdictions outside the EU are similarly introducing or enhancing laws and regulations relating to privacy and data security, which enhances risks relating to compliance with such laws.

Compliance with U.S. federal and state laws and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with United States and foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. And claims that we have violated individuals' privacy rights, failed to comply with data protection laws or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

***The Affordable Care Act and any changes in healthcare law may increase the difficulty and cost for us to successfully commercialize our products and affect the prices we may obtain.***

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the healthcare industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms.

There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate. Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than \$1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. Subsequent litigation extended the 2% reduction, on average, to 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, which was



designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 to December 31, 2021. The sequester will remain in place through 2030. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Affordable Care Act has been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions.

Further changes to and under the Affordable Care Act remain possible, but it is unknown what form any such changes or any law proposed to replace or revise the Affordable Care Act would take, and how or whether it may affect our business in the future.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control healthcare costs, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain and maintain profitability of our product and product candidates, if approved.

***Our business involves the use of hazardous materials and we and Aroa must comply with environmental laws and regulations, which may be expensive and restrict how we do business.***

Aroa’s activities in manufacturing our products may involve the controlled storage, use and disposal of hazardous materials. Aroa is or may be subject to federal, state, local and non-U.S. laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials.

Although we believe that Aroa’s safety procedures for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, federal, state or other applicable authorities may curtail Aroa’s use of these materials and interrupt their business operations which could adversely affect our business.

Compliance with environmental laws and regulations may be expensive and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and results of operations.

## **Risks Related to Our Business and Products**

***Our financial results may fluctuate significantly and may not fully reflect the underlying performance of our business.***

Our quarterly and annual results of operations may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control.

Factors that may cause fluctuations in our quarterly and annual results include:

- surgeon and patient adoption of our products;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- changes in coverage policies by third-party payors that affect the reimbursement of procedures in which our products are used;
- unanticipated pricing pressure;
- our ability to obtain and maintain regulatory clearance or approval for any products in development or for our current products for additional indications or in additional jurisdictions;
- the hiring, retention and continued productivity of our sales representatives;
- our ability to expand the geographic reach of our sales and marketing efforts;
- results of clinical research and trials on our existing products and products in development;
- delays in, or failure of, component and raw material deliveries by Aroa;
- recalls or other field safety corrective actions by Aroa;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters such as earthquakes, floods or public health emergencies such as the ongoing COVID-19 pandemic; and
- positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry.

Because our quarterly and annual results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business. In particular, we cannot predict at this time the extent of the impact that the ongoing COVID-19 pandemic will have on our sales and financial results. These fluctuations may also increase the likelihood that we will not meet our forecasted performance, which could negatively affect the market price for our common stock.

***We may be unable to compete successfully with larger competitors in our highly competitive industry.***

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, our products. Because of the complex and technical nature of our products and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could

materially harm our ability to develop and commercialize our products, which would have a material adverse effect on our business, financial condition and results of operations.

In the U.S., we currently compete with LifeCell Corporation, a subsidiary of AbbVie, and Davol Inc., a subsidiary of Becton, Dickinson and Company, which produce, among other things, soft-tissue reconstruction surgery products, including Strattice and Phasix, respectively. In the EEA, we compete with Bard, a subsidiary of Becton, Dickinson and Company, who produces other soft-tissue reinforcement products. Many of these competitors are large, well-capitalized companies with significantly greater market share and resources than us. As a consequence, they are able to spend more on product development, marketing, sales and other product initiatives than we can. We believe other emerging businesses are in the early stages of developing similar products designed for soft-tissue reconstruction surgery. Although we are the only ovine-derived implantable product designed for soft-tissue reconstruction surgery, there are other soft tissue reconstruction surgery products derived solely, or in part, from other biological sources.

Most of the other soft-tissue reconstruction surgery products currently have a greater penetration into the soft tissue reconstruction surgery market. Often, other soft-tissue reconstruction surgery products with which our products compete are marketed as part of a bundled product line, which may provide our potential customers a better price-per-product than we could offer. If we are unable to penetrate the soft-tissue reconstruction surgery market or offer competitive pricing on our products compared with products sold as part of a bundled product line, it could have a material adverse effect on our business, financial condition and results of operations.

In addition, competitors with greater financial resources could acquire other companies to gain enhanced name recognition and market share, as well as new technologies or products that could effectively compete with our existing products, which may cause our revenue to decline and would harm our business.

***We may be unable to renew existing contracts with GPOs or obtain additional contract positions with major GPOs and integrated delivery networks, or IDNs, for our products, and even if we are able to do so, such contracts may not generate sufficient sales of our products.***

Many existing and potential customers for our products within the U.S. are members of GPOs and IDNs, including accountable care organizations or public-based purchasing organizations, and our business strategy is focused on entering into major contracts with these organizations. Our products can be contracted under national tenders or with larger hospital GPOs. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. We are currently responding to bids and negotiating a number of GPO and IDN agreements.

We may not be able to renew existing contracts with GPOs or IDNs and due to the highly competitive nature of the bidding process and the GPO and IDN contracting processes in the U.S., we may not be able to obtain additional contract positions with major GPOs and IDNs for our products. If we are unable to renew existing contracts with GPOs or IDNs, our net sales and results of operations may be materially and adversely affected. In addition, while having a contract with a major purchaser for a given product category can facilitate sales, sales volumes of those products may not be maintained. For example, GPOs and IDNs are increasingly awarding contracts to multiple suppliers for the same product category. Even if we are the sole contracted supplier of a GPO or IDN for our product category, members of the GPO or IDN generally are free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause upon 60 to 90 days' notice.

***Supply chain disruptions could adversely impact our operations and financial condition.***

Global supply chains have been disrupted because of the COVID-19 pandemic and other factors, and this may impact the availability of raw materials and components used in the manufacture of our products. Additionally, even when we and our suppliers are able to source such materials and components, they may cost more and may only be available on a delayed basis. Higher materials and component costs could adversely affect our margins if we are unable to pass such costs along to customers in the form of price increases. Delays in receipt of materials and components could also interrupt our production and cause us to go into backorder on certain of our products, further exacerbating the effect of the global supply chain disruption.

***We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business.***

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. This risk exists even if a product is cleared or approved for commercial sale by the FDA or EMA, and manufactured in facilities licensed and regulated by the FDA or EMA. Any side effects, manufacturing defects or misuse associated with our products could result in patient injury or death. The industry in which we operate has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if our products cause, or merely appear to have caused, patient injury or death. In addition, an injury that is caused by the activities of Aroa may be the basis for a claim against us. Product liability claims may be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with our products. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in substantial litigation costs, product recalls or market withdrawals, decreased sales and demand for our products and damage to our reputation.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, financial condition and results of operations.

Although we have product liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. In addition, our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

***The continuing development of our products depends upon our maintaining strong working relationships with surgeons.***

The research, development, marketing and sale of our current and future products and any future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with surgeons. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Surgeons assist us in clinical trials and in marketing, and as researchers, product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition and results of operations. At the same time, the medical device industry's relationship with surgeons is under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General ("OIG"), the U.S. Department of Justice ("DOJ"), the state attorneys general and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry's relationships with surgeons or an investigation into our compliance by the OIG, the DOJ, state attorneys general and other government agencies, could have a material adverse effect on our business, financial condition and results of operations. Additional information regarding the laws impacting our relationships with surgeons and other healthcare professionals can be found above under "Risks Related to Government Regulation."

***We have limited data and experience regarding the safety and efficacy of our products. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products.***

Our single arm multicenter post-market clinical study, which we refer to as our BRAVO study, was fully enrolled at 92 patients. We conducted this study to support the marketing of our OviTex products for their cleared indicated uses, and do not currently have any clinical data for use of our OviTex PRS products in patients. The long-term effects of using our products in a large number of patients have not been studied and the results of short-term clinical use of such products do not necessarily predict long-term clinical benefits or reveal long-term adverse effects. The results of preclinical studies and clinical studies of our products conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials in other patient populations. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials.

***Interim or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose interim or preliminary data from our BRAVO studies or other clinical studies that we may conduct in the future, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a full analyses of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim or preliminary data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the interim or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to use such results to support the marketing of our products may be jeopardized.

***The sizes of the markets for our current and future products have not been established with precision, and may be smaller than we estimate.***

Our estimates of the annual total addressable markets for our current products and products under development are based on a number of internal and third-party estimates, including, without limitation, the number of hernia and soft-tissue reconstruction surgery patients and overall market and the assumed prices at which we can sell our products. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the

predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our products may prove to be incorrect. If the price at which we can sell future products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

***Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.***

Our reinforced tissue matrix products have a limited shelf life and will expire if not timely used. To ensure adequate inventory supply, we must forecast inventory needs and place orders with Aroa based on our estimates of future demand for our reinforced tissue matrix products. Our ability to accurately forecast demand for such products could be negatively affected by many factors, including:

- product introductions by competitors;
- an increase or decrease in surgeon demand for our products or for products of our competitors;
- our failure to accurately manage our expansion strategy;
- our failure to accurately forecast surgeon acceptance of new products;
- our failure to obtain contracts with a significant number of GPOs and IDNs;
- unanticipated changes in general market conditions or regulatory matters;
- the severity and duration of market disruptions as a result of the COVID-19 outbreak; and
- weakening of economic conditions or consumer confidence.

Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Additionally, we are subject to the risk that a portion of our inventory will expire, which could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. Conversely, if we underestimate customer demand for our products, Aroa may not be able to deliver products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or Aroa may not be able to allocate sufficient capacity to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

***We rely on our own direct sales force for our products, which may result in higher fixed costs than our competitors and may slow our ability to reduce costs.***

We rely on our own direct sales force, which as of December 31, 2021 consisted of 42 representatives in the U.S. and 5 representatives in Europe, to market and sell our products. A direct sales force may subject us to higher fixed costs than those of companies that market competing products through independent third parties, due to the costs that we will bear associated with employee benefits, training and managing sales personnel. As a result, we may be at a competitive disadvantage. Additionally, these fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products, which could have a material adverse effect on our business, financial condition and results of operations.

***Our employees, independent contractors, consultants, commercial partners, distributors and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the rules of the FDA and other similar foreign regulatory bodies; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws; (iv) data privacy laws and other similar non-U.S. laws; or (v) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs.

It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, additional integrity reporting and oversight obligations and possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition and results of operations.

***We could be adversely affected by any interruption to our ability to conduct business at our current location.***

We do not have redundant facilities. We perform substantially all of our research and development and back office activity and maintain all our finished goods inventory in a single location in Malvern, Pennsylvania. Our facility, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, tornadoes, flooding, fire, public health emergencies such as pandemics and power outages, which may render it difficult or impossible for us to perform our customer service research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it may take to rebuild our inventory of finished product, may result in the loss of customers or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

***If we experience significant disruption or a breach in our information technology systems, our business could be adversely affected.***

We rely extensively on information technology systems to conduct our business. These systems affect, among other things, ordering and managing products, shipping products to customers, processing transactions, summarizing and reporting results of operations, complying with regulatory, legal and tax requirements, data security and other processes necessary to manage our business. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, the increasing need to protect patient and customer information, and changing customer patterns. If our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security breaches, and our business continuity plans do not effectively compensate on a timely basis, we may experience interruptions in our operations, which could have an adverse effect on our business.

If we fail to maintain or protect our information systems and data integrity effectively, we could lose existing customers, have difficulty attracting new customers, suffer backlash from negative public relations, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy

breach, or suffer other adverse consequences. Furthermore, any breach in our information technology systems could lead to the unauthorized access, disclosure and use of non-public information from our patient registry or other patient information which is protected by HIPAA and other laws. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and damage to our reputation.

***If we become profitable, our ability to use our net operating loss carryforwards and other tax attributes to offset future taxable income or taxes may be subject to limitations.***

As of December 31, 2021, we had federal and state net operating loss carry forwards (“NOLs”) of approximately \$181.4 million and \$151.5 million, respectively. The federal carry forwards for losses incurred prior to 2017 will begin expiring in 2032 for federal purposes. Federal net operating losses incurred in 2018 and onward have an indefinite expiration under the 2017 Tax Cut & Jobs Act. The state carry forwards will begin expiring in 2026. A full allowance for the value of the NOLs is provided for in our audited financial statements for the year of December 31, 2021 included in this Annual Report on Form 10-K. We cannot guarantee what the ultimate outcome or amount of the benefit we may receive from the NOLs, if any, will be. If we become profitable in the future, our ability to use net operating loss carryforwards and other tax attributes to offset future taxable income or reduce taxes may be subject to limitations.

#### **Risks Related to Our Securities**

***The trading price of the shares of our common stock has been and could in the future be highly volatile.***

The price of our common stock has been and may continue to be volatile. Even though our common stock is listed on the Nasdaq Global Market (“Nasdaq”), an active trading market for our common stock may not be sustained. The lack of an active trading market may impair the value of your shares and your ability to sell your shares at the time you wish to sell them. An inactive trading market may also impair our ability to raise capital by selling shares of our common stock and enter into strategic partnerships or acquire other complementary products, technologies or businesses by using shares of our common stock as consideration. Furthermore, there can be no guarantee that we will continue to satisfy the continued listing standards of Nasdaq. If we fail to satisfy the continued listing standards, we could be de-listed, which would have a negative effect on the price of our common stock.

We cannot predict the prices at which our shares of common stock may trade. The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- the volume and timing of sales of our products;
- the introduction of new products or product enhancements by us or others in our industry;
- disputes or other developments with respect to our or others’ intellectual property rights;
- our ability to develop, obtain regulatory clearance for, and market new and enhanced products on a timely basis;
- product liability claims or other litigation;
- quarterly variations in our results of operations or those of others in our industry;
- media exposure of our products or of those of others in our industry;
- changes in governmental regulations or in reimbursement;
- changes in earnings estimates or recommendations by securities analysts; and



- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors, including any economic downturn as a result of the ongoing COVID-19 pandemic, or macroeconomic factors such as geopolitical tensions or the outbreak of hostilities or war.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance.

In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management's attention and resources from our business.

***We do not intend to pay cash dividends on our common stock for the foreseeable future.***

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the agreement governing our credit facility precludes, and any future debt agreements may preclude us from paying cash dividends. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Any return to stockholders will therefore be limited to the appreciation in the value of their stock, if any.

***Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.***

Our officers, directors and principal stockholders each holding more than 5% of our common stock, collectively, control approximately 62% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to significantly influence our management and affairs and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our capital stock or our assets, and might affect the prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders.

***We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.***

We are an emerging growth company, as defined in the JOBS Act, and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." In particular, while we are an "emerging growth company" (i) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, (ii) we will be exempt from any rules that could be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor's report on financial statements, (iii) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and (iv) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

We may remain an emerging growth company until as late as December 31, 2024, the fiscal year-end following the fifth anniversary of the completion of our IPO, though we may cease to be an "emerging growth company" earlier under certain circumstances, including if (i) we have more than \$1.07 billion in annual revenue in any fiscal year, (ii) the

market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30 or (iii) we issue more than \$1.0 billion of non-convertible debt over a three-year period.

The exact implications of the JOBS Act are still subject to interpretations and guidance by the SEC and other regulatory agencies, and we cannot assure you that we will be able to take advantage of all of the benefits of the JOBS Act. In addition, investors may find our common stock less attractive to the extent we rely on the exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or become more volatile.

***We are at risk of securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock depends in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, the price of our stock could decline. If one or more of these analysts cease coverage of us or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price to decline.

***Provisions in our corporate charter documents and under Delaware law could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our fourth amended and restated certificate of incorporation and our second amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. As our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions provide, among other things, that:

- our board of directors has the exclusive right to expand the size of our board of directors and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- our stockholders may not act by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- a special meeting of stockholders may be called only by the chair of our board of directors, our chief executive officer (or president, in the absence of a chief executive officer) or a majority of our board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;

- our fourth amended and restated certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- our board of directors may alter certain provisions of our second amended and restated bylaws without obtaining stockholder approval;
- the approval of the holders of at least two-thirds of our shares entitled to vote at an election of our board of directors is required to adopt, amend or repeal our second amended and restated bylaws or repeal the provisions of our fourth amended and restated certificate of incorporation regarding the election and removal of directors;
- stockholders must provide advance notice and additional disclosures to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain voting control of our shares; and
- our board of directors is authorized to issue shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware ("DGCL") which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

***Our fourth amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our fourth amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the United State District Court for the District of Delaware) is the exclusive forum, to the fullest extent permitted by law, for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our fourth amended and restated certificate of incorporation or second amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine, except, in each case, (A) any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), (B) which is vested in the exclusive jurisdiction of a court or forum other than such court, or (C) for which such court does not have subject matter jurisdiction, in all cases subject to the courts having jurisdiction over indispensable parties named as defendants. This provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. For example, stockholders who do bring a claim in the Court of Chancery could face additional litigations costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our fourth amended and restated certificate of incorporation to be inapplicable or unenforceable in such action. Alternatively, if a court were to find the choice of forum provision contained in our fourth amended and restated certificate of incorporation to be inapplicable or unenforceable in an

action, we may incur additional costs associated with resolving such action in other jurisdictions. This provision will not apply to actions arising under the Securities Act or Exchange Act. Our fourth amended and restated certificate of incorporation and second amended and restated bylaws further provide that the federal district courts of the U.S. will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Section 22 of the Securities Act, however, creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Accordingly, there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under the Securities Act.

## **General Risk Factors**

### ***Unstable markets and economic conditions may adversely affect our business.***

Adverse worldwide economic conditions may negatively impact our business. Our general business strategy may be adversely affected by such economic conditions or the presence of a volatile business environment or unpredictable and unstable market conditions, such as the economic turmoil resulting from the spread of the ongoing COVID-19 pandemic and the current conflict between Russia and Ukraine. Further, the impacts of political unrest, including as a result of geopolitical tensions, could lead to disruption, instability and volatility in the global markets, which may have an adverse impact on our business or ability to access the capital markets. Recently, the market has experienced volatility due to the conflict between Russia and Ukraine, and the resulting sanctions and other measures imposed by the U.S. and other countries against Russia. There can be no assurances that such situation will not further deteriorate, causing increased disruption, instability and volatility in the global markets. Adverse worldwide economic conditions may also adversely impact our suppliers' ability to provide us with materials and components, which could have a material adverse effect on our business, financial condition and results of operations.

### ***Our ability to maintain our competitive position depends on our ability to attract and retain senior management and other highly qualified personnel.***

We are highly dependent on our senior management and other key personnel. Our success depends in part on our continued ability to attract, retain and motivate highly qualified senior management and attract, retain and motivate qualified employees, including sales and marketing professionals, clinical specialists and other highly skilled personnel. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition and results of operations. The loss of highly qualified employees could result in delays in product development and commercialization and harm our business.

Although we have entered into employment agreements with all of our executive officers, each of them may terminate their employment with us at any time. The replacement of any of our key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives and could therefore have an adverse effect on our business. We also do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees.

### ***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well those controls and procedures are conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some

persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Our products are manufactured by our exclusive manufacturer and supplier of our products, Aroa, at their facility in Auckland, New Zealand which currently totals approximately 25,000 square feet.

We lease our corporate headquarters in Malvern, Pennsylvania, which houses our research and development operations, controlled environment room, and office space, and currently totals approximately 25,000 square feet.

We believe that our current facilities meet our current and future anticipated needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate office space will be readily available on commercially reasonable terms.

**ITEM 3. LEGAL PROCEEDINGS**

We may be subject to other legal proceedings and claims in the ordinary course of business. We cannot predict the results of any such disputes, and despite the potential outcomes, the existence thereof may have an adverse material impact on us due to diversion of management time and attention as well as the financial costs related to resolving such disputes.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II**

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

**Market Information**

Our common stock has been publicly traded on the Nasdaq Global Market under the symbol "TELA" since November 8, 2019.

**Holders**

As of March 16, 2022, the Company had approximately 66 record holders of its common stock.

**Dividends**

The Company has not declared or paid any dividends since its inception nor does it expect to pay dividends in the foreseeable future.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The information under the heading “Securities Authorized for Issuance Under Equity Compensation Plans” will be filed in the Company’s definitive proxy statement for the 2022 annual meeting of stockholders and is incorporated herein by reference.

**Recent Sales of Unregistered Securities**

None.

**Use of Proceeds**

The registration statement on Form S-1 (File No. 333-234217) relating to the IPO of shares of our common stock, became effective on November 7, 2019. The registration statement registered the offer and sale of 4,000,000 shares of our common stock (including 600,000 shares of our common stock subject to the underwriters’ option to purchase additional shares). In November 2019, we completed the sale of 4,398,700 of the shares of our common stock registered thereunder at an initial public offering price of \$13.00 per share for an aggregate offering price of approximately \$57.2 million, which included 398,700 shares of our common stock pursuant to the underwriters’ option to purchase additional shares. The underwriters of the offering were Jefferies LLC, Piper Jaffray & Co., Canaccord Genuity LLC and JMP Securities LLC. Following the sale of the shares in connection with the closing of the IPO, the offering terminated.

We received net proceeds of approximately \$50.6 million after deducting underwriting discount and commissions of \$4.0 million and offering costs of \$2.6 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates.

As of December 31, 2021, we have used all of the net proceeds from our IPO for working capital and general corporate purposes, including hiring additional sales and marketing personnel and expanding marketing activities to support the ongoing commercialization of our OviTex and OviTex PRS product lines and to fund product development and research and development activities. No amount of the net proceeds from our IPO have been paid directly or indirectly to (i) our directors, officers or any of their associates; (ii) persons owning 10% or more of our common stock; or (iii) our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board and board committee service. There were no material changes in the planned use of proceeds from our IPO from that described in the prospectus dated November 7, 2019 as filed with the SEC pursuant to Rule 424(b)(4).

**Issuer Purchases of Equity Securities**

None.

**ITEM 6.       RESERVED**

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations and the consolidated financial statements and the related notes included elsewhere in this Annual Report. In addition to historical financial information, the following discussion contains forward-looking statements based upon our current plans, expectations and beliefs that involve risks, uncertainties and assumptions. Our actual results may differ materially from those described in or implied by these forward-looking statements as a result of many factors, including those set forth under the section titled "Risk Factors" and in other parts of this Annual Report.*

### Overview

We are a commercial-stage medical technology company focused on providing innovative soft-tissue reconstruction solutions that optimize clinical outcomes by prioritizing the preservation and restoration of the patient's own anatomy. Our growing product portfolio is purposefully designed to leverage the patient's natural healing response while minimizing long-term exposure to permanent synthetic materials. We are committed to delivering our advanced technologies with a strong economic value proposition to assist surgeons and institutions in providing next-generation soft-tissue repair solutions to more patients worldwide.

Our first portfolio of products, the OviTex Reinforced Tissue Matrix ("OviTex"), addresses unmet needs in hernia repair and abdominal wall reconstruction by combining the benefits of biologic matrices and polymer materials while minimizing their shortcomings, at a cost-effective price. Our OviTex products have received 510(k) clearance from the U.S. Food and Drug Administration ("FDA"), which clearance was obtained and is currently held by Aroa Biosurgery Ltd. ("Aroa"), our exclusive manufacturer and supplier. Interim results of our single arm, multicenter post-market clinical study, which we refer to as our BRAVO study, were recently published in the Journal of Clinical Medicine. The interim analysis of patients reaching 12-month follow-up suggests that OviTex is safe and clinically effective for treatment of ventral hernias. The recurrence rate was 2.7% at 12 months. Twenty-four month follow-up has been completed for all possible patients in our BRAVO study, and the recurrence rate remains below 5%. Final analysis is underway and full results will be presented in a future peer-reviewed publication. Our second portfolio of products, the OviTex PRS Reinforced Tissue Matrix ("OviTex PRS"), addresses unmet needs in plastic and reconstructive surgery. In April 2019, our OviTex PRS products received 510(k) clearance from the FDA, which clearance was obtained by Aroa and is currently held by us.

We began commercialization of our OviTex products in the U.S. in July 2016. Our OviTex portfolio consists of multiple products for hernia repair and abdominal wall reconstruction, inguinal hernia repair and hiatal hernia repair. In addition, to address the significant increase in the number of robotic-assisted hernia repairs over the last several years, we have designed an OviTex product line for use in laparoscopic and robotic-assisted surgery ("OviTex LPR"), which we began commercializing in November 2018. We subsequently expanded the OviTex LPR product line in December 2019.

OviTex PRS is indicated for use in implantation to reinforce soft-tissue where weakness exists in patients requiring soft-tissue repair or reinforcement in plastic and reconstructive surgery. We commenced a limited launch in May 2019 and have gathered clinical feedback from our initial surgeon users. Based on this feedback, we expanded our commercial launch in June 2020 and expect to continue to expand our surgeon network. We have also engaged in discussions with the FDA regarding an Investigational Device Exemption protocol to study the safety and effectiveness of our OviTex PRS product for an indication in breast reconstruction surgery. The FDA has stated that a premarket approval, rather than a 510(k) clearance, will be required for such an indication.

We market our products through a single direct sales force, predominantly in the U.S., augmented by distributors in certain European countries. We have invested in our direct sales and marketing infrastructure to expand our presence and to promote awareness and adoption of our products. As of December 31, 2021, we had 46 sales territories in the United States. As part of our commercial strategy, we plan to continue to invest in our commercial organization by hiring additional account managers, clinical development specialists and administrative support staff to support and service new accounts for soft-tissue reconstruction procedures. Additionally, we believe we can enhance the productivity of our

sales force by improving customer segmentation and targeting, leveraging digital channels to engage customers and utilizing engagement analytics to support development.

We announced, in November 2021, that we entered into a distribution agreement with Next Science Technologies Pty Limited (“Next Science”), a medical technology company, granting us the exclusive rights to sell and market Next Science’s proprietary antimicrobial surgical wash with XBIO® technology across the U.S. plastic reconstructive market. We will commence private label marketing of the solution for plastic surgery in 2022. Next Science’s XBIO Technology delivers an advanced option for surgical infection control by addressing the biofilms that make bacteria more resistant to traditional antimicrobial agents, disinfectants and host immune defenses. We believe the infection control solution will expand our service offerings and diversify our supplier base as we continue to create a soft-tissue restoration portfolio.

We are currently devoting research and development resources to develop additional versions of our OviTex hernia product lines, including self-adhering technology to further enhance product compatibility in robotic procedures, as well as additional versions of our OviTex PRS product lines. We are also working to develop new product features and designs for both our existing OviTex and OviTex PRS products. Additionally, we are exploring new packaging technology to increase the shelf life of our OviTex and OviTex PRS products. We intend to continue to make investments in research and development efforts to develop improvements and enhancements. We are also assessing strategic partnerships with medical device companies whereby we may enter into distribution, product development and/or licensing agreements for products complimentary to, or related to, existing and future products in our distribution channel, which could result in the payment of low single digit royalties or other product acquisition costs.

Our products are manufactured by Aroa at their FDA registered and ISO 13485 facility in Auckland, New Zealand. We maintain our Aroa License for the exclusive supply of ovine rumen and manufacture of our reinforced tissue matrices under which we purchase product from Aroa at a fixed cost equal to 27% of our net sales of licensed products. This revenue sharing arrangement allows us to competitively price our products and pass along cost-savings to our customers.

The vast majority of our revenue to date has been generated by the sale of our OviTex products. Our revenue for the years ended December 31, 2021 and 2020 was \$29.5 million and \$18.2 million, respectively, an increase of \$11.3 million, or 62%. Net loss increased from \$28.8 million for the year ended December 31, 2020 to \$33.3 million for the year ended December 31, 2021, an increase of \$4.5 million, or 16%. We have not been profitable since inception and as of December 31, 2021, we had an accumulated deficit of \$229.9 million. We expect to incur losses for the foreseeable future.

#### ***Business Update Regarding COVID-19***

Our business, results of operations and commercial operations has been impacted by the ongoing COVID-19 pandemic and the development of variants of COVID-19. We continue to closely monitor developments related to the ongoing COVID-19 pandemic and our decisions will continue to be driven by the health and well-being of our employees, our customers, and their patients while maintaining operations to support our customers and their patients in the near-term. These developments include:

- ***Surgery Deferrals:*** To date, among other impacts on our business related to the pandemic, physicians and their patients are required by state mandates, or are choosing, to defer elective surgery procedures in which our products otherwise might be used. We believe our revenue was slightly impacted during the first quarter of 2021, mostly in January 2021, due to COVID-19 resurgences and corresponding lower surgical procedural volumes, though these were not at the levels seen in early 2020. This impact on surgical procedures subsided throughout the remaining months of the first quarter and the second quarter of 2021. However, we believe our revenue in September 2021 and December 2021 was also impacted due to the surge of new COVID-19 cases relating to new variants. The extent of future elective surgery deferrals and the timing and extent of the economic impact of the pandemic on us, and the pace at which the economy recovers therefrom, cannot be determined at this time, particularly in light of recent surges and the continued emergence of new variants. Further, the reallocation of hospital resources to treat COVID-19 may continue to cause a financial strain on healthcare systems and reduce procedural volume. We continue to work closely with our hospital and physician



customers and suppliers to navigate through this unforeseen event while maintaining flexible operations to respond to the ongoing COVID-19 pandemic.

- *Operations:* Our sales, marketing and research and development efforts have continued since the outbreak of the pandemic. As access to hospitals continues to evolve throughout this pandemic and vary from hospital to hospital and state to state, our sales team has continued to adapt to changing conditions within their regions. Most of our sales professionals have used a virtual selling program, which includes virtual sales calls with physicians, peer-to-peer discussions with key opinion leaders, physician webinars and sales professional training to supplement our in-person sales and marketing programs. We expect to continue to adapt our sales and marketing plans as we continue to gain better visibility into the effects of the ongoing COVID-19 pandemic on our business. As Aroa is located and headquartered in Auckland, New Zealand, where COVID-19 mitigation efforts have to date been effective, our manufacturing and supply chain has largely been uninterrupted. However, it could be disrupted in the future because of the pandemic due to staffing shortages, production slowdowns, stoppages, travel and shipping restrictions or disruptions in delivery systems.
- *Product Development:* We continue to evaluate the timing and scope of planned next generation product development and commercialization initiatives in light of the ongoing COVID-19 pandemic and we plan to continue to prioritize and invest in our critical R&D and clinical programs.
- *2021 Results:* During January 2021, we experienced increased volatility in demand for our products as COVID-19 cases and related hospitalizations increased. We saw improvement in our business during the second half of the first quarter and during the second quarter, however, we believe our revenue in September 2021 and December 2021 was also impacted by the surge of new COVID-19 cases relating to new variants. The timing, extent and continuation of any increase in procedures, any corresponding increase in sales of our products, and whether there could be a future decrease in the current level of procedures being performed, remain uncertain and are subject to a variety of factors, including:
  - A material increase in COVID-19 cases in one or more locations, including as a result of the development of new variants of COVID-19 may result in an increase in COVID-19 hospitalizations and a corresponding decrease in elective procedures in such impacted locations.
  - The perceived safety of COVID-19 vaccines and boosters, the speed of COVID-19 vaccine distribution and administration, the timing and extent to which the vaccination process will affect the progression of the virus, and the efficacy of such vaccines against the new variants of the virus.
  - Government vaccine mandates could affect our ability to retain or hire employees.
  - Government restrictions on elective procedures may change over time and may vary in different geographic locations due to localized increases or decreases of COVID-19 cases.
  - Patients electing to defer or avoid treatment for elective procedures due to concerns about being exposed to COVID-19, loss of employer-sponsored health insurance related to unemployment in the United States or other reasons.
  - Hospitals may reserve increased space, personal protective equipment and staff for potential COVID-19 patients, especially if the number of COVID-19 cases in a particular region spikes or a new variant of COVID-19 emerges in such region, limiting the space and resources allocated to inpatient and outpatient elective procedures.
  - Hospitals may experience staffing shortages due to normal turnover and due to COVID-19, which could reduce the number of elective procedures that can be performed at hospitals with staffing shortages.

- Hospitals may continue to preserve cash and may not immediately replenish their inventories of our products, which would impact our future sales and revenue and make it difficult to accurately predict our inventory requirements.

We continue to closely monitor local, regional and global COVID-19 surges as well as new variants of the virus for any potential impact on procedures during the first quarter of 2022 and beyond.

- *Outlook.* There remains uncertainty and lack of visibility regarding our near-term revenue growth prospects and product development plans due to the rapidly evolving environment and continued uncertainties resulting from the ongoing COVID-19 pandemic. While certain regions are experiencing a reduction in COVID-19 cases and a relaxing of governmental restrictions, at this time, the full extent of the impact of the ongoing COVID-19 pandemic on our business, financial condition and results of operations is uncertain and cannot be predicted with reasonable accuracy and will depend on future developments that are also uncertain, such as the potential development of new variants of COVID-19, and the future geographic scope of COVID-19.

## **Components of Our Results of Operations**

### ***Revenue***

Substantially all our revenue consists of direct sales of our products to hospital accounts in the U.S. Depending on the terms of our agreements with our customers, we recognize revenue related to product sales either when control transfers, which generally occurs when the product is shipped to the customer, or when the product is utilized in a surgical procedure in the case of consignment agreements. Fees charged to customers for shipping are recognized as revenue. Recent revenue growth has been driven by increasing revenue from product sales due to our expanding customer base, although it is unclear at this point what long-term effect the ongoing COVID-19 pandemic will have on our ability to continue to generate revenue and expand our customer base.

### ***Cost of Revenue***

Cost of revenue primarily consists of the costs of licensed products, charges related to excess and obsolete inventory adjustments, current and potential royalties and costs related to shipping. We purchase product from Aroa at a fixed cost equal to 27% of our net sales of licensed products. The initial term of our Aroa License terminates on the later of (i) August 3, 2022, or (ii) the expiration of the last patent covering bovine and ovine products, with an option to extend for an additional ten-year period. We expect our cost of revenue to increase in absolute dollars as, and to the extent, our sales volume grows although it is unclear at this point what long-term effect, if any, the ongoing COVID-19 pandemic will have on our product demand which could lead to additional charges to excess and obsolete inventory.

### ***Amortization of Intangible Assets***

Amortization of intangible assets relates to the amortization of capitalized milestone amounts paid or probable to be paid to Aroa related to license fees or commercialization rights after future economic benefit has been established for a product. These capitalized milestone amounts relate to regulatory clearances, the receipt of certain supply quantities of product, and amounts based upon aggregate net sales thresholds within a specified territory, and are amortized over the remaining useful life of the intellectual property.

### ***Gross Profit and Gross Margin***

Our gross profit is calculated by subtracting our cost of revenue and amortization of intangible assets from our revenue. We calculate our gross margin percentage as our gross profit divided by our revenue. Our gross margin has been, and we expect it will continue to be, affected by a variety of factors, including sales volume, current and potential royalties and excess and inventory obsolescence costs. Our gross profit may increase to the extent our revenue grows.

### ***Sales and Marketing Expenses***

Sales and marketing expenses consist of market research and commercial activities related to the sale of OviTex and OviTex PRS and salaries and related benefits, sales commissions and stock-based compensation for employees focused on these efforts. Other significant sales and marketing expenses include costs incurred with post-market clinical studies, conferences and trade shows, promotional and marketing activities, as well as travel and training expenses.

Over time we expect our sales and marketing expenses to increase in absolute dollars as we continue to expand our commercial organization to both drive and support our planned growth in revenue. It is unclear at this point, however, what long-term effect, if any, the ongoing COVID-19 pandemic will have on these expansion plans. We expect our sales and marketing expenses to continue to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

### ***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation for personnel in executive, finance, information technology and administrative functions. General and administrative expenses also include professional service fees for legal, accounting, consulting, investor and public relations, insurance costs and direct and allocated facility-related costs.

We expect that our general and administrative expenses will increase in absolute dollars as we execute our growth initiatives and expand our business and headcount to support these initiatives. It is unclear at this point, however, what long-term effect, if any, the ongoing COVID-19 pandemic will have on these expansion plans. We expect our general and administrative expenses to continue to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

### ***Research and Development Expenses***

Research and development expenses consist primarily of product research, engineering, product development, regulatory compliance and clinical development. These expenses include salaries and related benefits, stock-based compensation, consulting services, costs associated with our preclinical studies, costs incurred with our manufacturing partner under development agreements related to technology transfer, laboratory materials and supplies and an allocation of related facilities costs. We expense research and development costs as they are incurred.

We expect research and development expenses in absolute dollars to increase in the future as we develop new products and enhance existing products although it is unclear at this point what long-term effect, if any, the ongoing COVID-19 pandemic will have on these development plans. We expect research and development expenses as a percentage of revenue to vary over time depending on the level and timing of new product development initiatives.

### ***Interest Expense***

Interest expense consists of cash interest under our credit facilities and non-cash interest attributable to the amortization of final payment fees and deferred financing costs related to our indebtedness.

### ***Change in Fair Value of Preferred Stock Warrant Liability***

Prior to our IPO, our outstanding warrants to purchase shares of our preferred stock were classified as liabilities, recorded at fair value and were subject to remeasurement at each balance sheet date until they were exercised, expired or were otherwise settled. The change in fair value of our preferred stock warrant liability reflected a non-cash charge primarily driven by changes in the fair value of our underlying Series B preferred stock. All outstanding warrants to purchase shares of our preferred stock were converted into warrants to purchase shares of our common stock upon our IPO.

***Other (Expense) Income***

Other (expense) income consists primarily of miscellaneous tax expenses and foreign currency exchange gains and losses offset by income earned on our cash and cash equivalents.

**Results of Operations****Comparison of the Year Ended December 31, 2021 and 2020**

	<b>Year Ended December 31,</b>		<b>Change</b>	
	<b>2021</b>	<b>2020</b>	<b>Dollar</b>	<b>Percentage</b>
	(in thousands, except percentages)			
Revenue	\$ 29,463	\$ 18,213	\$ 11,250	62 %
Cost of revenue (excluding amortization of intangible assets)	10,346	6,675	3,671	55
Amortization of intangible assets	304	304	—	—
Gross profit	18,813	11,234	7,579	67
Gross margin	64 %	62 %		
Operating expenses:				
Sales and marketing	29,062	22,111	6,951	31
General and administrative	12,459	10,143	2,316	23
Research and development	6,743	4,255	2,488	58
Total operating expenses	48,264	36,509	11,755	32
Loss from operations	(29,451)	(25,275)	(4,176)	17
Other (expense) income:				
Interest expense	(3,597)	(3,564)	(33)	1
Other (expense) income	(228)	45	(273)	(607)
Total other expense	(3,825)	(3,519)	(306)	9
Net loss	\$ (33,276)	\$ (28,794)	\$ (4,482)	16 %

**Revenue**

Revenue increased by \$11.3 million, or 62%, to \$29.5 million for the year ended December 31, 2021 from \$18.2 million for the year ended December 31, 2020. The increase in revenue was primarily driven by an increase in unit sales of our products due to the expansion of our commercial organization with increased penetration within existing customer accounts and stronger international sales. During the year ended December 31, 2021, we sold 7,516 units of OviTex compared to 4,794 units of OviTex during the year ended December 31, 2020, a 57% increase in unit sales volume. Additionally, we sold 1,260 units of OviTex PRS compared to 663 units during the year ended December 31, 2020, a 90% increase in unit sales volume.

**Cost of Revenue**

Cost of revenue (excluding amortization of intangible assets) increased by \$3.7 million to \$10.3 million for the year ended December 31, 2021 from \$6.7 million for the year ended December 31, 2020. The increase in cost of revenue was primarily the result of an increase in products purchased to support our higher unit sales and an increase in our provision for excess and obsolete inventory.

**Amortization of Intangible Assets**

Amortization of intangible assets was \$0.3 million for both the years ended December 31, 2021 and 2020.

**Gross Margin**

Gross margin increased to 64% for the year ended December 31, 2021 from 62% for the year ended December 31, 2020. The increase was primarily due to a lower expense recognized for excess and obsolete inventory adjustments as a percentage of revenue due to longer shelf life and inventory management during the year ended December 31, 2021 as compared to the prior year.

***Sales and Marketing***

Sales and marketing expenses increased by \$7.0 million, or 31%, to \$29.1 million for the year ended December 31, 2021 from \$22.1 million for the year ended December 31, 2020. The increase was primarily due to higher salaries, benefits and commission costs as a result of an expansion of our commercialization activities, including an increase in headcount and increased travel and consulting expenses. The prior year period also included cost containment actions taken in response to the COVID-19 pandemic including salary reductions and reduced traveling which were not repeated in 2021.

***General and Administrative***

General and administrative expenses increased by \$2.3 million, or 23%, to \$12.5 million for the year ended December 31, 2021 from \$10.1 million for the year ended December 31, 2020. The increase was primarily due to higher salaries and benefits, increased professional, consulting and legal fees, higher stock-based compensation expense, increased insurance expense, higher recruiting fees and additional facilities expenses. The prior year period also included cost containment actions taken in response to the COVID-19 pandemic including salary reductions which were not repeated in 2021.

***Research and Development***

Research and development expenses increased by \$2.5 million, or 58%, to \$6.7 million for the year ended December 31, 2021 from \$4.3 million for the year ended December 31, 2020. The increase in research and development expense primarily relates to a non-cash stock-based compensation expense of \$0.7 million related to amendments to certain equity award agreements following the death of our co-founder and former Chief Medical Officer, higher salaries and benefits, increased testing and development expenses and increased consulting expenses. The prior year period also included cost containment actions taken in response to the COVID-19 pandemic including salary reductions which were not repeated in 2021.

***Interest Expense***

Interest expense was \$3.6 million for both the years ended December 31, 2021 and 2020.

***Other (Expense) Income***

Other (expense) income decreased by \$0.3 million, or 607%, to an expense of \$0.2 million for the year ended December 31, 2021 primarily due to a decrease in interest income.

**Comparison of the Year Ended December 31, 2020 and 2019**

	Year Ended December 31,		Change	
	2020	2019	Dollar	Percentage
	(in thousands, except percentages)			
Revenue	\$ 18,213	\$ 15,446	\$ 2,767	18 %
Cost of revenue (excluding amortization of intangible assets)	6,675	5,870	805	14
Amortization of intangible assets	304	304	—	—
Gross profit	11,234	9,272	1,962	21
Gross margin	62 %	60 %		
Operating expenses:				
Sales and marketing	22,111	18,060	4,051	22
General and administrative	10,143	6,223	3,920	63
Research and development	4,255	4,151	104	3
Total operating expenses	36,509	28,434	8,075	28
Loss from operations	(25,275)	(19,162)	(6,113)	32
Other (expense) income:				
Interest expense	(3,564)	(3,609)	45	(1)
Change in fair value of preferred stock warrant liability	—	(5)	5	(100)
Other income	45	351	(306)	(87)
Total other expense	(3,519)	(3,263)	(256)	8
Net loss	\$ (28,794)	\$ (22,425)	\$ (6,369)	28 %

**Revenue**

Revenue increased by \$2.8 million, or 18%, to \$18.2 million for the year ended December 31, 2020 from \$15.4 million for the year ended December 31, 2019. The increase in revenue was primarily driven by an increase in unit sales of our products due to the expansion of our commercial organization with increased penetration within existing customer accounts. During the year ended December 31, 2020, we sold 4,794 units of OviTex compared to 3,779 units of OviTex during the year ended December 31, 2019, a 27% increase in unit sales volume. Additionally, we sold 663 units of OviTex PRS compared to 240 units during the year ended December 31, 2019, a 176% increase in unit sales volume.

**Cost of Revenue**

Cost of revenue (excluding amortization of intangible assets) increased by \$0.8 million to \$6.7 million for the year ended December 31, 2020 from \$5.9 million for the year ended December 31, 2019. The increase in cost of revenue was primarily the result of higher revenue due to the growth in the number of OviTex and OviTex PRS units sold offset by a lower provision for excess and obsolete inventory.

**Amortization of Intangible Assets**

Amortization of intangible assets was \$0.3 million for both the years ended December 31, 2020 and 2019.

**Gross Margin**

Gross margin increased to 62% for the year ended December 31, 2020 from 60% for the year ended December 31, 2019. The increase was primarily due to a lower expense recognized for excess and obsolete inventory adjustments as a percentage of revenue due to longer shelf life and inventory management during the year ended December 31, 2020 as compared to the prior year.

**Sales and Marketing**

Sales and marketing expenses increased by \$4.1 million, or 22%, to \$22.1 million for the year ended December 31, 2020 from \$18.1 million for the year ended December 31, 2019. The increase was primarily due to higher salaries, benefits

and commission costs of \$4.5 million as a result of an expansion of our commercialization activities, including an increase in headcount, which was partially offset by lower travel and consulting expenses and other cost containment actions taken in response to the ongoing COVID-19 pandemic.

***General and Administrative***

General and administrative expenses increased by \$3.9 million, or 63%, to \$10.1 million for the year ended December 31, 2020 from \$6.2 million for the year ended December 31, 2019. The increase was primarily due to increased insurance costs of \$1.7 million, increased professional, legal and consulting fees of \$0.9 million, higher stock-based compensation expense of \$0.8 million and higher salaries and benefits costs of \$0.3 million which was partially offset by the cost containment actions taken in response to the ongoing COVID-19 pandemic.

***Research and Development***

Research and development expenses increased by \$0.1 million, or 3%, to \$4.3 million for the year ended December 31, 2020 from \$4.2 million for the year ended December 31, 2019. The increase in research and development expense primarily relates to increased salaries and benefits offset by a decrease in licensing payments.

***Interest Expense***

Interest expense was \$3.6 million for both the years ended December 31, 2020 and 2019.

***Change in Fair Value of Preferred Stock Warrant Liability***

We recognized a loss on the change in the fair value of our preferred stock warrant liability of \$5,000 during the year ended December 31, 2019. All outstanding warrants to purchase shares of our preferred stock were converted into warrants to purchase shares of our common stock and the liability was reclassified to additional paid-in capital in the accompanying consolidated balance sheet.

***Other Income***

Other income decreased by \$0.3 million, or 87%, to \$45,000 for the year ended December 31, 2020 from \$0.4 million for the year ended December 31, 2019 due to a decrease in interest income as a result of the decrease in short-term investments.

***Liquidity and Capital Resources***

***Overview***

As of December 31, 2021, we had cash and cash equivalents of \$43.9 million, working capital of \$48.5 million and an accumulated deficit of \$229.9 million. As of December 31, 2020, we had cash and cash equivalents of \$74.4 million, working capital of \$76.6 million and an accumulated deficit of \$196.7 million.

We have incurred operating losses since our inception, and we anticipate that our operating losses will continue in the near term as we seek to invest in our sales and marketing initiatives to support our growth in existing and new markets and in additional research and development activities. As of December 31, 2021, we had \$30.0 million of borrowings outstanding under our credit facility (the "OrbiMed Credit Facility"). This credit facility matures in November 2023 and requires that we maintain a minimum cash balance of \$2.0 million.

Based on our current business plan, we believe that our existing cash resources will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months from the issuance of this Annual Report. If these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional common or preferred equity or debt securities, or enter into a new credit facility. In December 2020, we entered into an Equity Distribution Agreement (the "Equity Agreement") with Piper Sandler & Co (the "Agent") in connection with the establishment of an



at-the-market offering program under which we may sell up to an aggregate of \$50.0 million of shares of our common stock, from time to time through the Agent, as sales agent. No sales were made under the Equity Agreement during the years ended December 31, 2021 or 2020. If we raise additional funds by issuing equity or equity-linked securities, our stockholders would experience dilution and any new equity securities could have rights, preferences and privileges superior to those of holders of our common stock. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. We cannot be assured that additional equity, equity-linked or debt financing will be available on terms favorable to us or our stockholders, or at all, including because of market volatility following the COVID-19 pandemic. If we are unable to obtain adequate financing, we may be required to delay the development, commercialization and marketing of our products.

### Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

(in thousands)	Year Ended December 31,		
	2021	2020	2019
Cash used in operating activities	\$ (30,432)	\$ (24,456)	\$ (25,523)
Cash (used in) provided by investing activities	(627)	9,122	(11,981)
Cash provided by financing activities	585	44,409	65,532
Effect of exchange rate on cash	11	17	(4)
Net (decrease) increase in cash and cash equivalents	\$ (30,463)	\$ 29,092	\$ 28,024

### Operating Activities

During the year ended December 31, 2021, we used \$30.4 million of cash in operating activities, resulting from our net loss of \$33.3 million and the change in operating assets and liabilities of \$3.5 million offset by non-cash charges of \$6.3 million. Our non-cash charges were comprised of stock-based compensation expense of \$3.7 million, our excess and obsolete inventory charge of \$1.4 million, interest expense of \$0.7 million and depreciation and amortization expense of \$0.5 million. The change in our operating assets and liabilities was primarily related to an increase in our inventory and prepaid expenses and other assets partially offset by increases in accrued expenses and other current and long-term liabilities.

During the year ended December 31, 2020, we used \$24.5 million of cash in operating activities, resulting from our net loss of \$28.8 million and the change in operating assets and liabilities of \$0.2 million offset by non-cash charges of \$4.5 million. Our non-cash charges were comprised of stock-based compensation expense of \$2.1 million, our excess and obsolete inventory charge of \$1.3 million, interest expense of \$0.6 million and depreciation and amortization expense of \$0.5 million.

During the year ended December 31, 2019, we used \$25.5 million of cash in operating activities, resulting from our net loss of \$22.4 million and the change in operating assets and liabilities of \$6.3 million, offset by non-cash charges of \$3.2 million. Our non-cash charges were primarily comprised of our excess and obsolete inventory charge of \$1.6 million, stock-based compensation expense of \$0.5 million, interest expense of \$0.5 million and depreciation and amortization expense of \$0.6 million. The change in our operating assets was primarily related to increases in accounts receivable, inventory and prepaid expenses and other assets.

### Investing Activities

During the year ended December 31, 2021, cash used in investing activities was \$0.6 million consisting of purchases of property and equipment.

During the year ended December 31, 2020, cash provided by investing activities was \$9.1 million consisting primarily of the proceeds from the sale and maturity of short-term investments.

During the year ended December 31, 2019, cash used in investing activities was \$12.0 million consisting primarily from the purchase of short-term investments of \$9.3 million and payments made for our intangible assets of \$2.5 million.

**Financing Activities**

During the year ended December 31, 2021, cash provided by financing activities was \$0.6 million, consisting primarily of the proceeds received from the exercise of stock options.

During the year ended December 31, 2020, cash provided by financing activities was \$44.4 million, consisting primarily of the net proceeds received from a follow-on public offering of our common stock.

During the year ended December 31, 2019, cash provided by financing activities was \$65.5 million, consisting primarily from the net proceeds received from our IPO and the net proceeds from the issuance of our Series B preferred stock.

**Indebtedness**

In November 2018, we entered into the OrbiMed Credit Facility, which consists of up to \$35.0 million in term loans (the “OrbiMed Term Loans”). The OrbiMed Term Loans consist of two tranches, a \$30.0 million Tranche 1 (“Tranche 1”) and a \$5.0 million Tranche 2 (“Tranche 2”). Upon closing, we borrowed \$30.0 million of Tranche 1. We elected not to borrow Tranche 2 prior to its expiration on December 31, 2019.

Pursuant to the OrbiMed Credit Facility, we provided a first priority security interest in all existing and future acquired assets, excluding intellectual property and certain other assets, owned by us. The OrbiMed Credit Facility contains a negative pledge on intellectual property owned by us. The OrbiMed Credit Facility also contains customary indemnification obligations and customary events of default, including, among other things, (i) non-payment, (ii) breach of warranty, (iii) non-performance of covenants and obligations, (iv) default on other indebtedness, (v) judgments, (iv) change of control, (vii) bankruptcy and insolvency, (viii) impairment of security, (ix) key permit events, (x) key person events, (xi) regulatory matters, (xii) and key contracts. In addition, we must maintain a minimum cash balance of \$2.0 million. In the event of default under the OrbiMed Credit Facility, we may become obligated to immediately pay all outstanding principal and interest and all other due and unpaid obligations at the current rate in effect plus 3%.

The OrbiMed Term Loans mature on November 16, 2023 and bear interest at a rate equal to 7.75% plus the greater of one-month LIBOR or 2.0%. We are required to make 60 monthly interest payments beginning on November 30, 2018 with the entire principal payment due at maturity. The OrbiMed Term Loans have a prepayment penalty equal to 10.0% of the prepaid principal amount prior to the second anniversary of the OrbiMed Term Loans, 5.0% of the prepaid principal amount after the second anniversary but prior to the third anniversary and 2.5% of the prepaid principal amount after the third anniversary. We are also required to pay an exit fee at the time of maturity or prepayment event equal to 10% of all principal borrowings and an administration fee equal to \$10,000 on the last day of each quarter until all obligations have been paid in full.

**Contractual Obligations and Commitments**

The following table summarizes our contractual obligations as of December 31, 2021 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

(in thousands)	Payments due by Period				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Principal payments on long-term debt	\$ 30,000	\$ —	\$ 30,000	\$ —	\$ —
Interest and end of term charge on long-term debt <sup>(1)</sup>	8,489	2,925	5,564	—	—
Operating lease commitments <sup>(2)</sup>	2,388	349	724	758	557
Purchase commitments	12,606	1,381	3,140	2,310	5,775
Total <sup>(3)</sup>	\$ 53,483	\$ 4,655	\$ 39,428	\$ 3,068	\$ 6,332

- (1) Interest payable reflects the rate in effect as of December 31, 2021. The interest rate on borrowings under the OrbiMed Credit Facility is variable and resets monthly. End of term fee reflects final payment fee due at maturity.
- (2) Reflects payments due for our lease of office and laboratory space in Malvern, Pennsylvania under an operating lease agreement that expires in 2028.
- (3) This table does not include (a) any milestone payments that are not deemed probable under license agreements as the timing and likelihood of such payments are not known with certainty and (b) contracts that are entered into in the ordinary course of business that are not material in the aggregate in any period presented above. Excluded amounts primarily consist of a \$1,000 milestone payment due to Aroa when certain sales milestones are met.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our cash is held on deposit in demand accounts at high credit quality financial institutions in amounts in excess of the Federal Deposit Insurance Corporation (“FDIC”) insurance coverage limit of \$250,000 per depositor, per FDIC-insured bank, per ownership category. We have reviewed the consolidated financial statements of these institutions and believe they have sufficient assets and liquidity to conduct their operations in the ordinary course of business with little or no credit risk to us.

Financial instruments that potentially subject us to concentrations of credit risk principally consist of cash equivalents and accounts receivable. We limit our credit risk associated with cash equivalents by placing investments in highly-rated money market funds. We limit our credit risk with respect to accounts receivable by performing credit evaluations when deemed necessary, but we do not require collateral to secure amounts owed to us by our customers.

As discussed above in the section of this Annual Report entitled “Liquidity and Capital Resources — Indebtedness,” the OrbiMed Credit Facility bears interest at a floating rate of interest, which resets monthly and is equal to 7.75% plus the greater of one-month LIBOR or 2.0%. As of December 31, 2021, LIBOR was below 1.0%. Therefore, a 1.0% increase in LIBOR would not increase the annual interest payments.

Inflationary factors, such as increases in our cost of revenue and operating expenses, may adversely affect our operating results. Although we do not believe inflation has had a material impact on our financial condition, results of operations or cash flows to date, a high rate of inflation in the future may have an adverse effect on our ability to maintain and increase our gross margin or decrease our operating expenses as a percentage of our revenue if our selling prices of our products do not increase as much or more than our costs increase.

We do not currently have any material exposure to foreign currency fluctuations and do not engage in any hedging activities as part of our normal course of business.

#### **Critical Accounting Policies and Significant Judgments and Estimates**

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the U.S. (“GAAP”). The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amount of revenue and expenses during the reporting period. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to our consolidated financial statements appearing elsewhere in this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

### **Revenue Recognition**

We account for revenue in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (“ASC 606”). Under ASC 606, we recognize revenue when our customer obtains control of our promised good, in an amount that reflects the consideration that the entity expects to be entitled in exchange for those goods.

### **Inventory Valuation**

Inventory is stated at the lower of cost or net realizable value, with cost determined using the first-in-first-out method. Inventory, which consists of our OviTex and OviTex PRS product held on consignment or held in our warehouse, is considered finished goods and is purchased from a third party.

We evaluate the carrying value of our inventory in relations to the estimated forecast of product demand, which takes into consideration the expiration date of the products. A significant decrease in demand could result in an increase in the amount of excess inventory on hand, which could lead to additional charges for excess and obsolete inventory. The need to maintain substantial levels of inventory impacts our estimates for excess and obsolete inventory. In addition, we continue to introduce new products and sizes, which we believe will increase our revenue. As a result, we may be required to take additional charges for excess and obsolete inventory in the future if the purchased units do not align with sales.

### **Recently Issued and Adopted Accounting Pronouncements**

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 3 to our consolidated financial statements appearing elsewhere in this Annual Report.

### **JOBS Act Accounting Election**

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933 for complying with new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The information required by this Item is set forth on pages F-1 through F-22 hereto.

### **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

### **ITEM 9A. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the

reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2021.

### **Management's Report on Internal Control Over Financial Reporting**

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that: (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Internal control over financial reporting may not prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are achieved. Further, the design of a control system must be balanced against resource constraints, and therefore the benefits of controls must be considered relative to their costs. Given the inherent limitations in all systems of controls, no evaluation of controls can provide absolute assurance all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Accordingly, given the inherent limitations in a cost-effective system of internal control, financial statement misstatements due to error or fraud may occur and may not be detected. Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance of achieving their objectives. We conduct periodic evaluations of our systems of controls to enhance, where necessary, our control policies and procedures.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "Internal Control—Integrated Framework (2013)" published by the Committee of Sponsoring Organizations of the Treadway Commission to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2021.

### **Changes in Internal Control over Financial Reporting**

During the fourth quarter ended December 31, 2021, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) which materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

The disclosure set forth below is provided in lieu of a separate Form 8-K filing pursuant to Item 5.02 of Form 8-K.

On March 22, 2022, the Board approved a reduced work schedule for E. Skott Greenhalgh, Ph.D., the Chief Technology Officer of the Company, effective immediately. Dr. Greenhalgh's annual base salary was reduced from \$360,500 to \$90,125. Subject to the conditions and provisions of the Company's equity incentive plans, equity awards held by Dr. Greenhalgh will continue to vest and become exercisable according to their respective terms.

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

### PART III

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information concerning directors and compliance with Section 16(a) of the Exchange Act and our Code of Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or controller called for by Item 10 of Form 10-K will be set forth in our definitive proxy statement for the 2022 annual meeting of stockholders, to be filed within 120 days after the end of the fiscal year covered by this annual report on Form 10-K, and is incorporated herein by reference.

#### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by Item 11 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2022 annual meeting of stockholders.

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by Item 12 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2022 annual meeting of stockholders.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by Item 13 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2022 annual meeting of stockholders.

#### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Our independent registered public accounting firm is KPMG LLP, Philadelphia, PA, Auditor Firm ID: 185.

The information required by Item 14 of Form 10-K is incorporated by reference to the information contained in our definitive proxy statement for the 2022 annual meeting of stockholders.

### PART IV

#### **ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

##### (a) 1. Financial Statements

See Index to the Consolidated Financial Statements on page F-1 of this Annual Report.

##### 2. Financial Statement Schedules

None, as all information required in these schedules is included in the Notes to the Consolidated Financial Statements.

##### 3. Exhibits

Reference is made to the Exhibit Index on page 96 of this Annual Report for a list of exhibits required by Item 601 of Regulation S-K to be filed as part of this Annual Report.

**ITEM 16. FORM 10-K SUMMARY**

None.



TELA BIO, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Stockholders and Board of Directors  
TELA Bio, Inc.:

*Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated balance sheets of TELA Bio, Inc. and subsidiary (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2021, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

*Basis for Opinion*

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2013.

Philadelphia, Pennsylvania  
March 23, 2022

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

	December 31,	
	2021	2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 43,931	\$ 74,394
Accounts receivable, net	4,234	2,683
Inventory	7,658	3,907
Prepaid expenses and other assets	3,232	2,241
Total current assets	59,055	83,225
Property and equipment, net	1,186	626
Intangible assets, net	2,303	2,607
Total assets	<u>\$ 62,544</u>	<u>\$ 86,458</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,414	\$ 652
Accrued expenses and other current liabilities	8,161	5,953
Total current liabilities	10,575	6,605
Long-term debt with related party	31,491	30,827
Other long-term liabilities	380	—
Total liabilities	<u>42,446</u>	<u>37,432</u>
Commitments and contingencies (Note 11)		
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; 14,529,606 and 14,437,289 shares issued and 14,529,577 and 14,437,107 shares outstanding at December 31, 2021 and December 31, 2020, respectively	15	14
Additional paid-in capital	250,064	245,736
Accumulated other comprehensive loss	(52)	(71)
Accumulated deficit	(229,929)	(196,653)
Total stockholders' equity	<u>20,098</u>	<u>49,026</u>
Total liabilities and stockholders' equity	<u>\$ 62,544</u>	<u>\$ 86,458</u>

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,		
	2021	2020	2019
Revenue	\$ 29,463	\$ 18,213	\$ 15,446
Cost of revenue (excluding amortization of intangible assets)	10,346	6,675	5,870
Amortization of intangible assets	304	304	304
Gross profit	18,813	11,234	9,272
Operating expenses:			
Sales and marketing	29,062	22,111	18,060
General and administrative	12,459	10,143	6,223
Research and development	6,743	4,255	4,151
Total operating expenses	48,264	36,509	28,434
Loss from operations	(29,451)	(25,275)	(19,162)
Other (expense) income:			
Interest expense	(3,597)	(3,564)	(3,609)
Change in fair value of preferred stock warrant liability	—	—	(5)
Other (expense) income	(228)	45	351
Total other expense	(3,825)	(3,519)	(3,263)
Net loss	(33,276)	(28,794)	(22,425)
Accretion of redeemable convertible preferred stock to redemption value	—	—	(7,783)
Net loss attributable to common stockholders	\$ (33,276)	\$ (28,794)	\$ (30,208)
Net loss per common share, basic and diluted	\$ (2.30)	\$ (2.23)	\$ (17.10)
Weighted average common shares outstanding, basic and diluted	14,473,213	12,934,421	1,766,412
Comprehensive loss:			
Net loss	\$ (33,276)	\$ (28,794)	\$ (22,425)
Foreign currency translation adjustment	19	(52)	(15)
Unrealized loss on short-term investments	—	—	(4)
Comprehensive loss	\$ (33,257)	\$ (28,846)	\$ (22,444)

See accompanying notes to consolidated financial statements.

**TELA Bio, Inc.**  
**Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
(In thousands, except share amounts)

	Redeemable Convertible Preferred Stock				Stockholders' Equity (Deficit)					
	Series A		Series B		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
<b>Balance at January 1, 2019</b>	22,501,174	\$ 33,112	63,032,500	\$ 91,038	295,717	\$ —	\$ —	\$ —	\$ (137,860)	\$ (137,860)
Vesting of common stock previously subject to repurchase	—	—	—	—	628	—	4	—	—	1
Exercise of stock options	—	—	—	—	2,527	—	14	—	—	—
Sale of Series B redeemable convertible preferred stock, net of stock issue costs of \$165	—	—	12,527,956	14,367	—	—	—	—	—	—
Unrealized loss on short-term investments	—	—	—	—	—	—	—	(4)	—	(4)
Foreign currency translation adjustment	—	—	—	—	—	—	—	(15)	—	(15)
Stock-based compensation expense	—	—	—	—	—	—	457	—	—	457
Accretion of redeemable convertible preferred stock to redemption value	—	1,563	—	6,220	—	—	(209)	—	(7,574)	(7,574)
Conversion of convertible preferred stock to common stock in connection with the initial public offering	(22,501,174)	(34,675)	(75,560,456)	(111,625)	6,708,649	7	146,293	—	—	146,307
Issuance of common stock upon initial public offering, net of underwriting discounts, commissions and offering costs	—	—	—	—	4,398,700	4	50,625	—	—	50,629
Conversion of preferred stock warrants to common stock warrants	—	—	—	—	—	—	1,645	—	—	1,645
Net loss	—	—	—	—	—	—	—	—	(22,425)	(22,425)
<b>Balance at December 31, 2019</b>	—	—	—	—	11,406,221	11	198,829	(19)	(167,859)	30,962
Vesting of common stock previously subject to repurchase	—	—	—	—	306	—	3	—	—	309
Exercise of stock options	—	—	—	—	27,783	—	175	—	—	27,958
Issuance of common stock under the employee stock purchase plan	—	—	—	—	2,797	—	34	—	—	2,831
Foreign currency translation adjustment	—	—	—	—	—	—	—	(52)	—	(52)
Stock-based compensation expense	—	—	—	—	—	—	1,976	—	—	1,976
Issuance of common stock upon follow-on offering, net of underwriting discounts, commissions and offering costs	—	—	—	—	3,000,000	3	44,719	—	—	44,722
Net loss	—	—	—	—	—	—	—	—	(28,794)	(28,794)
<b>Balance at December 31, 2020</b>	—	—	—	—	14,437,107	14	245,736	(71)	(196,653)	49,029
Vesting of common stock previously subject to repurchase	—	—	—	—	153	—	1	—	—	154
Exercise of stock options	—	—	—	—	77,154	1	546	—	—	77,701
Issuance of common stock under the employee stock purchase plan	—	—	—	—	3,163	—	38	—	—	3,201
Foreign currency translation adjustment	—	—	—	—	—	—	—	19	—	19
Stock-based compensation expense	—	—	—	—	12,000	—	3,661	—	—	15,661
Reclassification of liability-classified stock-based compensation awards	—	—	—	—	—	—	82	—	—	82
Net loss	—	—	—	—	—	—	—	—	(33,276)	(33,276)
<b>Balance at December 31, 2021</b>	—	\$ —	—	\$ —	14,529,577	\$ 15	\$250,064	\$ (52)	\$ (229,929)	\$ 20,656

See accompanying notes to consolidated financial statements.

**TELA Bio, Inc.**  
**Consolidated Statements of Cash Flows**  
(In thousands)

	Year ended December 31,		
	2021	2020	2019
<b>Cash flows from operating activities:</b>			
Net loss	\$ (33,276)	\$ (28,794)	\$ (22,425)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	231	221	278
Noncash interest expense	664	584	523
Amortization of intangible assets	304	304	304
Inventory excess and obsolescence charge	1,439	1,327	1,591
Change in fair value of warrants	—	—	5
Stock-based compensation expense	3,661	2,058	457
Loss on disposal of fixed assets	2	—	—
Change in operating assets and liabilities:			
Accounts receivable, net	(1,553)	149	(1,528)
Inventory	(5,194)	(620)	(1,839)
Prepaid expenses and other assets	(992)	66	(1,977)
Accounts payable	1,597	(2,002)	(773)
Accrued expenses and other current and long-term liabilities	2,673	2,321	(118)
Foreign currency remeasurement loss	12	(70)	(21)
Net cash used in operating activities	<u>(30,432)</u>	<u>(24,456)</u>	<u>(25,523)</u>
<b>Cash flows from investing activities:</b>			
Purchases of short-term investments	—	—	(9,284)
Proceeds from the sale and maturity of short-term investments	—	9,289	—
Payment for intangible asset	—	—	(2,500)
Purchase of property and equipment	(627)	(167)	(197)
Net cash (used in) provided by investing activities	<u>(627)</u>	<u>9,122</u>	<u>(11,981)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from follow-on offering, net of underwriting discounts, commissions and offering costs	—	44,722	—
Proceeds from initial public offering, net of underwriting discounts, commissions and offering costs	—	—	51,151
Proceeds from issuance of Series B redeemable convertible preferred stock, net of offering costs	—	—	14,367
Payment of initial public offering costs	—	(522)	—
Proceeds from exercise of stock options	547	175	14
Proceeds from issuance of common stock under the employee stock purchase plan	38	34	—
Net cash provided by financing activities	<u>585</u>	<u>44,409</u>	<u>65,532</u>
Effect of exchange rate on cash and cash equivalents	11	17	(4)
Net (decrease) increase in cash and cash equivalents	<u>(30,463)</u>	<u>29,092</u>	<u>28,024</u>
Cash and cash equivalents, beginning of year	74,394	45,302	17,278
Cash and cash equivalents, end of year	<u>\$ 43,931</u>	<u>\$ 74,394</u>	<u>\$ 45,302</u>
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid during the period for interest	<u>\$ 2,933</u>	<u>\$ 2,980</u>	<u>\$ 3,086</u>
<b>Supplemental disclosures of noncash investing and financing activities:</b>			
Accretion of redeemable convertible preferred stock	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 7,783</u>
Conversion of convertible preferred stock to common stock in connection with the initial public offering	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 146,300</u>
Conversion of outstanding preferred stock warrants	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,645</u>
Offering costs in accounts payable and accrued expenses and other current liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 522</u>
Property and equipment in accounts payable	<u>\$ 166</u>	<u>\$ 3</u>	<u>\$ —</u>
Issuance of common stock for early exercised stock options	<u>\$ 1</u>	<u>\$ 3</u>	<u>\$ 4</u>
Unrealized loss on short-term investments	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 4</u>
Liability-classified stock-based compensation in accrued expenses and other current liabilities	<u>\$ —</u>	<u>\$ 82</u>	<u>\$ —</u>
Reclassification of liability-classified stock-based compensation awards to equity-classified	<u>\$ 82</u>	<u>\$ —</u>	<u>\$ —</u>

See accompanying notes to consolidated financial statements.

**TELA BIO, INC.**

**Notes to Consolidated Financial Statements**

**(1) Background**

TELA Bio, Inc. (the “Company”) was incorporated in the state of Delaware on April 17, 2012 and wholly owns TELA Bio Limited, a company incorporated in the United Kingdom. The Company is commercial-stage medical technology company focused on providing innovation soft-tissue reconstruction solutions that optimize clinical outcomes by prioritizing the preservation and restoration of the patient’s own anatomy. OviTex Reinforced Tissue Matrix (“OviTex”), the Company’s first portfolio of products, addresses unmet needs in hernia repair and abdominal wall reconstruction by combining the benefits of biologic matrices and polymer materials while minimizing their shortcomings, at a cost-effective price. OviTex PRS Reinforced Tissue Matrix (“OviTex PRS”), the Company’s second portfolio of products, addresses unmet needs in plastic and reconstructive surgery. The Company’s principal corporate office and research facility is located in Malvern, Pennsylvania.

The Company has been impacted by the pandemic resulting from the novel coronavirus and the disease it causes, including variants thereof (“COVID-19”). To date, among other impacts on its business related to the pandemic, physicians and their patients are required by state mandates, or are choosing to defer elective surgery procedures in which its products otherwise would be used. There remains uncertainty and lack of visibility regarding the Company’s near-term revenue growth prospects and product development plans due to the rapidly evolving environment and continued uncertainties resulting from the ongoing COVID-19 pandemic. While certain regions are experiencing a reduction in COVID-19 cases and a relaxing of governmental restrictions, at this time, the full extent of the impact of the ongoing COVID-19 pandemic on its business, results of operations and financial condition, including revenue, expenses, manufacturing capability, supply chain integrity, research and development costs and employee-related compensation, will depend on future developments that are highly uncertain, including new information that may emerge concerning COVID-19 and the actions taken to mitigate the spread of or treat COVID-19, the emergence of new variants of COVID-19, as well as the economic impact on local, regional, national and international customers and markets.

**(2) Risks and Liquidity**

The Company’s operations to date have focused on commercializing products, developing and acquiring technology and assets, business planning, raising capital and organization and staffing. The Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit of \$229.9 million as of December 31, 2021. The Company anticipates incurring additional losses until such time, if ever, it can generate sufficient revenue from its products to cover its expenses.

The operations of the Company are subject to certain risks and uncertainties including, among others, uncertainty of product development, the impact of COVID-19 and the development of any variants, on the business, ongoing economic uncertainty, including as a result of geopolitical factors such as hostilities and the conflict between Russia and Ukraine, technological uncertainty, commercial acceptance of any developed products, alternative competing technologies, dependence on collaborative partners, uncertainty regarding patents and proprietary rights, comprehensive government regulations, and dependence on key personnel.

**(3) Summary of Significant Accounting Policies**

*Basis of Presentation and Principals of Consolidation*

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) promulgated by the Financial Accounting Standards Board (“FASB”). The consolidated financial statements include the accounts of TELA Bio, Inc. and its wholly owned subsidiary TELA Bio Limited. All intercompany accounts and transactions have been eliminated in consolidation.

**TELA BIO, INC.**

**Notes to Consolidated Financial Statements (continued)**

*Use of Estimates*

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. The most significant judgments are employed in estimates used to determine stock-based awards issued and recoverability of the carrying value of the Company's inventory. As future events and their effects cannot be determined with precision, actual results may differ significantly from these estimates.

*Segments*

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment.

*Concentration of Risk*

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company places its cash with high-credit-quality financial institutions and primarily invests in money market funds. The Company has established guidelines relative to credit ratings and maturities that seek to maintain safety and liquidity.

As described in Note 11, the Company has licensed patents and other intellectual property from Aroa Biosurgery Ltd. ("Aroa"). As part of this agreement, Aroa is also the sole manufacturer of the Company's products. The inability of Aroa to fulfill supply requirements of the Company could materially impact future operating results. A change in the relationship with Aroa, or an adverse change in their business, could materially impact future operating results.

*Cash and Cash Equivalents*

The Company considers cash equivalents to be highly liquid investments with maturities of three months or less from the date of purchase. Cash equivalents consist of investments in a money market fund. The Company's cash and cash equivalents are carried at the fair value based on quoted market prices.

*Inventory*

Inventory consists of finished goods and is identified and tracked by lot and stated at the lower of cost or net realizable value, with cost being determined on a first-in, first-out basis. The Company periodically analyzes its inventory levels and writes down inventory that has become obsolete or that has a cost basis in excess of its expected net realizable value based on expected customer demand. As of December 31, 2021 and 2020, the Company had \$1.7 million and \$1.4 million, respectively, in finished goods consigned to others.

*Property and Equipment*

Property and equipment are stated at the aggregate cost incurred to acquire and place the asset in service. Expenditures for routine maintenance and repairs are charged to expense as incurred and costs of improvements and renewals are capitalized. Depreciation is provided over the estimated useful lives of the assets using the straight-line method.



**TELA BIO, INC.**

**Notes to Consolidated Financial Statements (continued)**

*Intangible Assets*

Upfront payments and milestone payments due related to licenses or commercialization rights prior to future economic benefit being established are recorded as research and development expenses. Milestone payments due related to licenses or commercialization rights after future economic benefit is established are recorded as intangible assets. In 2021, 2020 and 2019, the Company recorded \$0.3 million of amortization expense in each year related to intangible assets. At December 31, 2021, the remaining life of intangible assets was 7.6 years. The Company anticipates recognizing amortization expense of \$0.3 million for the next five years and \$0.8 million thereafter.

*Long-Lived Assets*

Long-lived assets, such as property and equipment and intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by such asset or asset group to its carrying value. If the carrying value of the long-lived asset or asset group exceeds the undiscounted cash flows, an impairment is recognized to the extent the carrying value exceeds its fair value. Fair value is determined using various valuation techniques, including discounted cash flow models, quoted market values, and third-party independent appraisals, as considered necessary. No impairment losses were recognized during the years ended December 31, 2021, 2020 or 2019.

*Debt Issuance Costs*

Debt issuance costs incurred in connection with debt (Note 6) are amortized to interest expense over the term of the respective financing arrangement using the effective-interest method, and debt issuance costs incurred under the revolver are amortized to interest expense over the term of the respective financing arrangement using the straight-line method. Debt issuance costs, net of related amortization are deducted from the carrying value of the related debt.

*Revenue Recognition*

Under ASC Topic 606, *Revenue from Contracts with Customers*, an entity recognizes revenue when its customer obtains control of the promised good, in an amount that reflects the consideration that the entity expects to be entitled in exchange for those goods. The Company performs the following five steps to recognize revenue under ASC Topic 606: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only recognizes revenue when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that will be transferred to the customer.

A significant portion of the Company's revenue is generated from product shipped to a customer or from consigned inventory maintained at hospitals. Revenue from the sale of consigned products is recognized when control is transferred to the customer, which occurs at the time the product is used in a surgical procedure. For product that is not held on consignment, the Company recognizes revenue when control transfers to the customer which occurs at the time the product is shipped or delivered. For all of the Company's contracts, the only identified performance obligation is providing the product to the customer.

Revenue is recognized at the estimated net sales price which includes estimates of variable consideration. The Company contracts with certain third-party payors for the payment of rebates with respect to the utilization of its products. These rebates are based on contractual percentages. The Company estimates these rebates and records in the same period the related revenue is recognized, resulting in a reduction of product revenue.

**TELA BIO, INC.****Notes to Consolidated Financial Statements (continued)**

Payment terms with customers do not exceed one year and, therefore, the Company does not account for a financing component in its arrangements. There are no incremental costs of obtaining a contract that would rise to or enhance an asset other than product costs, which are a component of inventory. The Company expenses incremental costs of obtaining a contract with a customer (e.g., sales commissions) when incurred as the period of benefit is less than one year. Fees charged to customers for shipping are recognized as revenue.

The following table presents revenue disaggregated (in thousands):

	Year ended December 31,		
	2021	2020	2019
OviTex	\$ 22,990	\$ 15,093	\$ 14,041
OviTex PRS	6,473	3,120	1,405
Total revenue	<u>\$ 29,463</u>	<u>\$ 18,213</u>	<u>\$ 15,446</u>

Sales outside of the U.S. were immaterial for the years ended December 31, 2021, 2020 and 2019.

*Research and Development*

Research and development costs are charged to expense as incurred and consist primarily of salaries, benefits, and other related costs, including stock-based compensation for personnel serving in the research and development functions as well as costs incurred with Aroa under development agreements related to technology transfer, laboratory materials and supplies. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense relating to these costs. Costs incurred in obtaining patent and other intellectual property licenses for which there are no alternative future uses are charged to expense as incurred.

*Stock-Based Compensation*

The Company accounts for stock-based awards in accordance with provisions of ASC Topic 718, *Compensation—Stock Compensation*, under which the Company recognizes the grant-date fair value of stock-based awards issued to employees and nonemployee board members as compensation expense on a straight-line basis over the vesting period of the award while awards containing a performance condition are recognized as expense when the achievement of the performance criteria is considered probable. The Company uses the Black-Scholes option pricing model to determine the grant-date fair value of stock options. The Company estimates forfeitures that it expects will occur and adjusts expense for actual forfeitures in the periods they occur.

*Income Taxes*

Income taxes are accounted for under the asset-and-liability method as required by ASC Topic 740 - ("ASC 740"), *Income Taxes*. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period corresponding to the enactment date. Under ASC 740, a valuation allowance is required when it is more likely than not all or some portion of the deferred tax assets will not be realized through generating sufficient future taxable income.

**TELA BIO, INC.**

**Notes to Consolidated Financial Statements (continued)**

ASC Subtopic 740-10 (“ASC 740-10”), *Accounting for Uncertainty of Income Taxes*, defines the criterion an individual tax position must meet for any part of the benefit of the tax position to be recognized in consolidated financial statements prepared in conformity with GAAP. The Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not such tax position will be sustained on examination by the taxing authorities, based solely on the technical merits of the respective tax position. The tax benefits recognized in the consolidated financial statements from such a tax position should be measured based on the largest benefit having a greater than 50% likelihood of being realized upon ultimate settlement with the tax authority. In accordance with the disclosure requirements of ASC 740-10, the Company’s policy on income statement classification of interest and penalties related to income tax obligations is to include such items as part of income tax expense.

*Fair value of financial instruments*

Fair value is the price that could be received to sell an asset or paid to transfer a liability in an orderly transaction among market participants. Fair value determination in accordance with applicable accounting guidance requires that a number of significant judgments are made. Additionally, fair value is used on a nonrecurring basis to evaluate assets for impairment or as required for disclosure purposes by applicable accounting guidance on disclosures about fair value of financial instruments. Depending on the nature of the assets and liabilities, various valuation techniques and assumptions are used when estimating fair value. The carrying amounts of certain of the Company’s financial instruments, including cash and cash equivalents, accounts receivable and other assets, and accounts payable are shown at cost, which approximates fair value due to the short-term nature of these instruments. Due to the related-party relationship of our OrbiMed Credit Facility (Note 6), it is impractical to determine the fair value of the debt. Items measured at fair value on a recurring basis included the Company’s preferred stock warrants. The warrants were carried at their estimated fair value. All outstanding warrants to purchase shares of preferred stock were converted into warrants to purchase shares of common stock after our IPO.

The Company follows the provisions of ASC Topic 820, *Fair Value Measurement*, for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:

- *Level 1*: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- *Level 2*: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liabilities.
- *Level 3*: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

TELA BIO, INC.

Notes to Consolidated Financial Statements (continued)

The following fair value hierarchy table presents information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2021 and 2020 (in thousands):

	Fair value measurement at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>December 31, 2021:</b>			
Cash equivalents – money market fund	\$ 41,396	\$ —	\$ —
<b>December 31, 2020:</b>			
Cash equivalents – money market fund	\$ 72,889	\$ —	\$ —

A rollforward of the warrant liability (Level 3 measurement) was as follows (in thousands):

<b>January 1, 2019</b>	\$ 1,640
Change in fair value of warrants	5
Conversion into common stock warrants	(1,645)
<b>December 31, 2019</b>	<u>\$ —</u>

The fair value of the warrants at November 13, 2019 was determined using the Black-Scholes option pricing model with the following assumptions:

	MidCap Credit Facility	Convertible promissory notes	Notes payable
Expected dividend yield	—	—	—
Expected volatility	57.5 %	57.4 %	57.5 %
Risk-free interest rate	2.04 %	1.79 %	1.79 %
Remaining contractual term in years	8.4	7.2	7.4

*Net loss per share*

Basic and diluted net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted-average shares of common stock outstanding during the reporting period. The Company's outstanding redeemable convertible preferred stock contractually entitled the holders of such shares to participate in distributions but contractually did not require the holders of such shares to participate in losses of the Company. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since dilutive shares are not assumed to have been issued if their effect is antidilutive. Therefore, the weighted-average shares used to calculate both basic and diluted loss per share are the same.

## TELA BIO, INC.

## Notes to Consolidated Financial Statements (continued)

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of December 31, 2021, 2020 and 2019, as they would be antidilutive.

	Year ended December 31,		
	2021	2020	2019
Stock options (including shares subject to repurchase)	1,706,438	1,498,390	1,421,697
Unvested restricted stock units	163,043	—	—
Common stock warrants	88,556	88,556	88,556
Total	1,958,037	1,586,946	1,510,253

*Recently Issued Accounting Pronouncements*

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which requires a lessee to record a right-of-use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the consolidated financial statements as its date of initial application. If an entity chooses the second option, the transition requirements for existing leases also apply to leases entered into between the date of initial application and the effective date. The standard is effective for the Company beginning January 1, 2022, with early adoption permitted. The Company plans to adopt this standard on January 1, 2022 and anticipates the recognition of a right-of-use asset of approximately \$1.2 million to \$1.6 million and a lease liability of approximately \$1.5 million to \$1.9 million. The Company is continuing its assessment of potential changes to its disclosures under the standard.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes*. This guidance applies to all entities and aims to reduce the complexity of tax accounting standards while enhancing reporting disclosures. This guidance is effective for fiscal years beginning after December 15, 2020 and interim periods therein. The adoption of this guidance did not have any impact on the Company’s consolidated financial statements and related disclosures.

TELA BIO, INC.

Notes to Consolidated Financial Statements (continued)

**(4) Property and Equipment**

Property and equipment consisted of the following (in thousands):

Asset description	Estimated useful lives	December 31,	
		2021	2020
Lab equipment	5 Years	\$ 2,352	\$ 2,304
Furniture and fixtures	5 Years	242	118
Computer equipment and software	3 Years	468	577
Leasehold improvements	Lesser of useful life or lease term	1,881	1,360
Total		4,943	4,359
Less accumulated depreciation and amortization		(3,757)	(3,733)
Property and equipment, net		\$ 1,186	\$ 626

The cost of property and equipment at both December 31, 2021 and 2020 includes \$0.2 million of equipment located at Aroa. Depreciation expense was \$0.2 million, \$0.2 million and \$0.3 million for the years ended December 31, 2021, 2020 and 2019, respectively.

**(5) Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2021	2020
Compensation and related benefits	\$ 4,976	\$ 3,666
Interest	—	40
Third-party and professional fees	2,233	1,626
Amounts due to Aroa	842	498
Research and development expenses	31	7
Other	79	116
Total accrued expenses and other current liabilities	\$ 8,161	\$ 5,953

**(6) Debt**

Long-term debt consisted of the following (in thousands):

	December 31,	
	2021	2020
OrbiMed Term Loan (related party)	\$ 30,000	\$ 30,000
End of term charge	3,000	3,000
Unamortized end of term charge and issuance costs	(1,509)	(2,173)
Long-term debt with related party	\$ 31,491	\$ 30,827

*OrbiMed Term Loan (Related Party)*

In November 2018, the Company entered into a senior secured term loan facility (“OrbiMed Credit Facility”) with OrbiMed Royalty Opportunities II, LP (“OrbiMed”), a related party as the lender is affiliated with a stockholder of the Company, which consists of up to \$35.0 million in term loans (“OrbiMed Term Loans”). The OrbiMed Term Loans

**TELA BIO, INC.**

**Notes to Consolidated Financial Statements (continued)**

consist of two tranches, a \$30.0 million Tranche 1 (“Tranche 1”) and a \$5.0 million Tranche 2 (“Tranche 2”). In November 2018, the Company borrowed \$30.0 million of Tranche 1. The Company elected not to borrow Tranche 2 prior to its expiration on December 31, 2019.

Pursuant to the OrbiMed Credit Facility, the Company provided a first priority security interest in all existing and future acquired assets, excluding intellectual property and certain other assets, owned by the Company. The OrbiMed Credit Facility contains a negative pledge on intellectual property owned by the Company. The OrbiMed Credit Facility also contains customary indemnification obligations and customary events of default, including, among other things, (i) nonpayment, (ii) breach of warranty, (iii) nonperformance of covenants and obligations, (iv) default on other indebtedness, (v) judgments, (iv) change of control, (vii) bankruptcy and insolvency, (viii) impairment of security, (ix) key permit events, (x) key person events, (xi) regulatory matters, (xii) and key contracts. In addition, the Company must maintain a minimum cash balance of \$2.0 million. If an event of default occurs under the OrbiMed Credit Facility, the Company may become obligated to immediately pay all outstanding principal and interest and all other due and unpaid obligations at the current rate in effect plus 3%.

The OrbiMed Term Loan matures on November 16, 2023 and bears interest at a rate equal to 7.75% plus the greater of one-month LIBOR or 2.0%. At December 31, 2021, the interest rate was 9.75%. The Company is required to make 60 monthly interest payments beginning on November 30, 2018, with the entire principal payment due at maturity. The OrbiMed Term Loans have a prepayment penalty equal to 10.0% of the prepaid principal amount prior to the second anniversary of the Term Loans, 5.0% of the prepaid principal amount after the second anniversary but prior to the third anniversary and 2.5% of the prepaid principal amount after the third anniversary. The Company is also required to pay an exit fee at the time of maturity or prepayment event equal to 10.0% of all principal borrowings (the “End of Term Charge”) and an administration fee equal to \$10,000 on the last day of each quarter until all obligations have been paid in full. In conjunction with the closing of the OrbiMed Term Loans, the Company incurred \$0.3 million of third party and lender fees, which along with the End of Term Charge of \$3.0 million were recorded as debt issuance costs, and are being recognized as interest expense over the term of the loan using the effective-interest method. Interest expense associated with the OrbiMed Credit Facility recorded during each of 2021, 2020 and 2019 was \$3.6 million.

**(7) Redeemable Convertible Preferred Stock and Stockholders’ Equity (Deficit)**

*Public Stock Offerings*

In November 2019, the Company closed its initial public offering (“IPO”) in which the Company issued and sold 4,398,700 shares of its common stock at a public offering price of \$13.00 per share, including 398,700 shares of the Company’s common stock sold pursuant to the underwriters’ option to purchase additional shares. The Company received net proceeds of \$50.6 million after deducting underwriting discounts, commissions and other offering expenses. In addition, immediately prior to the closing of the IPO, all of the Company’s outstanding shares of redeemable convertible preferred stock, including accrued dividends payable converted into an aggregate of 6,708,649 shares of common stock and the Company’s outstanding warrants to purchase shares of preferred stock were automatically converted into warrants to purchase an aggregate of 88,556 shares of common stock.

In June 2020, the Company completed a follow-on public offering in which the Company issued and sold 3,000,000 shares of its common stock at a public offering price of \$16.00 per share. The Company received net proceeds of \$44.7 million after deducting underwriting discounts, commissions and other offering expenses.

In December 2020, the Company entered into an Equity Distribution Agreement (the “Equity Agreement”) with Piper Sandler & Co (the “Agent”) in connection with the establishment of an at-the-market offering program under which it may sell up to an aggregate of \$50.0 million of shares of the Company’s common stock, from time to time through the Agent as sales agent. No sales were made under the Equity Agreement during the years ended December 31, 2021 or 2020.

## TELA BIO, INC.

## Notes to Consolidated Financial Statements (continued)

*Preferred Stock*

Prior to the IPO, all of the Company's redeemable convertible preferred stock was classified outside of stockholders' deficit because the shares contain certain redemption features that were not solely within the control of the Company. At the time of issuance, the redeemable convertible preferred stock was recorded at its issuance price, less issuance costs.

Throughout 2019, the Company entered into various stock purchase agreements with new and existing investors pursuant to which the Company sold an aggregate 12,527,956 shares of the Company's Series B preferred stock at \$1.16 per share for aggregate gross proceeds of \$14.5 million. Transaction fees of \$0.2 million were recorded as a reduction of the carrying value of the Series B preferred stock.

*Warrants*

The Company had the following warrants outstanding at December 31, 2021:

	<u>Outstanding</u>	<u>Exercise price</u>	<u>Expiration dates</u>
Common stock warrants	8,379	\$ 28.65	2028
Common stock warrants	80,177	28.65	2027
	<u>88,556</u>		

**(8) Stock-Based Compensation**

The Company has two equity incentive plans: the 2012 Stock Incentive Plan and the Amended and Restated 2019 Equity Incentive Plan. New awards can only be granted under the Amended and Restated 2019 Equity Incentive Plan (the "Plan"). At December 31, 2021, 1,299,218 shares were available for future issuances under the Plan. The Plan is subject to an annual increase, subject to prior approval by the Company's board of directors, equal to the lesser of (i) 432,442 shares, (ii) 4% of the shares outstanding on the last day of the immediately preceding fiscal year and (iii) such smaller number of shares as determined by the board of directors. The Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock awards, restricted stock units and/or stock appreciation rights to employees, directors, and other persons, as determined by the Company's board of directors. The Company's stock options vest based on the terms in each award agreements and generally vest over four years and have a term of 10 years. The Company estimates forfeitures that it expects will occur and adjusts expense for actual forfeitures in the periods they occur.

The Company measures employee and nonemployee stock-based awards at grant-date fair value and records compensation expense ratably over the vesting period of the award. The Company recorded stock-based compensation expense in the following expense categories of its accompanying consolidated statements of operations (in thousands):

	<u>Year ended December 31,</u>		
	<u>2021</u>	<u>2020</u>	<u>2019</u>
Sales and marketing	\$ 961	\$ 696	\$ 164
General and administrative	1,542	1,030	225
Research and development	1,158	332	68
Total stock-based compensation	<u>\$ 3,661</u>	<u>\$ 2,058</u>	<u>\$ 457</u>



TELA BIO, INC.

Notes to Consolidated Financial Statements (continued)

The following table summarizes stock option activity for the Plan:

	Number of shares	Weighted average exercise price per share	Weighted average remaining contractual term (years)
Outstanding at January 1, 2019	489,222	\$ 5.84	
Granted	978,415	12.51	
Exercised	(2,527)	5.93	
Early exercised	(471)	5.93	
Canceled/forfeited	(43,697)	8.58	
Outstanding at December 31, 2019	1,420,942	10.35	
Granted	175,086	15.03	
Exercised	(27,783)	6.29	
Canceled/forfeited	(70,037)	12.41	
Outstanding at December 31, 2020	1,498,208	10.87	
Granted	468,000	14.80	
Exercised	(77,154)	7.08	
Canceled/forfeited	(182,645)	13.08	
Outstanding at December 31, 2021	1,706,409	\$ 11.88	7.36
Vested and expected to vest at December 31, 2021	1,657,511	\$ 11.83	7.31
Exercisable at December 31, 2021	917,602	\$ 10.23	6.18

At December 31, 2021, the aggregate intrinsic value of outstanding options and exercisable options was \$3.0 million and \$2.8 million, respectively.

The 2012 Stock Incentive Plan provided the holders of stock options an election to early exercise prior to vesting. The Company had the right, but not the obligation, to repurchase early exercised options without transferring any appreciation to the employee if the employee terminates employment before the end of the original vesting period. The repurchase price is the lesser of the original exercise price or the then fair value of the common stock. At December 31, 2021, an immaterial amount of proceeds from early exercised options are recognized as a current liability in accrued expenses and other current liabilities in the accompanying consolidated balance sheet.

The following table summarizes activity relating to early exercise of stock options:

	Number of shares
Unvested balance at January 1, 2019	912
Early exercised	471
Vested	(628)
Unvested balance at December 31, 2019	755
Vested	(306)
Forfeited	(267)
Unvested balance at December 31, 2020	182
Vested	(153)
Unvested balance at December 31, 2021	29

## TELA BIO, INC.

## Notes to Consolidated Financial Statements (continued)

The weighted average grant-date fair value per share of options granted was \$8.66, \$8.13 and \$6.81 for the years ended December 31, 2021, 2020 and 2019, respectively. The aggregate intrinsic value of options exercised was \$0.4 million and \$0.2 million for the years ended December 31, 2021 and 2020, respectively, and nominal for the year ended December 31, 2019. As of December 31, 2021, the total unrecognized compensation expense related to unvested employee and nonemployee stock option awards was \$5.1 million, which is expected to be recognized in expense over a weighted-average period of approximately 2.5 years.

*Estimating Fair Value of Stock Options*

The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. Certain of these inputs are subjective and generally require judgment to determine.

*Expected term* – The expected term of stock options represents the weighted average period the stock options are expected to be outstanding. The Company uses the simplified method for estimating the expected term as provided by the Securities and Exchange Commission. The simplified method calculates the expected term as the average time to vesting and the contractual life of the options.

*Expected volatility* – Due to the Company’s limited operating history and lack of adequate company-specific historical or implied volatility, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available.

*Risk-free interest rate* – The risk-free rate assumption is based on the U.S. Treasury instruments, the terms of which were consistent with the expected term of the Company’s stock options.

*Expected dividend* – The Company has not paid and does not intend to pay dividends.

The fair value of each option was estimated on the date of grant using the weighted average assumptions in the table below:

	Year ended December 31,		
	2021	2020	2019
Expected dividend yield	—	—	—
Expected volatility	63.9 %	59.1 %	55.9 %
Risk-free interest rate	0.99 %	0.87 %	1.82 %
Expected term (in years)	6.15	5.98	6.24

*Restricted Stock Units*

The Company’s restricted stock units (“RSUs”) vest based on the terms in each award agreement and generally vest over four years. The following table summarizes restricted stock units for the Plan:

	Number of shares
Outstanding at January 1, 2021	—
Granted	194,232
Vested	(12,000)
Canceled/forfeited	(19,189)
Outstanding at December 31, 2021	163,043

The weighted average grant-date fair value per RSU granted was \$16.57 during the year ended December 31, 2021. The aggregate intrinsic value of RSUs outstanding was \$2.1 million at December 31, 2021. The total unrecognized

**TELA BIO, INC.****Notes to Consolidated Financial Statements (continued)**

compensation expense at December 31, 2021 related to RSUs was \$1.6 million, which is expected to be recognized in expense over a weighted-average period of approximately 3.2 years.

**(9) Employee Benefit Plans****401(k) Defined Contribution Plan**

The Company sponsors a 401(k) defined-contribution plan covering all employees. Participants are permitted to contribute up to 100% of their eligible annual pretax compensation up to an established federal limit on aggregate participant contributions. Discretionary contributions made by the Company, if any, are determined annually by the board of directors. Effective January 1, 2020, the Company matched 50% of employees' contributions up to 6%, subject to a maximum annual amount. The Company's contributions were \$0.3 million and \$0.2 million for the years ended December 31, 2021 and 2020, respectively. The match was suspended from April to August 2020 due to COVID-19. Participants are immediately vested in their own contributions to the plan and are fully vested in discretionary profit sharing made by the Company after three years of service.

**2019 Employee Stock Purchase Plan**

In November 2019, the Company adopted the 2019 Employee Stock Purchase Plan (the "ESPP"). At December 31, 2021, 317,701 shares were available for future issuance under the ESPP. The ESPP is subject to an annual increase, subject to prior approval by the Company's board of directors, equal to the least of (i) 107,887 shares of common stock, (ii) 1% of the shares outstanding on the final day of the immediately preceding calendar year, and (iii) such smaller number of shares as determined by the board of directors. The ESPP provides the opportunity to purchase the Company's common stock at a 5% discount to the market price through payroll deductions. As of December 31, 2021 and 2020, 3,163 and 2,797 shares, respectively, have been issued under the ESPP. No shares were issued under the ESPP as of December 31, 2019.

**(10) Income Taxes**

The Company has incurred losses since inception. Deferred tax assets and liabilities are determined based on the differences between the financial statement carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect for years in which differences are expected to reverse.

Significant components of the Company's deferred tax assets for federal income taxes consisted of the following (in thousands):

	December 31,	
	2021	2020
<b>Deferred tax assets</b>		
Net operating loss carryforwards	\$ 47,737	\$ 39,937
Research and development credits	623	747
Depreciation and amortization	(89)	239
Accrued expenses and other	1,356	611
Inventory reserve	171	205
Gross deferred tax asset	49,798	41,739
Valuation allowance	(49,798)	(41,739)
<b>Net deferred tax asset</b>	<b>\$ —</b>	<b>\$ —</b>

The Company does not have unrecognized tax benefits as of December 31, 2021 and 2020. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

TELA BIO, INC.

Notes to Consolidated Financial Statements (continued)

The Company's net operating loss ("NOL") carryforwards for federal and state income tax purposes consisted of the following (in thousands):

NOL carryforwards	December 31,	
	2021	2020
Federal	\$ 181,443	\$ 150,642
State	151,488	128,912

The NOL carryforwards begin expiring in 2032 for federal purposes and in 2026 for state income tax purposes. The Company recorded a valuation allowance on the deferred tax assets as of December 31, 2021 and 2020 because of the uncertainty of their realization. The valuation allowance increased by \$8.1 million and \$6.9 million for the years ended December 31, 2021 and 2020, respectively, mainly due to losses incurred.

Utilization of the net operating losses and general business tax credits carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if changes in ownership of the company have occurred previously or occur in the future. Ownership changes may limit the amount of net operating losses and general business tax credits carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of 5% shareholders in the stock of a corporation by more than 50 percentage points over a three-year period. If the Company experiences a Section 382 ownership change, the tax benefits related to the NOL carryforwards may be further limited or lost. The Company has not performed an analysis under Section 382 and cannot predict or otherwise determine whether there would be any limitation to the amount of net operating losses and general business tax credits carryforwards that can be utilized.

A reconciliation of income tax benefit at the statutory federal income tax rate and as reflected in the consolidated financial statements is as follows:

Rate reconciliation	Year ended December 31,		
	2021	2020	2019
Federal tax benefit at statutory rate	(21.0)%	(21.0)%	(21.0)%
State rate, net of federal benefit	(3.5)	(4.2)	(2.9)
Permanent differences	0.2	0.6	0.4
Research and development	0.4	0.7	(0.7)
Change in valuation allowance	24.2	24.0	24.2
Other	(0.3)	(0.1)	—
Total tax provision	—%	—%	—%

The Company files income tax returns in the U.S. federal jurisdiction, various state jurisdictions and the United Kingdom. Tax years 2017 and forward remain open for examination for federal tax purposes and tax years 2017 and forward remain open for examination for the Company's more significant state tax jurisdictions. Carryforward attributes from prior years may be adjusted upon examination by taxing authorities if used in an open period.

Many governments have enacted or are currently contemplating economic stimulus and financial aid measures. Many of these measures include deferring the due dates for tax payments, including both income tax and other taxes. The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted on March 27, 2020 in the United States to address the economic impacts of the COVID-19 pandemic. The CARES Act includes corporate income tax, payroll tax, and other provisions. While the Company may receive financial, tax, or other benefits under the bill, this

**TELA BIO, INC.**

**Notes to Consolidated Financial Statements (continued)**

legislation did not impact the Company during the year ended December 31, 2020. During the year ended December 31, 2021, the Company claimed an employee retention payroll tax credit of \$0.5 million for certain employment taxes.

**(11) Commitments and Contingencies**

**Legal Proceedings**

From time to time, the Company may be a party to various other lawsuits, claims, and other legal proceedings that arise in the ordinary course of its business. While the outcomes of these matters are uncertain, management does not expect that the ultimate costs to resolve these matters will have a material adverse effect on the Company's financial position, results of operations, or cash flows.

**Agreements with Aroa**

In August 2012, the Company entered into a License, Product Development, and Supply Umbrella Agreement ("Aroa Agreement") with Aroa. The Aroa Agreement provides the Company a license to patent rights and other intellectual property related to Aroa's products and technologies for use in certain indications and expires on the expiration of the last patent covering the products (currently April 19, 2031). The Company has the right to extend the term of the agreement by an additional 10 years following the expiration of the last patent covering the products on commercially reasonable terms to be negotiated by the parties. This agreement initially limited the Company's license rights to the U.S. but was subsequently amended in March 2013 to include the European Union and certain former Union of Soviet Socialist Republic satellite nations. The Aroa Agreement required payments aggregating up to \$4.0 million upon the achievement of U.S. and European cumulative product sales targets.

The Company paid \$1.0 million to Aroa in 2018 related to one of the cumulative product sales targets and the remaining \$2.0 million in 2019. With respect to the sales milestone payments in the European territory, a payment of \$1.0 million is due when cumulative product net sales in the European territory reach certain amounts.

Other key terms of the amended Aroa agreement in addition to those disclosed above are as follows:

- The transfer price for product produced by Aroa is 200% of Aroa's cost of goods sold. The transfer price and the quarterly true-up amount continued to equal 27% of Company's net sales of licensed products. Upon a change in control of the Company (as defined in the amended agreement), the annual minimum amounts will be extended for a sixth year with a \$5.0 million minimum amount for the North American territory and \$1.0 million minimum amount for the European territory. If a change in control of the Company occurs prior to the first product launch in the applicable territory, then the annual minimum requirements shall commence upon such change in control. If the make whole payments, if any, are not made by the Company after a notice and cure period, then the license will convert to a nonexclusive basis in the territory for which the payment was required but not made.
- Provisions exist for the Company to step in and operate Aroa's plant if a supply failure occurs and is not cured within a set timeframe. Under the amended agreement, the criteria for a supply failure was modified to mean a failure by Aroa to timely supply, during any consecutive 60-day period, at least 75% of the products ordered by the Company under binding purchase orders. During the period that the Company steps in and assumes manufacturing responsibility, it shall not be required to purchase product from or pay transfer prices to Aroa, the annual minimums shall be proportionately reduced to reflect the lack of supply responsibility by Aroa and the Company shall pay a royalty of 6% of net sales in lieu of 27% of net sales of the licensed products.

**TELA BIO, INC.****Notes to Consolidated Financial Statements (continued)**

The Company expects to enter into similar milestone-based agreements with its strategic partner for both product territories and new products in order to expand and extend its product portfolio.

As of December 31, 2021, the Company had \$1.8 million in purchase commitments with Aroa and certain other suppliers to maintain exclusivity rights.

**Other Commitments**

In November 2021, the Company entered into an exclusive distribution agreement with Next Science, a medical technology company, granting the Company exclusive rights to sell and market Next Science's proprietary antimicrobial surgical wash in the U.S. plastic reconstructive surgery market. To maintain exclusivity, the Company has \$10.8 million in purchase commitments and annual license fees over a ten-year period.

**Employment Agreements**

The Company entered into employment agreements with key personnel providing for compensation and severance in certain circumstances, as defined in the respective employment agreements.

**Operating Leases**

The Company leases office and laboratory space in Malvern, Pennsylvania under a noncancelable lease, which was amended in December 2020 to extend the term of the lease from May 2021 to May 2028. The facility lease agreement has annual scheduled payment increases. The Company is recognizing the rent expense on a straight-line basis over the lease term. The Company recognized rent expense of \$0.4 million, \$0.3 million and \$0.3 million for the years ended December 31, 2021, 2020 and 2019, respectively.

The future minimum lease payments under the facility operating lease agreement as of December 31, 2021 are as follows (in thousands):

2022	\$	349
2023		358
2024		366
2025		375
2026		383
Thereafter		557
	\$	<u>2,388</u>

**(12) Related-Party Transactions**

On November 16, 2018, the Company entered into a senior secured term loan facility with OrbiMed, an entity affiliated with an owner of a material amount of the Company's outstanding voting securities. The terms of the debt and related components are further described in more detail in Note 6.

**Exhibits.**

The following exhibits are being filed herewith:

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Exhibit</b>
3.1	<a href="#">Fourth Amended and Restated Certificate of Incorporation (incorporated by reference to exhibit 3.1 of the Company's Current Report on Form 8-K filed on November 19, 2019).</a>
3.2	<a href="#">Second Amended and Restated Bylaws (incorporated by reference to exhibit 3.2 of the Company's Current Report on Form 8-K filed on November 19, 2019).</a>
4.1	<a href="#">Specimen Common Stock Certificate of the Company (incorporated by reference to exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
4.2	<a href="#">Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to exhibit 4.2 to the Company's Report on Form 10-K, filed on March 30, 2020).</a>
10.1	<a href="#">Form of Indemnification Agreement by and between the Company and its individual directors and officers (incorporated by reference to exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.2	<a href="#">TELA Bio, Inc. 2012 Stock Incentive Plan (incorporated by reference to exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.3	<a href="#">Amendment to the TELA Bio, Inc. 2012 Stock Incentive Plan (incorporated by reference to exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.4	<a href="#">Second Amendment to the TELA Bio, Inc. 2012 Stock Incentive Plan (incorporated by reference to exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.5	<a href="#">Third Amendment to the TELA Bio, Inc. 2012 Stock Incentive Plan (incorporated by reference to exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.6	<a href="#">Fourth Amendment to the TELA Bio, Inc. 2012 Stock Incentive Plan (incorporated by reference to exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.7	<a href="#">Fifth Amendment to the TELA Bio, Inc. 2012 Stock Incentive Plan (incorporated by reference to exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.8	<a href="#">Form of Incentive Stock Option Agreement pursuant to the 2012 Stock Incentive Plan (incorporated by reference to exhibit 10.8 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.9	<a href="#">Form of Nonstatutory Stock Option Agreement pursuant to 2012 Stock Incentive Plan (incorporated by reference to exhibit 10.9 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.10	<a href="#">TELA Bio, Inc. Amended and Restated 2019 Equity Incentive Plan (incorporated by reference to exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 8, 2020).</a>
10.11	<a href="#">Form of TELA Bio, Inc. Amended and Restated 2019 Equity Incentive Plan Stock Option Grant Notice and Stock Option Agreement (incorporated by reference to exhibit 10.11 to the Company's Report on Form 10-K, filed on March 25, 2021).</a>
10.12	<a href="#">Form of TELA Bio, Inc. Amended and Restated 2019 Equity Incentive Plan Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement (incorporated by reference to exhibit 10.12 to the Company's Report on Form 10-K, filed on March 25, 2021).</a>
10.13	<a href="#">TELA Bio, Inc. 2019 Employee Stock Purchase Plan (incorporated by reference to exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.14	<a href="#">TELA Bio, Inc. Amended and Restated Non-Employee Director Compensation Policy (filed herewith).</a>
10.15	<a href="#">Amended and Restated Employment Agreement, dated October 25, 2019, by and between the Company and Antony Koblish (incorporated by reference to exhibit 10.16 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.16	<a href="#">Amended and Restated Employment Agreement, dated October 25, 2019, by and between the Company and Skott Greenhalgh (incorporated by reference to exhibit 10.21 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.17	<a href="#">Employment Agreement, dated January 17, 2020, by and between the Company and Peter Murphy (incorporated by reference to exhibit 10.26 to the Company's Report on Form 10-K, filed on March 30, 2020).</a>

10.18	<a href="#">Employment Agreement, dated August 27, 2021, by and between the Company and Roberto Cuca (incorporated by reference to exhibit 10.1 to the Company's Report on Form 8-K, filed on September 27, 2021).</a>
10.19	<a href="#">Employment Agreement, dated September 15, 2020, by and between the Company and Paul Talmo (filed herewith).</a>
10.20	<a href="#">Credit Agreement, dated November 16, 2018, by and between the Company and OrbiMed Royalty Opportunities II, LP (incorporated by reference to exhibit 10.22 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.21*	<a href="#">Second Amended and Restated License, Product Development and Supply Umbrella Agreement, dated July 16, 2015, by and between the Company and Aroa Biosurgery Ltd. (incorporated by reference to exhibit 10.23 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.22*	<a href="#">Amendment to Second Amended and Restated License, Product Development and Supply Umbrella Agreement, dated November 26, 2015, by and between the Company and Aroa Biosurgery Ltd. (incorporated by reference to exhibit 10.24 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.23*	<a href="#">Amendment to Second Amended and Restated License, Product Development and Supply Umbrella Agreement, dated January 3, 2019, by and between the Company and Aroa Biosurgery Ltd. (incorporated by reference to exhibit 10.25 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.24*	<a href="#">Addendum to the Second Amended and Restated License, Product Development and Supply Umbrella Agreement, dated August 27, 2019, by and between the Company and Aroa Biosurgery Ltd. (incorporated by reference to exhibit 10.22 on the Company's Report on Form 10-K filed on March 30, 2020).</a>
10.25*	<a href="#">Addendum to the Second Amended and Restated License, Product Development and Supply Umbrella Agreement, dated February 15, 2020, by and between the Company and Aroa Biosurgery Ltd. (incorporated by reference to exhibit 10.2 on the Company's Report on Form 10-Q filed on May 15, 2020).</a>
10.26	<a href="#">Lease between the Company and Liberty Property Limited Partnership, dated January 31, 2013 (incorporated by reference to exhibit 10.26 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.27	<a href="#">First Amendment to Lease between the Company and Liberty Property Partnership, dated June 19, 2014 (incorporated by reference to exhibit 10.27 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.28	<a href="#">Second Amendment to Lease between the Company and WPT Land 2 LP (as successor in interest to Liberty Property Limited Partnership), dated January 17, 2018 (incorporated by reference to exhibit 10.28 to the Company's Registration Statement on Form S-1 (File No. 333-234217), dated November 7, 2019).</a>
10.29	<a href="#">Third Amendment to Lease between the Company and WPT Land 2 LP (as successor in interest to Liberty Property Limited Partnership), dated December 22, 2020 (incorporated by reference to exhibit 10.29 to the Company's Report on Form 10-K, filed on March 25, 2021).</a>
10.30	<a href="#">Equity Distribution Agreement, dated December 18, 2020 (incorporated by reference to Exhibit 1.2 of the Company's Registration Statement on Form S-3 (File No. 333-251505) filed on December 18, 2020).</a>
21.1	<a href="#">Subsidiaries of the Registrant (filed herewith).</a>
23.1	<a href="#">Consent of KPMG LLP (filed herewith).</a>
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Rules 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).</a>
32.1	<a href="#">Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).</a>
32.2	<a href="#">Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).</a>
101 INS	XBRL Instance Document (filed herewith).
101 SCH	XBRL Taxonomy Extension Schema Document (filed herewith).
101 CAL	XBRL Taxonomy Extension Calculation Linkbase Document (filed herewith).



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101 DEF	XBRL Taxonomy Extension Definition Linkbase Document (filed herewith).
101 LAB	XBRL Taxonomy Extension Label Linkbase Document (filed herewith).
101 PRE	XBRL Taxonomy Extension Presentation Linkbase Document (filed herewith).
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

\* Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TELA BIO, INC.

By: /s/ ANTONY KOBLISH

Name: Antony Koblisch

Title: President, Chief Executive Officer  
and Director

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ ANTONY KOBLISH</u> Antony Koblisch	President, Chief Executive Officer and Director (Principal Executive Officer)	March 23, 2022
<u>/s/ ROBERTO CUCA</u> Roberto Cuca	Chief Operating Officer and Chief Financial Officer (Principal Financial Officer)	March 23, 2022
<u>/s/ MEGAN SMEYKAL</u> Megan Smeykal	Chief Accounting Officer and Controller (Principal Accounting Officer)	March 23, 2022
<u>/s/ DOUG EVANS</u> Doug Evans	Chairman, Board of Directors	March 23, 2022
<u>/s/ KURT AZARBARZIN</u> Kurt Azarbarzin	Director	March 23, 2022
<u>/s/ VINCE BURGESS</u> Vince Burgess	Director	March 23, 2022
<u>/s/ LISA COLLERAN</u> Lisa Colleran	Director	March 23, 2022
<u>/s/ JOHN NOSENZO</u> John Nosenzo	Director	March 23, 2022
<u>/s/ FEDERICA O'BRIEN</u> Federica O'Brien	Director	March 23, 2022

**AMENDED AND RESTATED  
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY**

Non-employee members of the board of directors (the “**Board**”) of TELA Bio, Inc. (the “**Company**”) shall be eligible to receive cash and equity compensation as set forth in this Amended and Restated Non-Employee Director Compensation Policy (this “**Policy**”). The cash and equity compensation described in this Policy shall be paid or granted, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a “**Non-Employee Director**”), unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Policy shall become effective on January 1, 2022 (the “**Effective Time**”) and shall remain in effect until it is revised or rescinded by further action of the Board. This Policy may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Policy shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors and between any subsidiary of the Company and any of its non-employee directors.

(1) **Cash Compensation.**

(a) Annual Retainers. Each Non-Employee Director shall receive an annual retainer of \$40,000 for service on the Board.

(b) Additional Annual Retainers. In addition, a Non-Employee Director shall receive the following annual retainers:

(i) Chairperson of the Board. A Non-Employee Director serving as Chairperson of the Board shall receive an additional annual retainer of \$35,000 for such service.

(ii) Audit Committee. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of \$20,000 for such service. A Non-Employee Director serving as a member of the Audit Committee (other than the Chairperson) shall receive an additional annual retainer of \$10,000 for such service.

(iii) Compensation Committee. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of \$15,000 for such service. A Non-Employee Director serving as a member of the Compensation Committee (other than the Chairperson) shall receive an additional annual retainer of \$7,500 for such service.

(iv) Nominating and Corporate Governance Committee. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of \$10,000 for such service. A Non-Employee Director serving as a member of the Nominating and Corporate Governance Committee (other than the Chairperson) shall receive an additional annual retainer of \$5,000 for such service.

(c) Payment of Retainers.

(i) Timing. The annual retainers described in Sections 1(a) and 1(b) shall be earned on a quarterly basis based on a calendar quarter and shall be paid by the Company in arrears not later than the fifteenth day following the end of each calendar quarter.

(ii) Form. The annual retainers shall be paid in the form of cash; provided that the Board may, in its discretion, permit a Non-Employee Director to elect to receive any portion of the annual retainer in the form of shares of common stock of the Company (“**Common Stock**”) in lieu of cash. If such an election is permitted by

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the Board and made by a Non-Employee Director, the number of shares of Common Stock to be paid shall be determined by dividing the portion of the annual retainer payable in the form of Common Stock by the Fair Market Value (as defined in the Company's Amended and Restated 2019 Equity Incentive Plan or any other applicable Company equity plan then maintained by the Company (such plan, as may be amended from time to time, the "**Equity Plan**") per share of Common Stock on the date the annual retainer is payable. Shares issued in lieu of cash shall be fully vested and unrestricted shares of Common Stock. Any election by a Non-Employee Director to receive a portion of the annual retainer in shares of Common Stock must be made prior to the applicable payment date for such portion of the annual retainer and pursuant to an election form to be provided by the Company. An election must comply with all rules established from time to time by the Board, including any insider trading policy or similar policy. A Non-Employee Director may not make an election pursuant to this Section 1(c)(ii) during a Company blackout period or when the Non-Employee Director is otherwise in possession of material non-public information.

(iii) **Termination of Service.** In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section 1(b), for an entire calendar quarter, such Non-Employee Director shall receive a prorated portion of the retainer(s) otherwise payable to such Non-Employee Director for such calendar quarter pursuant to Section 1(b), with such prorated portion determined by multiplying such otherwise payable retainer(s) by a fraction, the numerator of which is the number of days during which the Non-Employee Director serves as a Non-Employee Director or in the applicable positions described in Section 1(b) during the applicable calendar quarter and the denominator of which is the number of days in the applicable calendar quarter.

(2) **Equity Compensation.** Non-Employee Directors shall be granted the equity awards described below (collectively, the "**Awards**"). The Awards shall be granted under and shall be subject to the terms and provisions of the Equity Plan and shall be granted subject to the execution and delivery of award agreements in substantially the forms approved by the Board. The approval of this Policy by the Board is intended to be effective for all purposes, including for purposes of satisfying Rule 16b-3(d)(1) of the Securities Exchange Act of 1934, as amended, in respect of each award issued hereunder.

(a) **Initial Awards.** Upon a Non-Employee Director's initial appointment or election to the Board after the Effective Time, he or she will be granted: (i) an option to purchase 8,040 shares of Common Stock at a per-share exercise price equal to the closing price per share of Common Stock on the date of such appointment or election (or on the last preceding trading day, if the date of such appointment or election is not a trading day), and (ii) a restricted stock unit award with respect to 4,702 shares of Common Stock. The Awards described in this Section 2(a) shall be referred to as "**Initial Awards**."

(b) **Annual Awards.** Each Non-Employee Director who serves on the Board as of the date of any annual meeting of the Company's stockholders (an "**Annual Meeting**") after the Effective Time, and will continue to serve as a Non-Employee Director immediately following such Annual Meeting, shall be automatically granted on the date of such Annual Meeting: (i) an option to purchase 5,360 shares of Common Stock at a per-share exercise price equal to the closing price per share of Common Stock on the date of such Annual Meeting (or on the last preceding trading day, if the date of the Annual Meeting is not a trading day), and (ii) a restricted stock unit award with respect to 3,135 shares of Common Stock. The Awards described in this Section 2(b) shall be referred to as "**Annual Awards**."

(c) **Vesting of Awards.** Awards will vest as follows, in each case subject to the continued service of the grantee to the Company through the applicable vesting date or event:

(i) Initial Awards described in Section 2(a)(i) will vest in 36 equal monthly installments, on the monthly anniversary of the date of grant over the 36 calendar months commencing after the grantee's initial appointment or election to the Board.

(ii) Initial Awards described in Section 2(a)(ii) will vest in three equal annual installments, on the first three anniversaries of the grantee's initial appointment or election to the Board.

(iii) Annual Awards will vest on the earlier of (A) the first anniversary of the date of grant, and (B) the date of the subsequent Annual Meeting following the date of grant.

(iv) In addition, any otherwise unvested Awards will vest and become exercisable in full immediately prior to and contingent upon the occurrence of a Change in Control (as defined in the Equity Plan).

## EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement"), dated as of September 15, 2020, is made and entered into by and between TELA Bio, Inc., a Delaware corporation (the "Company"), and Paul Talmo (the "Executive").

WHEREAS, the Company and Executive desire to continue the employment of Executive with the Company, on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein and intending to be bound hereby, the parties agree as follows:

1. Duration of Agreement. This Agreement is effective on the date set forth above and has no specific expiration date. Unless terminated or amended in writing by the parties, this Agreement will govern the Executive's continued employment by the Company until that employment ceases in accordance with Section 5 hereof.

2. Position; Duties. The Executive will be employed as the Company's Chief Strategic Officer, reporting directly to the Company's President and Chief Executive Officer. In such position, the Executive shall perform such duties and shall have such authority consistent with such position as may be assigned to him from time to time by the Company's President and Chief Executive Officer. The Executive shall devote his best efforts and all of his business time and services to the Company and its Affiliates. The Executive shall not, in any capacity, engage in other business activities or perform services for any other Person without the prior written consent of the Board; *provided, however*, that without such consent, the Executive may engage in charitable or public service, so long as such activities do not interfere with the Executive's performance of his duties and obligations hereunder.

3. Place of Performance. The Executive may perform his services hereunder at, among other locations, the principal executive offices of the Company, the Executive's home office and/or during business related travel.

4. Compensation.

4.1. Base Salary. The Executive's annual salary will be \$300,000 (the "Base Salary"). The Company shall pay the Base Salary, less such withholdings and deductions as required by applicable law, to the Executive in accordance with the Company's usual payroll practices as in effect from time to time. The Base Salary shall be reviewed on an annual basis by the Board and may adjusted from time to time by the Board; *provided, however*, that any decrease in the Base Salary shall be made only if the Company contemporaneously decreases the salaries of all senior executives and vice presidents of the Company and the Executive's Base Salary is decreased by a percentage that is not greater than the average percentage by which the salaries of such other senior executives and vice presidents are decreased.

4.2. Annual Bonus. Executive will be eligible to participate in an annual incentive program established by the Board. Executive's annual incentive compensation under such incentive program (the "Annual Bonus") shall be targeted at 50% of Executive's Base Salary (the "Target Bonus"). The Annual Bonus payable under the incentive program shall be

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based on the achievement of performance goals to be determined by the Board. Any Annual Bonus earned will be paid at the same time annual bonuses are paid to other executives of the Company generally, subject to Executive's continuous employment through the date of payment, except as otherwise provided in Section 5.

4.3. Employee Benefits. The Executive will be eligible to participate in the employee benefit plans, policies or arrangements maintained by the Company for its senior executive employees generally, subject to the terms and conditions of such plans, policies or arrangements; *provided, however*, that this Agreement will not limit the Company's ability to amend, modify or terminate such plans, policies or arrangements at any time for any reason.

4.4. Paid Time Off. Subject to the terms and conditions of the Company's policy, as may be amended from time to time, the Executive will be eligible for four weeks of paid time off each calendar year.

4.5. Reimbursement of Expenses. The Company will pay or reimburse the Executive for all reasonable business expenses incurred or paid by the Executive in the performance of his duties and responsibilities for the Company in accordance with the business expense reimbursement policies of the Company, as may be amended from time to time.

5. Termination; Severance. The Executive's employment hereunder shall terminate (i) on the date specified in a written notice from the Company that Executive's employment with the Company will be terminated, (ii) on the date not less than 30 days following written notice from the Executive that he is resigning from the Company, (iii) on the date of his death or (iv) on the date of his Disability, as reasonably determined by the Company. Upon cessation of his employment for any reason, unless otherwise consented to in writing by the Board, the Executive shall resign immediately from any and all officer, director and other positions he then holds with the Company and/or its Affiliates. Upon any cessation of his employment with the Company, the Executive shall be entitled only to such compensation and benefits as described in this Section 5.

5.1. Termination without Cause or upon Good Reason. If the Executive's employment by the Company ceases due to a termination by the Company without Cause (as defined below) or a termination by the Executive for Good Reason (as defined below), the Company shall:

5.1.1. pay to the Executive all accrued and unpaid Base Salary through the termination date at the time such Base Salary would otherwise be paid according to the Company's usual payroll practices;

5.1.2. pay to the Executive any accrued and unpaid Annual Bonus for the year preceding the year in which the termination date occurs at the time such Annual Bonus would otherwise be paid in accordance with Section 4.2, but in no event later than March 15 of the year immediately following the year in which the termination date occurs;

5.1.3. make severance payments to the Executive in the form of continuation of the Executive's then current Base Salary for a period of nine (9) months following the termination date (or, if the termination occurs within the Change of Control Period,

for a period of twelve (12) months following the termination date), in accordance with the Company's normal payroll practices (such 9- or 12-month period, as applicable, the "Severance Period");

5.1.4. provide to the Executive a continuation of health, dental and vision insurance during the Severance Period and, to the extent that the continuation of such insurance coverage is not permitted under the Company's insurance policies, pay to the Executive a cash amount equal to the monthly cost of continued coverage under the Consolidated Omnibus Budget Reconciliation Act ("COBRA"); and

5.1.5. in the event that the termination occurs on or within the Change of Control Period, (i) pay to the Executive an amount equal to 100% of the Executive's then current Target Bonus, payable in the form of cash payments in regular installments over the Severance Period in accordance with the Company's normal payroll practices, (ii) pay to the Executive a pro-rated portion (based on the number of days Executive was employed by the Company during the calendar year in which the termination date occurs) of the Annual Bonus that Executive would have earned for the year of termination had Executive remained employed, as determined by the Board in good faith; *provided* that such pro-rated Annual Bonus shall be paid out at the same time annual bonuses are paid generally to other executives of the Company for the relevant year, but in no event later than March 15<sup>th</sup> of the year immediately following that in which the termination date occurs, and (iii) the vesting and, if applicable, exercisability shall be accelerated (and, if applicable, all restrictions and rights of repurchase on such awards shall lapse) effective as of immediately prior to the termination date with respect to 100% of the shares subject to Executive's then outstanding equity awards; provided, however, that for any awards that vest in whole or in part based on the attainment of performance-vesting conditions, only the service-vesting conditions (if any) of such award shall be deemed satisfied, while the performance-vesting conditions of such award shall remain eligible to be achieved based upon actual performance over the remainder of the applicable performance period.

5.1.6. Except as otherwise provided in this Section 5.1, all compensation and benefits will cease at the time of the Executive's cessation of employment and the Company will have no further liability or obligation by reason of such cessation of employment. The payments and benefits described in this Section 5.1 are in lieu of, and not in addition to, any other severance arrangement maintained by the Company. Notwithstanding any provision of this Agreement, the payments described in Section 5.1 (other than Section 5.1.1) are conditioned on: (a) the Executive's execution and delivery to the Company of a general release of claims against the Company and its Affiliates substantially in form and substance satisfactory to the Company (the "Release") and on such Release becoming irrevocable by the 60<sup>th</sup> day following the effective date of the Executive's cessation of employment; and (b) the Executive's continued compliance with the provisions of the Restrictive Covenant Agreement (as defined below). Subject to Section 5.3 below, to the extent that any payments under this Section 5.1 (other than Section 5.1.1) are delayed pending the Release becoming irrevocable, the delayed amounts will be paid in a lump sum as soon as administratively practicable after the Release becomes irrevocable, provided that if the 60 day period described above begins in one taxable year and ends in a second taxable year, the payment of the delayed amounts and the commencement of the remaining payments shall not occur until the second taxable year.



5.2. Other Terminations. If the Executive's employment with the Company ceases for any reason other than as described in Section 5.1 above (including but not limited to (a) termination by the Company for Cause, (b) resignation by the Executive without Good Reason, (c) termination as a result of the Executive's Disability, or (d) the Executive's death), then the Company's obligation to the Executive will be limited solely to the payment of accrued and unpaid Base Salary as described in Section 5.1.1 through the date of such cessation of employment and, in the case of Executive's death or Disability, any Annual Bonus as described in Section 5.1.2. All compensation and benefits will cease at the time of such cessation of employment and, except as otherwise provided by COBRA, the Company will have no further liability or obligation by reason of such termination. The foregoing will not be construed to limit the Executive's right to payment or reimbursement for claims incurred prior to the date of such termination under any insurance contract funding an employee benefit plan, policy or arrangement of the Company in accordance with the terms of such insurance contract.

5.3. Compliance with Section 409A. Notwithstanding anything to the contrary in this Agreement, no portion of the benefits or payments to be made under Section 5.1 will be payable until the Executive has a "separation from service" from the Company within the meaning of Section 409A of the Code. In addition, to the extent compliance with the requirements of Treas. Reg. § 1.409A-3(i)(2) (or any successor provision) is necessary to avoid the application of an additional tax under Section 409A of the Code to payments due to the Executive upon or following his "separation from service", then notwithstanding any other provision of this Agreement (or any otherwise applicable plan, policy, agreement or arrangement), any such payments that are otherwise due within six months following the Executive's "separation from service" (taking into account the preceding sentence of this paragraph) will be deferred without interest and paid to the Executive in a lump sum on the earlier of (i) the expiration of such six month period and (ii) the date of Executive's death. This paragraph should not be construed to prevent the application of Treas. Reg. § 1.409A-1 (b)(9)(iii) (or any successor provision) to amounts payable hereunder. For purposes of the application of Section 409A of the Code, each payment in a series of payments will be deemed a separate payment.

6. Restrictive Covenants. The Executive acknowledges and agrees to abide by the terms of, and agrees that his continued employment by the Company is contingent upon, his valid and binding execution of the Confidential Information, Non-Competition and Assignment Agreement which the Executive previously executed and delivered to the Company (the "Restrictive Covenant Agreement"). By execution and delivery of this Agreement, the Executive reaffirms his obligations under the Restrictive Covenant Agreement. The Executive acknowledges that the terms of the Restrictive Covenant Agreement shall continue to remain in full-force and effect following the cessation of the Executive's employment with the Company for any reason.

7. Certain Definitions. For purposes of this Agreement:

7.1. "Affiliate" means, with respect to any specified Person, any other Person that directly or indirectly, through one or more intermediaries, Controls, is Controlled by, or is under common Control with, such specified Person, provided that, in any event, any business in

which the Company has any direct ownership interest shall be treated as an Affiliate of the Company.

7.2. “Cause” means (i) indictment, commission of, or the entry of a plea of guilty or no contest to, (A) a felony or (B) any crime (other than a felony) that causes the Company or its Affiliates public disgrace or disrepute, or adversely affects the Company’s or its Affiliates’ operations or financial performance or the relationship the Company has with its Affiliates, customers and suppliers; (ii) commission of an act of gross negligence, willful misconduct, fraud, embezzlement, theft or material dishonesty with respect to the Company or any of its Affiliates; (iii) a breach of the Executive’s fiduciary duty of loyalty to the Company or any of its Affiliates; (iv) alcohol abuse or use of controlled substances (other than prescription drugs taken in accordance with a physician’s prescription); (v) material breach of any agreement with the Company or any of its Affiliates, including this Agreement and the Restrictive Covenant Agreement; (vi) a material breach of any Company policy regarding employment practices; or (vii) refusal to perform the lawful directives of the Board, if not cured within 30 days following receipt by the Executive from the Company of written notice thereof.

7.3. “Change of Control” means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events: (A) any sale, lease, exclusive license or other transfer of all or substantially all of the assets of the Company and its Subsidiaries taken as a whole by means of a single transaction or series of related transactions, except where such sale, lease, exclusive license or other transfer is to a wholly owned Subsidiary of the Company; or (B) any transaction or series of transactions involving the Company, or its securities, whether by consolidation, merger, purchase of shares of capital stock or other reorganization or combination or otherwise, in which the holders of the Company’s outstanding shares of capital stock immediately prior to such transaction or series of related transactions own, immediately after such transaction or series of related transactions, securities representing fifty percent (50%) or less of the voting power of the entity surviving such transaction or series of related transactions or the entity whose securities are issued pursuant to such transaction or series of related transactions.

7.4. “Change of Control Period” means the period beginning on the date of the consummation of a Change in Control and ending on the first anniversary of such date.

7.5. “Code” means the Internal Revenue Code of 1986, as amended.

7.6. “Control” (including, with correlative meanings, the terms “Controlled by” and “under common Control with”), as used with respect to any Person, means the direct or indirect possession of the power to direct or cause the direction of the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.

7.7. “Disability” means a condition entitling the Executive to benefits under the Company’s long term disability plan, policy or arrangement; *provided, however*, that if no such plan, policy or arrangement is then maintained by the Company and applicable to the Executive, “Disability” will mean the Executive’s inability to perform the essential duties of his position due to a mental or physical condition (other than alcohol or substance abuse), with or

without a reasonable accommodation. Termination as a result of a Disability will not be construed as a termination by the Company “without Cause.”

7.8. “Good Reason” means one or more of the following: (i) a material reduction in the Executive’s title, duties, authority or responsibilities, provided that a material reduction of the Executive’s title, duties, authority or responsibilities hereunder shall be deemed not to have occurred if, following a Change of Control, (A) if the Company remains a separate entity, Executive is the most senior executive directly responsible for the Commercial functions of the Company, or (B) if the Company does not remain a separate entity, Executive is the most senior executive directly responsible for the Commercial functions of the acquiring entity that are comprised of the former business of the Company; (ii) a material breach of this Agreement by the Company; (iii) a material reduction in Base Salary or Target Bonus opportunity by the Company to the Executive that is not in accordance with Section 4.1 and to which the Executive has not provided written consent; or (iv) any requirement following a Change of Control that the Executive be based 50 or more miles from the facility where the Executive is based immediately prior to the Change of Control. The notice by the Executive of the condition constituting Good Reason under this Agreement shall be provided to the Company in writing within ninety (90) days of the initial existence of the condition constituting Good Reason, the Company shall then have thirty (30) days after receipt of such written notice to remedy the condition, and in the event the Company fails to remedy the condition, the Executive’s resignation based on such Good Reason must be effective within thirty (30) days after the expiration of such remedy period.

7.9. “Person” means any individual, firm, corporation, partnership, limited liability company, trust, joint venture, association, governmental entity, unincorporated entity or other entity.

7.10. “Subsidiary” means any corporation, limited liability company, partnership or other entity of which a majority of the outstanding voting stock or voting power is beneficially owned directly or indirectly by the Company.

8. Miscellaneous.

8.1. Cooperation. The Executive further agrees that, subject to reimbursement of his reasonable expenses, he will cooperate fully with the Company and its counsel with respect to any matter (including litigation, investigations, or governmental proceedings) in which the Executive was in any way involved during his employment with the Company. The Executive shall render such cooperation in a timely manner on reasonable notice from the Company, so long as the Company exercises commercially reasonable efforts to schedule and limit its need for the Executive’s cooperation under this paragraph so as not to interfere with the Executive’s other personal and professional commitments.

8.2. Section 409A.

8.2.1. Notwithstanding anything herein to the contrary or otherwise, except to the extent any expense, reimbursement or in-kind benefit provided to the Executive does not constitute a “deferral of compensation” within the meaning of Section 409A of the Code, and its implementing regulations and guidance, (i) the amount of expenses eligible for

reimbursement or in-kind benefits provided to the Executive during any calendar year will not affect the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive in any other calendar year, (ii) the reimbursements for expenses for which the Executive is entitled to be reimbursed shall be made on or before the last day of the calendar year following the calendar year in which the applicable expense is incurred and (iii) the right to payment or reimbursement or in-kind benefits hereunder may not be liquidated or exchanged for any other benefit.

8.2.2. Anything to the contrary herein notwithstanding, all benefits or payments provided by the Company to the Executive that would be deemed to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code are intended to comply with Section 409A of the Code. Notwithstanding anything in this Agreement to the contrary, distributions may only be made under this Agreement upon an event and in a manner permitted by Section 409A of the Code or an applicable exemption.

8.3. Section 280G. Notwithstanding any other provision of this Agreement, in the event that any payment or benefit by the Company or otherwise to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (all such payments and benefits, including the payments and benefits under Section 5 above, being hereinafter referred to as the "Total Payments"), would be subject (in whole or in part) to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then the Total Payments shall be reduced to the minimum extent necessary to avoid the imposition of the Excise Tax on the Total Payments, but only if (i) the net amount of such Total Payments, as so reduced (and after subtracting the net amount of federal, state and local income and employment taxes on such reduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such reduced Total Payments), is greater than or equal to (ii) the net amount of such Total Payments without such reduction (but after subtracting the net amount of federal, state and local income and employment taxes on such Total Payments and the amount of the Excise Tax to which Executive would be subject in respect of such unreduced Total Payments and after taking into account the phase out of itemized deductions and personal exemptions attributable to such unreduced Total Payments). The reduction of the Total Payments contemplated in this Section 8.3 shall be implemented by determining the Parachute Payment Ratio (as defined below), as determined in good faith by the Company (or its successor), for each Total Payment and then reducing the Total Payments in order beginning with the Total Payment with the highest Parachute Payment Ratio. For Total Payments with the same Parachute Payment Ratio, such Total Payments shall be reduced based on the time of payment of such Total Payments, with amounts having later payment dates being reduced first. For Total Payments with the same Parachute Payment Ratio and the same time of payment, such Total Payments shall be reduced on a pro rata basis (but not below zero) prior to reducing Total Payments with a lower Parachute Payment Ratio. For purposes hereof, the term "Parachute Payment Ratio" shall mean a fraction, (x) the numerator of which is the value of the applicable Total Payment (as calculated for purposes of Section 280G of the Code), and (y) the denominator of which is the intrinsic (i.e., economic) value of such Total Payment.

8.4. Other Agreements. The Executive represents and warrants to the Company that there are no restrictions, agreements, including but not limited to confidentiality,

non-compete, invention assignment, or consulting agreements, or understandings whatsoever to which he is a party that would prevent or make unlawful his execution of this Agreement, that would be inconsistent or in conflict with this Agreement or the Executive's obligations hereunder, or that would otherwise prevent, limit or impair the performance by the Executive of his duties under this Agreement.

8.5. Successors and Assigns. The Company may assign this Agreement to any Affiliate or to any successor to its assets and business by means of liquidation, dissolution, merger, sale of assets or otherwise. Upon such assignment, the rights and obligations of the Company hereunder shall become the rights and obligations of such Affiliate or successor. For avoidance of doubt, a termination of the Executive's employment by the Company in connection with a permitted assignment of the Company's rights and obligations under this Agreement is not a termination "without Cause" so long as the assignee offers employment to the Executive substantially on the terms herein specified (without regard to whether the Executive accepts employment with the assignee). The rights and duties of the Executive hereunder are personal to Executive and may not be assigned by him.

8.6. Governing Law and Enforcement. This Agreement will be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania, without regard to the principles of conflicts of laws. Any legal proceeding arising out of or relating to this Agreement will be instituted in a state or federal court in the Commonwealth of Pennsylvania, and the Executive and the Company hereby consent to the personal and exclusive jurisdiction of such court(s) and hereby waive any objection(s) that they may have to personal jurisdiction, the laying of venue of any such proceeding and any claim or defense of inconvenient forum.

8.7. Waivers. The waiver by either party of any right hereunder or of any breach by the other party will not be deemed a waiver of any other right hereunder or of any other breach by the other party. No waiver will be deemed to have occurred unless set forth in writing. No waiver will constitute a continuing waiver unless specifically stated, and any waiver will operate only as to the specific term or condition waived.

8.8. Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law. However, if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provision, and this Agreement will be reformed, construed and enforced as though the invalid, illegal or unenforceable provision had never been herein contained.

8.9. Survival. This Agreement will survive the cessation of the Executive's employment to the extent necessary to fulfill the purposes and intent of this Agreement.

8.10. Notices. Any notice or communication required or permitted under this Agreement will be made in writing and (a) sent by reputable overnight courier, (b) mailed by overnight U.S. express mail, return receipt requested or (c) sent by telefax. Any notice or communication to the Executive will be sent to the address contained in his personnel file. Any notice or communication to the Company will be sent to the Company's principal executive

offices, to the attention of the Board. Notwithstanding the foregoing, either party may change the address for notices or communications hereunder by providing written notice to the other in the manner specified in this paragraph.

8.11. Withholding. All payments (or transfers of property) to the Executive will be subject to tax withholding to the extent required by applicable law.

8.12. Section Headings. The headings of sections and paragraphs of this Agreement are inserted for convenience only and will not in any way affect the meaning or construction of any provision of this Agreement.

8.13. Counterparts; Facsimile. This Agreement may be executed in multiple counterparts (including by facsimile signature), each of which will be deemed to be an original, but all of which together will constitute but one and the same instrument.

8.14. Entire Agreement; Amendments. This Agreement contains the entire agreement and understanding of the parties hereto relating to the subject matter hereof, and supersedes all prior discussions, agreements and understandings of every nature relating to that subject matter. This Agreement may not be changed or modified, except by an agreement in writing signed by each of the parties hereto.

8.15. Policies. Executive acknowledges that Executive shall be subject to, and hereby agrees to abide by the terms of, Company policies in effect from time to time, including, without limitation, any clawback or recoupment policies, securities trading policies and stock ownership guidelines.

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its duly authorized officer, and the Executive has executed this Agreement, in each case on the date first above written.

COMPANY:

TELA Bio, Inc.

By: /s/ Antony Koblish

Name: Antony Koblish

Title: Chief Executive Officer

EXECUTIVE:

/s/ Paul Talmo

Paul Talmo

(Signature Page to Employment Agreement)

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## LIST OF SUBSIDIARIES

Subsidiary	Ownership Percentage	Jurisdiction of Incorporation or Organization
TELA Bio, Limited	100%	England and Wales

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**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the registration statements (No. 333-251505) on Form S-3 and (Nos. 333-245707 and 333-235241) on Form S-8 of our report dated March 23, 2022, with respect to the consolidated financial statements of TELA Bio, Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania  
March 23, 2022

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## CERTIFICATION

Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934,  
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Antony Koblisch, certify that:

1. I have reviewed this Form 10-K of TELA Bio, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2022

/s/ Antony Koblisch

Antony Koblisch

President and Chief Executive Officer

(Principal Executive Officer)

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## CERTIFICATION

Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934,  
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Roberto Cuca, certify that:

1. I have reviewed this Form 10-K of TELA Bio, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2022

/s/ Roberto Cuca  
Roberto Cuca  
Chief Operating Officer and Chief Financial Officer  
(Principal Financial Officer)

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**CERTIFICATION**

Pursuant to 18 U.S.C. Section 1350,  
as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), that: Antony Koblisch, Chief Executive Officer of TELA Bio, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

- (1) The Company's Annual Report on Form 10-K for the period ended December 31, 2021, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- (2) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2022

/s/ Antony Koblisch

Antony Koblisch

*President and Chief Executive Officer*

*(Principal Executive Officer)*

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**CERTIFICATION**

Pursuant to 18 U.S.C. Section 1350,  
as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), that: Roberto Cuca, Chief Operating Officer and Chief Financial Officer of TELA Bio, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

- (1) The Company's Annual Report on Form 10-K for the period ended December 31, 2021, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
- (2) The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2022

/s/ Roberto Cuca

Roberto Cuca

*Chief Operating Officer and Chief Financial Officer*  
*(Principal Financial Officer)*

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