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As submitted confidentially to the Securities and Exchange Commission on September 19, 2019.
This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1
to

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

TELA Bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**45-5320061**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

1 Great Valley Parkway, Suite 24
Malvern, Pennsylvania 19355
(484) 320-2930
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Antony Koblish
President and Chief Executive Officer
TELA Bio, Inc.
1 Great Valley Parkway, Suite 24, Malvern, Pennsylvania 19355
(484) 320-2930
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Rachael M. Bushey	**Marc D. Jaffe**
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Pepper Hamilton LLP	**Latham & Watkins LLP**
3000 Two Logan Square	**885 Third Avenue**
Philadelphia, Pennsylvania 19103	**New York, New York 10022**
(215) 981-4331	**(212) 906-1200**

Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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 o	Accelerated filer o	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 7(a)(2)(B) of the Securities Act. o

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed Maximum Aggregate Offering Price[1][2]	Amount of registration fee[2]
Common stock, $0.001 par value per share	$	$

(1) Includes shares of common stock that the underwriters have the option to purchase.
(2) Estimated solely for the purpose of computing the amount of registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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SUBJECT TO COMPLETION, DATED , 2019

PRELIMINARY PROSPECTUS

Shares

TELA Bio, Inc.

Common Stock

We are offering shares of our common stock. This is our initial public offering and no public market currently exists for our common stock. We expect the initial public offering price to be between $ and $ per share. We have applied to list our common stock on The Nasdaq Global Market under the symbol "TELA".

Investing in our common stock involves a high degree of risk. Please read "Risk Factors" beginning on page 15 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

We are an "emerging growth company" under the federal securities laws and will be subject to reduced public company reporting requirements for this prospectus and future filings.

	PER SHARE	TOTAL
Public Offering Price	$	$
Underwriting Discounts and Commissions[(1)]		
Proceeds to TELA Bio, Inc. (Before Expenses)		

(1) We refer you to "Underwriting" beginning on page 163 for additional information regarding underwriter compensation.

Delivery of the shares of common stock is expected to be made on or about , 2019. We have granted the underwriters an option for a period of 30 days to purchase an additional shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $, and the total proceeds to us, before expenses, will be $.

Joint Book-Running Managers

Jefferies **Piper Jaffray**

Lead Manager

Canaccord Genuity

Co-Manager

JMP Securities

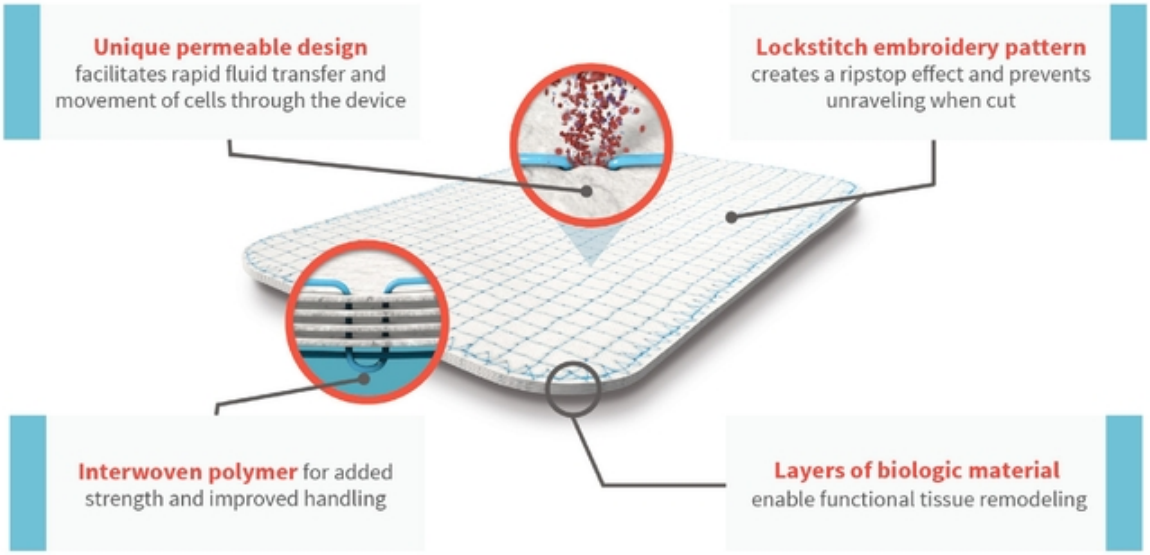
Prospectus dated , 2019

TELA BIO®
SURGICAL RECONSTRUCTION COMPANY

SCIENCE. VALUE. INNOVATION.

OviTex® – a new approach to soft tissue reinforcement for hernia repair and abdominal wall reconstruction

An innovative bioscaffold designed to reduce stretch compared to biologics and long-term complications experienced with resorbable and permanent synthetic meshes



0% hernia recurrence at 12-months in first 32 patients of BRAVO post-market study

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

Until , 2019 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

TRADEMARKS

"TELA," the Tela logo, TELA Bio®, OviTex® and Restella® and other trademarks, trade names or service marks of TELA Bio, Inc. appearing in this prospectus are the property of TELA Bio, Inc. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the rights of the applicable licensor to these trademarks and tradenames.

INVESTORS OUTSIDE THE UNITED STATES

For investors outside of the United States: neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, especially the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. Unless the context otherwise requires, the terms "TELA," "TELA Bio," "the company," "we," "us," "our" and similar references in this prospectus refer to TELA Bio, Inc. and its wholly-owned subsidiary.

TELA Bio

We are a commercial stage medical technology company focused on designing, developing and marketing a new category of tissue reinforcement materials to address unmet needs in soft tissue reconstruction. We offer a portfolio of advanced bioscaffolds that improve clinical outcomes and reduce overall costs of care in hernia repair, abdominal wall reconstruction and plastic and reconstructive surgery. Our products are an innovative solution that integrate multiple layers of minimally-processed biologic material with interwoven polymers in a unique embroidered pattern, which we refer to as a bioscaffold. These products have been implanted by surgeons in more than 5,700 patients with no reported explantations due to failure of the product.

Our first portfolio of products, the OviTex Reinforced Bioscaffold, or 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, or FDA, which clearance was obtained and is currently held by Aroa Biosurgery Ltd., or Aroa, our exclusive manufacturer and supplier, and have demonstrated safety and clinical effectiveness in our ongoing prospective, single arm, multicenter post-market clinical study, which we refer to as our BRAVO study. The first 32 patients who reached one year follow-up in the BRAVO study experienced no ventral hernia recurrences, no explantations and no surgical site occurrences requiring follow-up surgery. Our second portfolio of products, the OviTex PRS — Restella Reconstructive Bioscaffold, or Restella, addresses unmet needs in plastic and reconstructive surgery. In April 2019, our Restella products received 510(k) clearance from the FDA, which clearance was obtained and is currently held by Aroa.

We began commercialization of our OviTex products in the United States in July 2016, and they are now sold to more than 200 hospital accounts. 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.

Restella 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 Restella 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. We commenced a limited launch in May 2019 and expect to fully launch our Restella products in the United States through our direct sales force in the first half of 2020. We also intend to engage in discussions with the FDA regarding an Investigational Device Exemption, or IDE, protocol to study the safety and effectiveness of our Restella product for an indication in breast reconstruction surgery.

We have a broad portfolio of intellectual property protecting our products, which 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 raw materials. In addition, we believe our exclusive manufacturing and long-term supply and license agreement, or 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 our products, 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 United States. We have invested in our direct sales and marketing infrastructure in order to expand our presence and to promote awareness and adoption of our products. As of June 30, 2019, we had 22 sales territories in the United States. We plan to continue to invest in our commercial organization by hiring additional account managers, clinical development specialists, business managers and administrative support staff in order to cover the top 500 hospitals that we believe perform approximately 55% of our targeted soft tissue reconstruction procedures. We plan to continue to contract with group purchasing organizations, or GPOs, and integrated delivery networks, or IDNs, to increase access to and penetration of hospital accounts.

Our revenue for the years ended December 31, 2017 and 2018 was $4.2 million and $8.3 million, respectively, and our revenue for the six months ended June 30, 2018 and 2019 was $3.6 million and $6.6 million, respectively. For the years ended December 31, 2017 and 2018, we had net losses of $21.3 million and $21.1 million, respectively, and for the six months ended June 30, 2018 and 2019, we had net losses of $10.9 million and $11.2 million, respectively.

Our Market Opportunity

OviTex

Hernia repair is one of the most common surgeries performed in the United States. A hernia occurs when pressure causes an organ, intestine or fatty tissue to squeeze through a hole caused by a defect or weak area in the surrounding muscle or connective tissue. For patients who have had multiple prior hernia surgeries that have failed, the anatomy of their abdominal wall is often compromised and surgeons must perform more advanced techniques to repair the abdomen, known as 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. 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 repair over the last several years.

There are an estimated 1.2 million hernia repairs annually in the United States, including recurrences. 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. 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.

Restella

Plastic and reconstructive surgery is performed to treat structures of the human body that are affected aesthetically or functionally due to defects, abnormalities, trauma, infection, burns, tumors or disease. Plastic and reconstructive surgery is generally performed to improve function and ability, but may also be performed to achieve a more typical appearance of the affected anatomical structure. Modern advances in tissue engineering have transformed plastic and reconstructive surgeons' management strategies across a

wide variety of applications. 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. Based on the current sales of biologic matrices in the United States, we estimate the annual U.S. current addressable market opportunity for our Restella products to be approximately $500 million.

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

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 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 the abdominal wall. Based on longitudinal data from the Danish Hernia Database, in an analysis of approximately 2,900 patients who received a mesh hernia repair, the observed rate of surgical intervention due to either recurrence or mesh-related complications at five years post operatively was approximately 17%.

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 tissue, which allows them to become replaced entirely by the patient's own tissue over time, a process known as remodeling. Compared to permanent synthetic mesh, biologic matrices are less likely to induce an 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.

A multicenter, prospective study sponsored by LifeCell Corporation that evaluated the performance of Strattice, the current market-leading biologic matrix, in open ventral incisional hernia repair in contaminated abdominal wall defects, demonstrated post operative hernia recurrence rates of 22% and 33% 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 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 synthetic 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.

Data from a recently published, multicenter, prospective study sponsored by C.R. Bard, Inc. 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 12% at 18-months follow-up.

Current Materials Used in Plastic and Reconstructive Surgery and Their Limitations

The most common materials used in plastic and reconstructive surgery are biologic matrices, including in the vast majority of tumor removal, defects, abnormalities, burns and implant-based breast reconstructive surgery, 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, biologic matrices can be prone to excessive stretching over time and are 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.

Our bioscaffolds are designed to improve the outcomes of hernia repair, abdominal wall reconstruction and plastic and reconstructive surgery by reinforcing soft 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.

We believe the principal benefits of our bioscaffolds are:

- ***Reduced foreign body inflammatory response.*** The biologic material utilized in our bioscaffolds acts to reduce the body's inflammatory response to the device. 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 biologics, and less foreign body inflammatory response than all the synthetic mesh tested at 24 weeks.

- ***Enhanced remodeling of soft tissue and rate of healing.*** Our bioscaffolds 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 was reminiscent of 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 bioscaffolds are engineered to create hundreds of micro-channels to promote fluid exchange to allow host cells and new blood vessels to penetrate the bioscaffold. In our non-human primate comparative study, at four weeks our OviTex products had host cells between and within the layers of the bioscaffold. We believe this early cell infiltration may reduce the potential for bacterial colonization and the risk for infection. In our BRAVO study, there were no wound infections that required surgical intervention or device removal in the first 32 patients who reached one year follow-up.

- ***Highly engineered biomechanical properties with durability of results.*** Our bioscaffolds are reinforced with interwoven polymer fibers to provide mid-term and long-term strength. The interwoven polymer in our bioscaffolds increases the strength of our OviTex products by approximately 25% compared to the biologic material alone. 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 no hernia recurrences in the first 32 patients who reached one year follow-up, despite 80% of these patients having one or more factors known to increase the risk of recurrence.

- ***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. We have also designed an OviTex product for use in robotic-assisted surgery.

- ***Lower upfront cost products.*** Our bioscaffolds provide our customers with meaningful cost savings over leading competitive products, while maintaining clinical efficacy 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 Restella portfolio is priced below leading biologic matrices.

Clinical Data

The table below presents recurrence rate data published in clinical literature or presented at industry conferences from prospective clinical studies in ventral hernia repairs utilizing our competitors' products.

Product Name	Tissue Reinforcement Material	Hernia Recurrence Rate[1]	Number of Hernia Recurrence[1]	Number of Patients who Completed Follow-up[1]	Follow-up Period in Months
Phasix[1]	Resorbable Synthetic Mesh	5%	5	95	12
Phasix[1]	Resorbable Synthetic Mesh	12%	11	95	18
Phasix[1]	Resorbable Synthetic Mesh	23%	19	82	36
Strattice[1]	Biologic Matrix	22%	15	69	12
Strattice[1]	Biologic Matrix	33%	22	67	24

(1) Hernia Recurrence Rate based on number of hernia recurrences reported in patients who completed follow up and patients who reported recurrent hernia before the specified follow up period. Clinical literature and conference presentations included hernia recurrence rates based on number of hernia recurrences in patients who comprised the initial intent-to-treat population (including those who did not complete the follow up period and did not report a hernia recurrence).

The table below presents the recurrence rate for the first 32 patients who reached 12-month follow-up in our BRAVO study.

Product Name	Tissue Reinforcement Material	Hernia Recurrence Rate	Number of Hernia Recurrence	Number of Patients who Completed Follow-up	Follow-up Period in Months
OviTex	**Reinforced Bioscaffold**	**0%**	**0**	**32**	**12**

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 Restella products are the only FDA-cleared products to incorporate polymer fibers interwoven through layers of biologic material in a lockstitch pattern creating a unique embroidered construction. The biologic matrix is derived from ovine rumen and utilizes a patented process to create a bioscaffold that is optimized for soft tissue reconstruction. Our OviTex and Restella products are available in resorbable and permanent polymer versions in a variety of configurations and sizes.

- ***Disruptive technology supported by compelling clinical evidence.*** The safety, efficacy and durability of our OviTex products are supported by compelling clinical evidence that includes studies in more than 200 non-human primates, and our BRAVO study.

- ***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 Restella 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 Restella products to hospitals and healthcare systems at prices substantially below competitive products based on national average competitive pricing. We anticipate that our customers will realize approximately 20% to 40% cost savings over biologic matrices and resorbable synthetic mesh.

- ***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 Medicare Severity Diagnosis Related Groups, or 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 intellectual property broadly covers changing a biologic matrix's biomechanical properties by interweaving a polymer thread through the biologic matrix. Through our Aroa License, our intellectual property broadly covers the development of extracellular matrix scaffolds derived from ovine rumen and methods for isolating these scaffolds from ovine rumen.

- ***Industry leading executive team with proven track record.*** Our executive team consists of seasoned medical device professionals with deep industry experience and expertise who have led and managed companies through significant growth and introduction and commercialization of multiple new products, including driving surgeon adoption of biologic and biosurgery technologies.

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 United States and plan to continue to invest in our commercial organization by adding account managers, clinical development specialists, business managers and administrative support staff.

- ***Promote awareness of our products to drive surgeon use.*** We educate surgeons regarding the value proposition of our products and plan to continue to drive awareness of our products, while expanding their geographic reach and increasing the number of surgeon interactions.

- ***Increase access to group purchasing organizations and integrated delivery networks.*** We continue to pursue contracts with several large GPOs and IDNs and believe that the addition of multiple contracts with national GPOs and high-volume IDNs will materially increase our access to surgeon customers, broaden awareness for our products and help drive utilization of our products within a larger number of hospitals and healthcare 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.

- ***Advance our portfolio of bioscaffolds 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.

Risks Associated with Our Business

Our business is subject to numerous risks, as more fully described in the section titled "Risk Factors" immediately following this prospectus summary. You should read these risks before you invest in our common stock. In particular, risks associated with our business include, but are not limited to, the following:

- 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.
- To date, substantially all of our revenue has been generated from sales of our OviTex products, and we therefore are highly dependent on their success.
- The commercial success of our products will largely depend upon attaining significant market acceptance.
- We currently have limited sales and marketing capabilities.
- We are highly dependent upon Aroa, as the exclusive manufacturer and supplier of our products.
- 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 may be unable to compete successfully with larger competitors in our highly competitive industry.
- 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 long-term growth depends on our ability to enhance our product offerings.
- Our success depends in part on our intellectual property portfolio.
- Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

Corporate Information

We were incorporated in Delaware on April 17, 2012. Our principal 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. The information contained on, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

Implications of Being an Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earliest to occur of: the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates; the issuance, in any three-year period, by us of more than $1 billion in non-convertible debt securities; and the last day of the fiscal year ending after the fifth anniversary of our initial public offering. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the "JOBS Act," and any reference herein to "emerging growth company" has the meaning ascribed to it in the JOBS Act.

An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have elected to take advantage of certain of the reduced disclosure obligations in this prospectus and may elect to take advantage of other reduced reporting requirements in our future filings with the U.S. Securities and Exchange Commission, or the SEC. The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to avail ourselves of this exemption. As a result of these elections the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

THE OFFERING

Common stock offered by us	shares
Common stock to be outstanding immediately after this offering	shares (shares if the underwriters exercise their option to purchase additional shares)
Underwriters' option to purchase additional shares	shares
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $ million (or approximately $ million if the underwriters exercise in full their option to purchase up to additional shares of common stock), based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents to hire additional sales and marketing personnel and expand marketing activities to support the ongoing commercialization of our OviTex and Restella product lines, to fund product development and research and development activities, which may include post-market clinical studies and IDE protocol development for our Restella products, and the remainder for working capital and general corporate purposes. See "Use of Proceeds" for additional information.
Directed share program	At our request, the underwriters have reserved for sale at the initial public offering price per share up to % of the shares offered hereby for our directors, officers and certain employees and other persons with whom we have a relationship. See "Underwriting" for additional information.
Risk factors	You should read the section titled "Risk Factors" for a discussion of factors to consider carefully, together with all the other information included in this prospectus, before deciding to invest in our common stock.
Proposed Nasdaq Global Market symbol	"TELA"

The number of shares of our common stock to be outstanding immediately after this offering is based on shares of common stock outstanding as of August 30, 2019, after giving effect to the automatic conversion of all our redeemable convertible preferred stock, or preferred stock, into an aggregate of shares of our common stock immediately prior to the completion of this offering and excludes:

- 13,779,213 shares of our common stock issuable upon the exercise of stock options as of August 30, 2019, at a weighted-average exercise price of $0.24 per share;
- 23,108 shares of our unvested common stock that are subject to repurchase by us as of August 30, 2019;

- shares of our common stock issuable upon the exercise of warrants to purchase shares of our Series B preferred stock outstanding as of August 30, 2019, which will convert into warrants to purchase shares of our common stock immediately prior to the completion of this offering, at an exercise price of $1.16 per share;
- 603,203 shares of our common stock that remain available for issuance as of August 30, 2019 under our 2012 Stock Incentive Plan, or the 2012 Plan; and
- shares of our common stock reserved for future issuance under our 2019 Equity Incentive Plan, or the 2019 Plan, which will become effective immediately prior to the completion of this offering, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to the 2019 Plan.

Unless otherwise indicated, all information contained in this prospectus assumes or gives effect to:

- a for reverse stock split of our common stock to be effected prior to the completion of this offering;
- the automatic conversion of all our preferred stock outstanding into an aggregate of shares of our common stock immediately prior to the completion of this offering, including accrued dividends payable into an aggregate of shares of our common stock based on an assumed initial offering price of $ per share, which is the midpoint of the price range shown on the cover page of this prospectus;
- the conversion of all outstanding warrants to purchase shares of our Series B preferred stock into warrants to purchase shares of our common stock, at an exercise price of $, upon the completion of this offering;
- the effectiveness of our fourth amended and restated certificate of incorporation immediately prior to the completion of this offering and the adoption of our second amended and restated bylaws immediately prior to the completion of this offering;
- no exercise of the outstanding options or warrants described above; and
- no exercise by the underwriters of their option to purchase up to additional shares of our common stock.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated statements of operations data for the years ended December 31, 2017 and 2018 and the six months ended June 30, 2018 and 2019 and our consolidated balance sheet data as of June 30, 2019. We have derived the following consolidated statements of operations data for the years ended December 31, 2017 and 2018 from our audited consolidated financial statements included elsewhere in this prospectus. We have derived the following statements of operations data for the six months ended June 30, 2018 and 2019 and balance sheet data as of June 30, 2019 from our unaudited interim consolidated financial statements included elsewhere in this prospectus. The unaudited interim consolidated financial data, in management's opinion, have been prepared on the same basis as the audited consolidated financial statements and the related notes included elsewhere in this prospectus, and include all adjustments, consisting only of normal recurring adjustments, that management considers necessary for a fair presentation of the information for the periods presented. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. The following summary consolidated financial data should be read with the sections titled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	Year ended December 31,		Six months ended June 30,	
	2017	2018	2018	2019
	(in thousands, except share and per share data)			
Statement of Operations:				
Revenue	$ 4,245	$ 8,274	$ 3,635	$ 6,609
Cost of revenue (excluding amortization of intangible assets)	1,713	4,547	2,455	2,752
Amortization of intangible assets	—	785	633	152
Gross profit	2,532	2,942	547	3,705
Operating expenses:				
Sales and marketing	8,712	13,646	6,022	7,942
General and administrative	4,958	4,899	1,967	2,529
Research and development	5,786	4,339	2,318	2,714
Gain on litigation settlement	—	(2,160)	—	—
Total operating expenses	19,456	20,724	10,307	13,185
Loss from operations	(16,924)	(17,782)	(9,760)	(9,480)
Other (expense) income:				
Interest expense	(4,558)	(1,802)	(728)	(1,826)
Loss on extinguishment of debt	—	(1,822)	(615)	—
Change in fair value of preferred stock warrant liability	54	244	174	(38)
Other income	94	70	34	117
Total other (expense) income	(4,410)	(3,310)	(1,135)	(1,747)
Net loss	(21,334)	(21,092)	(10,895)	(11,227)
Accretion of redeemable convertible preferred stock to redemption value	(5,893)	(8,823)	(7,948)	(4,787)
Net loss attributable to common stockholders	$ (27,227)	$ (29,915)	$ (18,843)	$ (16,014)
Net loss per common share, basic and diluted	$ (3.78)	$ (4.11)	$ (2.59)	$ (2.19)
Weighted average common shares outstanding, basic and diluted	7,208,547	7,283,167	7,273,968	7,313,934
Pro forma net loss per common share basic and diluted (unaudited)[1]		$		$
Pro forma weighted average shares outstanding, basic and diluted (unaudited)[1]				

(1) See Note 3 to our annual and interim consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate our historical and pro forma basic and diluted net loss per common share.

	As of June 30, 2019		
	Actual	Pro Forma[2]	Pro Forma As Adjusted[3][4]
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$ 15,873		
Working capital[1]	15,104		
Total assets	26,627		
Long-term debt with related party	29,977		
Preferred stock warrant liability	1,678		
Redeemable convertible preferred stock	141,063		
Total stockholders' (deficit) equity	(153,747)		

(1) Working capital is calculated as current assets minus current liabilities.

(2) The pro forma consolidated balance sheet gives effect to (1) the issuance of 1,463,959 shares of Series B preferred stock that were sold in July 2019 for net proceeds of $1.7 million, (2) the automatic conversion of all our preferred stock outstanding, including accrued dividends payable into an aggregate of shares of our common stock immediately prior to the completion of this offering based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus and (3) the reclassification of $1.7 million preferred stock warrant liability into additional paid-in capital upon the conversion of all outstanding warrants to purchase shares of our Series B preferred stock into warrants to purchase shares of our common stock.

(3) Reflects the pro forma adjustments set forth above and the issuance and sale of shares of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(4) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity, by $ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity, by $ million, assuming the assumed initial public offering price of $ per share remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

Investing in our common stock involves a high degree of risk. These risks include, but are not limited to, those described below, each of which may be relevant to an investment decision. You should carefully consider the risks described below, together with all of the other information in this prospectus, including our consolidated financial statements and related notes, before investing in our common stock. 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. In that event, the trading price of our common stock could decline, and you may lose part or all of your investment.

Risks Related to Our Limited Operating History, 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, 2017 and 2018, we had net losses of $21.3 million and $21.1 million, respectively and for the six months ended June 30, 2018 and 2019, we had net losses of $10.9 million and $11.2 million, respectively. As of June 30, 2019, we had an accumulated deficit of $153.8 million. To date, we have financed our operations primarily through private placements of our preferred stock, borrowings under our credit facility and sales of our OviTex Reinforced Bioscaffold, or OviTex, products.

We expect to continue to incur significant sales and marketing, research and clinical development, regulatory and other expenses as we expand our 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. In addition, we expect our general and administrative expenses to increase following this offering due to the additional costs associated with being a public company. 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.

We have limited history operating as a commercial company.

We began commercializing our OviTex products in the United States in 2016 and in certain European countries in 2019, and therefore do not have a long history operating as a commercial company. Since 2016, our revenue has been derived almost entirely from sales of our OviTex products. In April 2019, Aroa Biosurgery, Ltd., or Aroa, our exclusive manufacturer and supplier, received and continues to hold 510(k) marketing clearance from the U.S. Food and Drug Administration, or FDA, for our Restella products. In May 2019 we commenced a limited launch and expect to fully launch our Restella products through our direct sales force in the first half of 2020. As a result of its recent commercial introduction, our OviTex products have limited product and brand recognition, and demand for our OviTex products may not increase as quickly as we expect, or may decline. Our limited commercialization experience and limited number of cleared products make it difficult to evaluate our current business and predict future prospects. Our ability to generate revenue from sales of our OviTex products, Restella and other products we may seek to develop and commercialize in the future will depend on a number of factors, including our ability to successfully market and commercialize our OviTex and Restella products in the United States. If our assumptions

regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

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

As of June 30, 2019, we had $30.0 million of indebtedness outstanding under our credit facility with OrbiMed Royalty Opportunities II, LP, or OrbiMed, that matures in November 2023. In addition, this credit facility has $5.0 million of additional capacity through December 31, 2019, provided that our consolidated net revenue on a trailing six-month basis equals or exceeds $7.5 million.

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, we will be less able to plan for, or react to, changes in our business, industry and the economy generally.

In addition, the agreement governing our 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 costs of operating as a public company;
- 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.

We have limited experience marketing and selling our products, and if we are unable to expand, manage and maintain our direct sales and marketing organizations, we may not be able to generate anticipated revenue.

We began selling our OviTex products in the United States in 2016. As a result, we currently have limited sales and marketing capabilities. As of June 30, 2019, our commercial organization consisted of 44 employees. Building the requisite sales, marketing or distribution capabilities to successfully market and sell our products will be expensive and time-consuming and will require significant attention from our leadership team to manage. Any failure or delay in the development 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.

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.

We may be unable to accurately forecast customer demand and our inventory levels.

Anticipating demand for our products may be challenging as surgeon demand and adoption rates are unpredictable. In addition, as an increasing number of our products are adopted by surgeons, we anticipate greater fluctuations in demand for our products, which makes demand forecasting more difficult.

We place orders with our supplier based on forecasts of demand and, in some instances, may acquire additional inventory to accommodate anticipated demand. Our forecasts are based on management's judgment and assumptions, each of which may introduce error into our estimates. If we overestimate customer demand, our excess or obsolete inventory may increase significantly, which would reduce our gross margin and adversely affect our financial results. For example, during the six months ended June 30, 2019, we took an inventory charge of $0.9 million due to excess inventory levels. Conversely, if we underestimate customer demand or if insufficient manufacturing capacity is available, we would miss revenue opportunities and potentially lose market share and damage our customer relationships.

The report of our independent registered public accounting firm includes a "going concern" explanatory paragraph.

The report of our independent registered public accounting firm on our consolidated financial statements as of and for the year ended December 31, 2018 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. If we are unable to raise sufficient capital in this offering or otherwise when needed, our business, financial condition and results of operations will be materially and adversely affected, and we will need to significantly modify our operational plans to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our consolidated financial statements. The inclusion of a going concern explanatory paragraph by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

Risks Related to the Commercialization of our Products

To date, substantially all of our revenue has been generated from sales of our OviTex products, and we therefore are highly dependent on their success.

Sales of our OviTex products accounted for all of our revenue for the years ended December 31, 2017 and 2018. We first commercialized OviTex products in the United States in 2016 and in the last twelve months, we have introduced our larger sized OviTex products, our OviTex LPR product for use in laparoscopic and robotic-assisted hernia surgical repairs and sold initial units of our Restella 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, once fully commercialized, our Restella 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 bioscaffold 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

bioscaffold 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 group purchasing organizations, or 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 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 Restella 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 bioscaffold 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 bioscaffolds 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 body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome. Our Restella products are reconstructive bioscaffolds 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 Restella, has been cleared or approved for use in breast surgery, and that to obtain such indication, the product sponsor must obtain an approved premarket approval application, or PMA. Our Restella products are not cleared or approved specifically for breast reconstruction surgery and thus we are prohibited from marketing them for that use. Restella or any other product we may develop for use in breast reconstruction surgery will need to be approved specifically for that indication. We intend to engage in discussions with the FDA regarding an Investigational Device Exemption, or IDE, protocol to study the safety and effectiveness of our Restella 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 Restella 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 a clearance or approval specifically for use in breast surgery. We train our marketing personnel and direct sales force to not promote our OviTex or Restella 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 Restella 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, 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, 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. In those possible events, our reputation could be damaged and adoption of the products would be impaired.

If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our OviTex, Restella 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 United States),

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 United States 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 Restella products and develop and introduce new bioscaffold 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 bioscaffold product offering or product enhancements to our OviTex and Restella 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 bioscaffold products or that would render our bioscaffold 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 bioscaffold 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 United States, we must address many international business risks with which we have limited experience.

We did not have any sales in markets outside of the United States for the year ending December 31, 2018 and approximately 1.7% of our revenue for the six month period ending June 30, 2019 came from sales in markets outside of the United States. 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 potential 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;
- 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 exclusive manufacturing and long-term supply and license agreement, or the Aroa License, which was amended and restated in July 2015. The Aroa License grants us an exclusive license in North America, the European Union, or EU, 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 $1.0 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, 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 bioscaffold 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, 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. Based upon our current planned market adoption we believe we will reach our capacity limitations in the Aroa facility. We have plans to expand capacity but there can be no assurance that we will be successful. 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 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 United States 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 Restella 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 Restella 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 or other service interruptions affecting delivery services we use would adversely affect our ability to deliver our OviTex and Restella products (or any other products we commercialize in the future) on a timely basis.

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 United States 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 six issued or allowed patents and have ten pending patent applications. As of July 30, 2019, we had rights, whether through ownership or licensing, to eight issued or allowed U.S. patents, six pending U.S. patent applications, three issued non-U.S. patents and four pending non-U.S. patent applications. Our issued U.S. patents will expire between 2035 and 2037. 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 Restella products, any additional features we develop for our OviTex and Restella 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 Restella 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 United States 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 Restella 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 United States, 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 Restella 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 and could prevent us from selling our products or affect our stock price.

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 United States 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 United States, 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, or 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. 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 any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products.

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 United States. 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 United States 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 United States, 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 United States under the Hatch-Waxman Act and in foreign countries under similar legislation.

In the United States, 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 United States and internationally.

Our products are regulated as medical devices. We and our products are subject to extensive regulation in the United States and internationally including by the FDA and European Medicines Agency, or the 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 and have become more stringent over time. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; 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 United States, 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 Federal Food, Drug, and Cosmetic Act, or 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 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 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 United States, Aroa has obtained and holds 510(k) clearances from the FDA to market our OviTex and Restella products. An element of our strategy is to continue to upgrade our bioscaffold 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. 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 November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals include plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA also announced that it intends to finalize guidance to establish a premarket review pathway for "manufacturers of certain well-understood device types" as an alternative to the 510(k) clearance pathway and that such premarket review pathway would allow manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. These proposals have not yet been finalized or adopted, and the FDA announced that it would seek public feedback prior to publication of any such proposals, and may work with Congress to implement such proposals through

legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

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 bioscaffold products and result in enforcement actions such as:

- warning letters;
- 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 European Economic Area, or the EEA, our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC) and the Active Implantable Medical Devices Directive (Council Directive 90/385/EEC). Compliance with these 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 United States 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 Quality System Regulation, or 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 Restella 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 Restella 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 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 EMA 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. For example, in November

2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. These proposals have not yet been finalized or adopted, and the FDA announced that it would seek public feedback prior to publication of any such proposals, and may work with Congress to implement such proposals through legislation. 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. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. 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 Medical Devices Regulation will become applicable in 2020, and, once applicable, the new regulations will, 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.

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, including for 35 days beginning on December 22, 2018, 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, or HIPAA, 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 United States 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, or the 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. Data breaches could result in a violation of applicable U.S. and international privacy, data protection and other laws, and subject us to individual or consumer class action litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. 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 United States, 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 California Consumer Privacy Act, or CCPA, on June 28, 2018, which takes effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases 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 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. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data

protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

This risk is enhanced in certain jurisdictions and, as we expand our operations domestically and internationally, we may be subject to additional laws in other jurisdictions. Any failure, or perceived failure, by us to comply with privacy and data protection laws, rules and regulations could result in proceedings or actions against us by governmental entities or others. These proceedings or actions may subject us to significant penalties and negative publicity, require us to change our business practices, increase our costs and severely disrupt our business. The EU's General Data Protection Regulation, or GDPR, became effective in May 2018. The GDPR applies extraterritorially and imposes several stringent requirements for controllers and processors of personal data, including, for example, 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. 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 costs to increase, harming our business and financial condition. 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.

Additionally, we are subject to laws and regulations regarding cross-border transfers of personal data, including laws relating to transfer of personal data outside of the EEA. We rely on transfer mechanisms permitted under these laws, including EU Standard Contract Clauses. If we cannot rely on existing mechanisms for transferring personal data from the EEA, the United Kingdom or other jurisdictions, we could be prevented from transferring personal data of users or employees in those regions. This could adversely affect the manner in which we provide our services and thus materially affect our operations and financial results.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our business, financial condition and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the Affordable Care Act, or ACA, was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the ACA:

- imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions (described in more detail below), although the effective rate paid may be lower. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020;

- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;

- implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other healthcare providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and

- expanded the eligibility criteria for Medicaid programs.

We do not yet know the full impact that the ACA will have on our business. There have been judicial and political challenges to certain aspects of the ACA. For example, since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements of the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees. In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Texas District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and implemented fixed annual updates and a new system of incentive payments that began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our products or other products we may commercialize in the future or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our products or other products we may commercialize in the future, which in turn could impact our ability to successfully commercialize our products or other products we may commercialize in the future and could have a material adverse effect on our business, financial condition and results of operations.

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; 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. 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 United States, we currently compete with LifeCell Corporation, an affiliate of Allergan plc, and Davol Inc., a subsidiary of C.R. Bard, Inc. which produce, among other things, soft tissue reconstruction surgery products, including Strattice and Phasix, respectively. In the EEA, we compete with C.R. Bard, Inc. 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 obtain 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 United States 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. Due to the highly competitive nature of the bidding process and the GPO and IDN contracting processes in the United States, we may not be able to obtain contract positions with major GPOs and IDNs for our products. 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.

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, or the OIG, the U.S. Department of Justice, or the 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.

We currently have 91 patients enrolled in our ongoing prospective, single arm multicenter post-market clinical study, or our BRAVO study, which we are conducting 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 Restella 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 study 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 bioscaffold 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 bioscaffold 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; 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.

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.

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 June 30, 2019 consisted of 23 representatives in the United States and 2 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 United States 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 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. 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. 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.

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. 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.

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 described under "—Risks Related to Our Limited Operating History, Financial Position and Capital Requirements," we have incurred net losses since our inception, and expect to continue to incur operating losses for the foreseeable future. If we become profitable in the future, our ability to use net operating loss carryforwards, or NOLs, and other tax attributes to offset future taxable income or reduce taxes may be subject to limitations. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" (generally defined as a greater than 50% cumulative change by value in its equity ownership of certain stockholders over a rolling three-year period) is subject to an annual limitation on its ability to utilize its pre-change NOLs and other tax attributes (including any research and development credit carryforwards). Similar provisions of state tax law may also apply to limit the use of our state NOLs and other tax attributes.

We have not performed an analysis to determine whether our past issuances of stock and other changes in our stock ownership may have resulted in one or more ownership changes within the meaning of Sections 382 and 383 of the Code. In addition, we may experience an ownership change in connection with this offering or in the future as a result of subsequent changes in our stock ownership, some of which are outside our control. If an ownership change has occurred in the past or occurs in the future, we may not

be able to use a material portion of our NOLs and other tax attributes to offset future taxable income or taxes if we attain profitability.

In addition to any limitation imposed by Section 382 of Code, the use of NOLs arising after December 31, 2017 generally is limited to a deduction of 80% of taxable income for the corresponding taxable year. NOLs arising after December 31, 2017 may not be carried back to previous taxable years, but may be carried forward indefinitely.

Risks Related to Our Common Stock and this Offering

There has been no prior public market for our common stock and an active trading market may never develop or be sustained.

Prior to this offering, there has been no public market for our common stock. Although we have applied to list our common stock on the Nasdaq Global Market, or Nasdaq, an active trading market for our common stock may never develop following completion of this offering or, if developed, 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, even if approved for listing 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.

The price of our common stock may be volatile and you may lose all or part of your investment.

The initial public offering price for the shares of our common stock sold in this offering is determined by negotiation between the representatives of the underwriters and us. This price may not reflect the market price of our common stock following this offering. In addition, 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.

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. These fluctuations may be even more pronounced in the trading market for our common stock shortly following this offering. If the market price of shares of our common stock after this offering does not ever exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

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 dividends on our common stock, so any returns will be limited to increases, if any, in our stock's value. Your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

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.

After this offering, our officers, directors and principal stockholders each holding more than 5% of our common stock, collectively, will control approximately % 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. Certain of our existing stockholders, including certain of our directors and entities affiliated with certain of our directors, have indicated an interest in purchasing up to % of the shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, fewer or no shares in this offering to any or all of these stockholders, or any or all of these stockholders may determine to purchase more, fewer or no shares in this offering. The foregoing discussion does not give effect to any potential purchases by these stockholders in this offering.

A significant portion of our outstanding shares of common stock are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that these sales may occur, could result in a decrease in the market price of our common stock. Immediately after this offering, we will have outstanding shares of common stock, based on the number of shares common stock outstanding as of June 30, 2019, (after giving effect to the automatic conversion of all shares of our preferred stock into shares of our common stock immediately prior to the closing of this offering). This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates or existing stockholders. Of the remaining shares, shares are currently restricted as a result of securities laws or 180-day lock-up agreements (which may be waived, with or without notice, by the

representatives of the underwriters) but will be able to be sold beginning 180 days after this offering, unless held by one of our affiliates, in which case the resale of those securities will be subject to volume limitations under Rule 144 of the Securities Act of 1933, as amended, or the Securities Act. See "Shares Eligible for Future Sale." Moreover, after this offering, holders of an aggregate of up to shares of our common stock, (including shares of our common stock issuable upon the automatic conversion of all shares of our preferred stock into shares of our common stock immediately prior to the closing of this offering), will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders as described in the section of this prospectus entitled "Description of Capital Stock — Registration Rights." We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market, subject to volume limitations applicable to affiliates and the lockup agreements referred to above and described in the section of this prospectus entitled "Underwriting."

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 this initial public offering, 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.

If you purchase shares of our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

Investors purchasing shares of our common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted net tangible book value per share of our common stock. As a result, investors purchasing common stock in this offering will incur immediate dilution of $ per share, representing the difference between our assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and our pro forma as adjusted net tangible book value per share as of . To the extent outstanding options to purchase shares of our common stock are exercised, new investors may incur further dilution. For more information

on the dilution you may experience as a result of investing in this offering, see the section of this prospectus entitled "Dilution."

We will have broad discretion in the use of proceeds of this offering designated for working capital and general corporate purposes.

We intend to use the net proceeds from this offering to hire additional sales and marketing personnel and expand marketing activities to support the ongoing commercialization of our OviTex and Restella product lines, to fund the research and development of new product offerings, post-market studies and IDE protocol development for our Restella products and for working capital and general corporate purposes. Within those categories, we have not determined the specific allocation of the net proceeds of this offering. Our management will have broad discretion over the use and investment of the net proceeds of this offering within those categories. Accordingly, investors in this offering have only limited information concerning our management's specific intentions and will need to rely upon the judgment of our management with respect to the use of proceeds.

We expect to incur significant additional costs as a result of being a public company.

Upon completion of this offering, we expect to incur costs associated with corporate governance requirements that will become applicable to us as a public company, including rules and regulations of the SEC, under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, as well as the rules of Nasdaq. These rules and regulations are expected to significantly increase our accounting, legal and financial compliance costs and make some activities more time-consuming. We also expect these rules and regulations to make it more expensive for us to maintain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers. Accordingly, increases in costs incurred as a result of becoming a publicly traded company may adversely affect our business, financial condition and results of operations.

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

Upon the closing of this offering, we will become 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.

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.

If a trading market for our common stock develops, the trading market will be influenced to some extent by the research and reports that industry or financial analysts publish about us and our business. We do not control these analysts. As a newly public company, we may be slow to attract research coverage and the analysts who publish information about our common stock will have had relatively little experience with us or our business and products, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us provide inaccurate or unfavorable research or issue an adverse opinion regarding our stock price, our stock price 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 or trading volume to decline and result in the loss of all or a part of your investment in us.

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 that will become effective upon the closing of this offering 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, or 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 that will become effective upon the completion of this offering 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 United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements concerning 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. These forward-looking statements include, but are not limited to, statements regarding:

- 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 United States;
- the performance of Aroa in connection with the development and production 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 or 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 United States and internationally;
- 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 this offering; 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. You should refer to the

section titled "Risk Factors" and elsewhere in this prospectus for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. These forward-looking statements speak only as of the date of this prospectus. 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.

MARKET AND INDUSTRY DATA

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. All of the market and industry data used in this prospectus involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those described in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $ million (or approximately $ million if the underwriters exercise in full their option to purchase up to additional shares of common stock), based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by $ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million in the number of shares of common stock offered by us, as set forth on the cover of this prospectus, would increase (decrease) the net proceeds to us by $ million, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $ to hire additional sales and marketing personnel and expand marketing activities to support the ongoing commercialization of our OviTex and Restella product lines,
- approximately $ to fund product development and research and development activities, which may include post-market clinical studies and IDE protocol development for our Restella products, and
- the remainder for working capital and general corporate purposes.

We may also use a portion of the remaining net proceeds to in-license, acquire or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

This expected use of the net proceeds from this offering represents our intentions based on our current plans and business conditions, which could change in the future as our plans and business conditions evolve. Our management will have broad discretion over the use of the net proceeds from this offering, and our investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering.

Pending the use of the net proceeds from this offering as described above, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States government.

DIVIDEND POLICY

Immediately prior to the completion of this offering, we intend to issue shares of common stock to our existing holders of Series A and Series B preferred stock representing accrued dividends, or the Accrued Dividends, due upon the conversion of their Series A and Series B preferred stock into common stock in connection with this offering at a fair market value determined by our board of directors which we expect will equal the initial public offering price. The Series A and Series B preferred stock are entitled to receive the Accrued Dividends at a rate per year of 8% of the original issuance price of $1.00 and $1.16, respectively.

The number of shares of common stock to be issued in satisfaction of the Accrued Dividends will be determined by dividing the amount of the Accrued Dividends by the fair value of one share of our common stock immediately prior to the payment of the Accrued Dividends. The following demonstrates the number of shares of common stock that would be outstanding immediately after the conversion of all of our preferred stock and the issuance of shares of our common stock in satisfaction of the Accrued Dividends, but before this offering, assuming the fair market values of one share of our common stock as set forth below:

Fair Market Value	$	$	$	$	$
Shares Outstanding					

Other than the Accrued Dividends, we do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business. Any future determination related to dividend policy will be made at the discretion of our board of directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions, capital requirements and other factors the board of directors deem relevant. In addition, our credit agreement with OrbiMed contains covenants that restrict our ability to pay cash dividends and our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt or preferred securities we issue or any other credit facilities we enter into.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of June 30, 2019, as follows:

- an actual basis;
- on a pro forma basis to give effect to (1) the issuance of 1,463,959 shares of Series B preferred stock that were sold in July 2019 for net proceeds of $1.7 million, (2) the automatic conversion of all our preferred stock outstanding including accrued dividends payable into an aggregate of shares of our common stock immediately prior to the completion of this offering based on an assumed initial public offering price of $ per share (3) the reclassification of $1.7 million preferred stock warrant liability into additional paid-in capital upon the conversion of all outstanding warrants to purchase shares of our Series B preferred stock into warrants to purchase shares of our common stock.
- a pro forma as adjusted basis, giving effect to the pro forma adjustments discussed above, and giving further effect to the issuance and sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our cash and capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with the sections titled "Selected Consolidated Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

(in thousands except share and per share data)	As of June 30, 2019		
	Actual	Pro Forma (unaudited)	Pro Forma As Adjusted[1]
Cash and cash equivalents	$ 15,873	$	$
Long-term debt with related party	$ 29,977	$	$
Preferred stock warrant liability	1,678		
Redeemable convertible preferred stock, $0.001 par value per share 105,392,793 shares authorized, 96,088,188 issued and outstanding, actual; no shares authorized, issued or outstanding pro forma and pro forma as adjusted	141,063		
Stockholders' (deficit) equity:			
Preferred stock; $0.001 par value: no shares authorized, issued or outstanding, actual; shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	—		
Common stock; $0.001 par value: 127,157,528 shares authorized; 7,372,350 shares issued and 7,345,531 shares outstanding, actual; shares authorized, issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	7		
Additional paid-in capital	—		
Accumulated other comprehensive loss	(3)		
Accumulated deficit	(153,751)		
Total stockholders' (deficit) equity	$ (153,747)		
Total capitalization	$ 18,971	$	$

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share (which is the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) each of cash and cash equivalents, additional paid-in capital and total stockholders' (deficit) equity by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million in the number of shares of common stock offered by us would increase (decrease) the cash and cash equivalents, additional paid-in capital and stockholders' (deficit) equity by $ million, assuming the assumed initial public offering price of $ per share remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock in the table above is based on shares of common stock outstanding as of June 30, 2019, which gives effect to the pro forma transactions described above, and excludes:

- 13,074,180 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2019, at a weighted-average exercise price of $0.24 per share;
- 26,819 shares of our unvested common stock that are subject to repurchase by us as of June 30, 2019;
- shares of our common stock issuable upon the exercise of warrants to purchase shares of our Series B preferred stock outstanding as of June 30, 2019, which will convert into warrants to purchase shares of our common stock immediately prior to the completion of this offering, at an exercise price of $ per share;

- shares of common stock issuable upon the conversion immediately prior to completion of this offering of 1,463,959 shares of Series B preferred stock issued to investors on July 31, 2019;
- 1,318,203 shares of our common stock as of June 30, 2019 that remain available for issuance under the 2012 Plan; and
- shares of our common stock reserved for future issuance under our 2019 Plan, which will become effective immediately prior to the completion of this offering, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to the 2019 Plan.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book deficit as of June 30, 2019 was $156.9 million, or $21.36 per share of common stock based on 7,345,531 shares of common stock outstanding as of such date. Our historical net tangible book deficit represents our total tangible assets less total liabilities and preferred stock divided by the number of shares of our common stock outstanding as of June 30, 2019.

Our pro forma net tangible book value (deficit) as of June 30, 2019 was $ million, or $ per share of our common stock. Pro forma net tangible book value (deficit) represents the amount of our total tangible assets less our total liabilities after giving effect to (i) the issuance of 1,463,959 shares of Series B preferred stock that were sold in July 2019 for net proceeds of $1.7 million, (ii) the automatic conversion of all our preferred stock outstanding including accrued dividends payable into an aggregate of shares of our common stock based on an assumed initial public offering price of $ per share and (iii) the reclassification of $1.7 million preferred stock warrant liability into additional paid-in capital upon the conversion of all outstanding warrants to purchase shares of our Series B preferred stock into warrants to purchase shares of our common stock. Pro forma net tangible book value (deficit) per share is our pro forma net tangible book value (deficit) divided by the number of shares of our common stock deemed to be outstanding as of June 30, 2019.

After giving effect to the issuance and sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value (deficit) as of June 30, 2019 would have been $ million, or $ per share. This represents an immediate increase (decrease) in pro forma as adjusted net tangible book value (deficit) of $ per share to our existing stockholders and an immediate dilution of $ per share to new investors purchasing shares of our common stock in this offering. We determine dilution per share to new investors by subtracting our pro forma as adjusted net tangible book value per share after this offering from the assumed public offering price per share paid by new investors in this offering.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$
Historical net tangible book deficit per share as of June 30, 2019	$ (21.36)	
Decrease in historical net tangible book deficit per share attributable to pro forma transactions and other adjustments described above		
Pro forma net tangible book value (deficit) per share as of June 30, 2019		
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors participating in this offering		$

Each $1.00 increase (decrease) in the assumed initial public offering price of $ (which is the midpoint of the price range set forth on the cover page of this prospectus) would increase (decrease) our pro forma as adjusted net tangible book value (deficit) per share after this offering by $ per share

and the dilution per share to new investors participating in this offering by $ per share, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million in the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value (deficit) per share after this offering by $ per share and increase (decrease) the dilution per share to new investors participating in this offering by $ per share, assuming that the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise in full their option to purchase up to additional shares of common stock, the pro forma as adjusted net tangible book value (deficit) per share after giving effect to this offering would be $ per share, representing an immediate increase to existing stockholders of $ per share and immediate dilution to new investors participating in this offering of $ per share assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table shows, as of June 30, 2019, on a pro forma as adjusted basis as described above, the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid, or to be paid, by existing stockholders and by new investors purchasing common stock in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		
	Number	Percent	Amount (in thousands)	Percent	Average Price Per Share
Existing stockholders before this offering		%	$	%	$
New investors participating in this offering					
Total		100%		100%	

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share (which is the midpoint of the price range set forth on the cover page of this prospectus), would increase (decrease) the total consideration paid by new investors participating in this offering and total consideration paid by all stockholders by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The above table assumes no exercise of the underwriters' option to purchase additional shares. If the underwriters exercise their option to purchase additional shares in full, our existing stockholders before this offering would own % and our new investors participating in this offering would own % of the total number of shares of our common stock outstanding immediately prior to the completion of this offering. Additionally, the consideration paid to us by existing stockholders before this offering would be $ million, or approximately % of the total consideration, and the consideration paid to us by new investors participating in this offering would be $ million, or approximately % of the total consideration.

The above table assumes no exercise of options or warrants for our common stock as of June 30, 2019 that will remain outstanding after this offering. If the holders of options and warrants were to exercise and purchase additional shares of common stock in full, our existing stockholders before this offering would own % and our new investors participating in this offering would own % of the total number of shares of our common stock outstanding immediately prior to the completion of this offering. Additionally, the consideration paid to us by existing stockholders before this offering would be $ million, or approximately % of the total consideration, and the consideration paid to us by new investors participating in this offering would be $ million, or approximately % of the total consideration.

The foregoing discussion and tables (other than the historical net tangible book value calculation) are based on shares of common stock outstanding as of June 30, 2019, which gives effect to the pro forma transactions described above, and excludes:

- 13,074,180 shares of our common stock issuable of stock options outstanding as of June 30, 2019, at a weighted-average exercise price of $0.24 per share;
- 26,819 shares of our unvested common stock that are subject to repurchase by us as of June 30, 2019;
- shares of our common stock issuable upon the exercise of warrants to purchase shares of our Series B preferred stock outstanding as of June 30, 2019, which will convert into warrants to purchase shares of our common stock immediately prior to the completion of this offering, at an exercise price of $ per share;
- 1,318,203 shares of our common stock as of June 30, 2019 that remain available for issuance under the 2012 Plan; and
- shares of our common stock reserved for future issuance under our 2019 Plan, which will become effective immediately prior to the completion of this offering, as well as any automatic increases in the number of shares of our common stock reserved for future issuance pursuant to the 2019 Plan.

To the extent that stock options are exercised, new stock options are issued under our stock incentive plans, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. The selected consolidated financial data included in this section are not intended to replace the consolidated financial statements and are qualified in their entirety by the consolidated financial statements and the related notes included elsewhere in this prospectus.

We derived the selected consolidated statement of operations data for the years ended December 31, 2017 and 2018 and the selected consolidated balance sheet data as of December 31, 2017 and 2018 from our audited consolidated financial statements and accompanying notes appearing elsewhere in this prospectus. We derived the selected statements of operations data for the six months ended June 30, 2018 and 2019 and the selected balance sheet data as of June 30, 2019 from our unaudited interim consolidated financial statements and accompanying notes appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

	Year ended December 31,		Six months ended June 30,	
	2017	2018	2018	2019
	(in thousands, except share and per share data)			
Statement of Operations:				
Revenue	$ 4,245	$ 8,274	$ 3,635	$ 6,609
Cost of revenue (excluding amortization of intangible assets)	1,713	4,547	2,455	2,752
Amortization of intangible assets	—	785	633	152
Gross profit	2,532	2,942	547	3,705
Operating expenses:				
Sales and marketing	8,712	13,646	6,022	7,942
General and administrative	4,958	4,899	1,967	2,529
Research and development	5,786	4,339	2,318	2,714
Gain on litigation settlement	—	(2,160)	—	—
Total operating expenses	19,456	20,724	10,307	13,185
Loss from operations	(16,924)	(17,782)	(9,760)	(9,480)
Other (expense) income:				
Interest expense	(4,558)	(1,802)	(728)	(1,826)
Loss on extinguishment of debt	—	(1,822)	(615)	—
Change in fair value of preferred stock warrant liability	54	244	174	(38)
Other income	94	70	34	117
Total other (expense) income	(4,410)	(3,310)	(1,135)	(1,747)
Net loss	(21,334)	(21,092)	(10,895)	(11,227)
Accretion of redeemable convertible preferred stock to redemption value	(5,893)	(8,823)	(7,948)	(4,787)
Net loss attributable to common stockholders	$ (27,227)	$ (29,915)	$ (18,843)	$ (16,014)
Net loss per common share, basic and diluted	$ (3.78)	$ (4.11)	$ (2.59)	$ (2.19)
Weighted average common, shares outstanding, basic and diluted	7,208,547	7,283,167	7,273,968	7,313,934
Pro forma net loss per common, share basic and diluted (unaudited)[1]		$		$
Pro forma weighted average shares outstanding, basic and diluted (unaudited)[1]				

(1) See Note 3 to our annual and interim consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma net loss per common share, basic and diluted.

	As of December 31, 2017	As of December 31, 2018	June 30, 2019
Balance Sheet Data (in thousands):			
Cash and cash equivalents	$ 11,346	$ 17,278	$ 15,873
Working capital[(1)]	8,199	13,695	15,104
Total assets	15,532	27,227	26,627
Long-term debt	3,610	29,733	29,977
Preferred stock warrant liability	1,697	1,640	1,678
Redeemable convertible preferred stock	111,349	124,150	141,063
Total stockholders' deficit	$ (108,171)	$ (137,860)	$ (153,747)

(1) We define working capital as current assets minus current liabilities.

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 together with the section titled "Selected Consolidated Financial Data" and the consolidated financial statements and the related notes included elsewhere in this prospectus. 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 prospectus.

Overview

We are a commercial stage medical technology company focused on designing, developing and marketing a new category of tissue reinforcement materials to address unmet needs in soft tissue reconstruction. We offer a portfolio of advanced bioscaffolds that improve clinical outcomes and reduce overall costs of care in hernia repair, abdominal wall reconstruction and plastic and reconstructive surgery. Our products are an innovative solution that integrate multiple layers of minimally-processed biologic material with interwoven polymers in a unique embroidered pattern, which we refer to as a bioscaffold. Our products have been implanted by surgeons in more than 5,700 patients with no reported explantations due to failure of the product.

Our first portfolio of products, the OviTex Reinforced Bioscaffold, or 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, or FDA, which clearance was obtained and is currently held by Aroa Biosurgery, Ltd., or Aroa, our exclusive manufacturer and supplier, and have demonstrated safety and clinical effectiveness in our ongoing, prospective, single arm multicenter post-market clinical study, which we refer to as our BRAVO study. The first 32 patients who reached one year follow-up in the BRAVO study had experienced no ventral hernia recurrences, no explantations and no surgical site occurrences requiring follow-up surgery. Our second portfolio of products, the OviTex PRS — Restella Reconstructive Bioscaffold, or Restella, addresses unmet needs in plastic and reconstructive surgery.

Prior to obtaining FDA clearance for our first OviTex product, we devoted substantially all of our resources to the design and development of our bioscaffolds. Our development efforts to date have included an extensive non-human primate preclinical research data set for OviTex. We began commercialization of our OviTex products in the United States in July 2016 and they are now sold to more than 200 hospital accounts. In the first half of 2017, we began scaling our U.S. direct commercial presence and we initiated our BRAVO study in April 2017. 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 for use in laparoscopic and robotic-assisted surgery called OviTex LPR which we began commercializing in November 2018. We introduced additional sizes of our OviTex products in both 25 × 30 cm and 25 × 40 cm sizes in January 2019. In April 2019, our Restella products received 510(k) clearance from the FDA for plastic and reconstructive surgery, which clearance was obtained and is currently held by Aroa. In addition to our current portfolio, we are developing new product features and designs for both our OviTex and Restella portfolios.

We market our products through a single direct sales force, predominantly in the United States. We plan to continue to invest in our commercial organization by adding account managers, clinical development

specialists, business managers and administrative support staff in order to cover the top 500 hospitals that we believe perform approximately 55% of our targeted soft tissue reconstruction procedures. We plan to continue to contract with group purchasing organizations, or GPOs, and integrated delivery networks, or IDNs, to increase access to and penetration of hospital accounts.

Our products are manufactured by our exclusive manufacturer and supplier of our products, Aroa at their FDA registered and ISO 13485 facility in Auckland, New Zealand. We maintain our exclusive manufacturing and long-term supply and license agreement, or Aroa License, for the exclusive supply of ovine rumen and manufacture of our bioscaffolds 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. Pursuant to the terms of this agreement, we made payments to Aroa totaling $2.3 million upfront and $3.0 million in connection with certain milestones. In addition, we are obligated to pay Aroa up to an aggregate of $3.0 million in remaining revenue-based milestone payments.

Since inception, we have financed our operations primarily through private placements of our preferred stock, issuance of convertible promissory notes, amounts borrowed under our credit facilities and sales of our products. We have devoted the majority of our resources to defending our intellectual property and researching and developing our products and product candidates. We have invested in our direct sales and marketing infrastructure in order to expand our presence and to promote awareness and adoption of our products. As of June 30, 2019, we had 22 sales territories in the United States.

Substantially all of our revenue to date has been generated by the sale of our OviTex products. Our revenue for the years ended December 31, 2017 and 2018 was $4.2 million and $8.3 million, respectively, an increase of $4.0 million, or 95% in the year ended December 31, 2018 as compared to the year ended December 31, 2017. Net loss decreased from $21.3 million in the year ended December 31, 2017 to $21.1 million in the year ended December 31, 2018.

Our revenue for the six months ended June 30, 2018 and 2019 was $3.6 million and $6.6 million, respectively, an increase of $3.0 million, or 82%. Net loss increased from $10.9 million for the six months ended June 30, 2018 to $11.2 million for the six months ended June 30, 2019. We have not been profitable since inception and as of June 30, 2019, we had an accumulated deficit of $153.8 million.

Components of Our Results of Operations

Revenue

Substantially all of our revenue consists of direct sales of our products to hospital accounts in the United States. 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, and we expect continued growth as a result of, increasing revenue from product sales due to our expanding customer base.

Cost of Revenue

Cost of revenue primarily consists of the costs of licensed products purchased from Aroa, charges related to excess and obsolete inventory adjustments, 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.

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 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 Restella 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. 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 direct and allocated facility-related costs, insurance costs and professional fees for legal, consulting, investor and public relations, accounting, and audit services.

We expect that our general and administrative expenses will increase in absolute dollars as we expand our headcount to support our growth and incur additional expenses related to operating as a public company, including director and officer insurance coverage, legal costs, accounting costs, costs related to exchange listing and costs related to U.S. Securities and Exchange Commission, or SEC, compliance and investor relations. 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. 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.

Gain on Litigation Settlement

In 2018, we recognized a gain on litigation settlement related to a litigation claim that we had brought against the former carrier for our directors and officer and employment practices liability insurance for breach of contract and failure to reimburse us for defense costs incurred in litigation against LifeCell Corporation, or LifeCell, that was fully settled in 2016.

Interest Expense

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

Loss on Extinguishment of Debt

Loss on extinguishment of debt consists of the excess consideration paid over the net carrying value of our debt at the time of extinguishment.

Change in Fair Value of Preferred Stock Warrant Liability

Outstanding warrants to purchase shares of our preferred stock are classified as liabilities, recorded at fair value and are subject to re-measurement at each balance sheet date until they are exercised, expire or are otherwise settled. The change in fair value of our preferred stock warrant liability reflects a non-cash charge primarily driven by changes in the fair value of our underlying Series B preferred stock.

Results of Operations

Comparison of the Six Months Ended June 30, 2018 and 2019

	Six months ended June 30,		Change	
	2018	2019	Dollar	Percentage
	(in thousands except percentages)			
Revenue	$ 3,635	$ 6,609	$ 2,974	82%
Cost of revenue (excluding amortization of intangible assets)	2,455	2,752	297	12%
Amortization of intangible assets	633	152	(481)	(76)%
Gross profit	547	3,705	3,158	577%
Gross margin	15%	56%		
Operating expenses:				
Sales and marketing	6,022	7,942	1,920	32%
General and administrative	1,967	2,529	562	29%
Research and development	2,318	2,714	396	17%
Total operating expenses	10,307	13,185	2,878	28%
Loss from operations	(9,760)	(9,480)	280	(3)%
Other (expense) income:				
Interest expense	(728)	(1,826)	(1,098)	151%
Loss on extinguishment of debt	(615)	—	615	(100)%
Change in fair value of preferred stock warrant liability	174	(38)	(212)	(122)%
Other income	34	117	83	244%
Total other (expense) income	(1,135)	(1,747)	(612)	54%
Net loss	$ (10,895)	$ (11,227)	$ (332)	3%

Revenue

Revenue increased by $3.0 million, or 82%, from $3.6 million for the six months ended June 30, 2018 to $6.6 million for the six months ended June 30, 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 and increased penetration within existing customer accounts as well as the introduction of larger sizes of OviTex during 2019. During the six months ended June 30, 2019, we sold 1,694 units of OviTex compared to 945 units of OviTex during the six months ended June 30, 2018, a 79% increase in unit sales volume. We commenced a limited launch of Restella in May 2019, selling 13 units during the six months ended June 30, 2019.

Cost of Revenue

Cost of revenue (excluding amortization of intangible assets) increased by $0.3 million to $2.8 million for the six months ended June 30, 2019 from $2.5 million for the six months ended June 30, 2018. The increase in cost of revenue was primarily the result of higher revenue due to the growth in the number of OviTex and Restella units sold offset by a lower charge related to excess and obsolete inventory. During the six months ended June 30, 2018, we recognized a $1.4 million charge related to excess and obsolete inventory adjustments, primarily due to Aroa reducing the shelf life of a certain product line. During the six months ended June 30, 2019, we recognized a $0.9 million charge related to excess and obsolete inventory adjustments as the hospital contract approval process for our new products was longer than anticipated. We launched several new products in 2019 and inventory was purchased to accommodate anticipated demand, which has been slower to materialize than anticipated. Such demand was slower to materialize than anticipated because the expected sales by product did not correlate with the actual sales by product after launch, we experienced longer than expected turnaround times for approvals to add new products to hospital contracts and usage ramp-up was slower than initially predicted. This trend has not continued and accordingly we do not expect this to impact our business. We continue to monitor our products' shelf life, have adjusted our consigned inventory deployment strategies, have adjusted our ordering patterns and have implemented smaller lot sizes for certain size products in an attempt to reduce the need for future inventory reserve charges.

Amortization of Intangible Assets

Amortization of intangible assets was $0.6 million for the six months ended June 30, 2018 as compared to $0.2 million for the six months ended June 30, 2019. In May 2018, we achieved one of our regulatory milestones, and we determined that certain commercial sales milestone targets under our licensing agreement with Aroa became probable of being met. As a result, we recorded a payment obligation as an intangible asset that required a cumulative amortization charge of $0.4 million to be recognized during the six months ended June 30, 2018.

Gross Margin

Gross margin increased from 15% for the six months ended June 30, 2018 to 56% for the six months ended June 30, 2019. The increase was primarily due to a $0.5 million decrease in excess and obsolete inventory adjustments recognized during the six months ended June 30, 2019 as compared to the prior year period, primarily due to Aroa reducing the shelf life of a certain product line during the six months ended June 30, 2018 and the $0.4 million cumulative amortization charge recognized during the six months ended June 30, 2018.

Sales and Marketing

Sales and marketing expenses increased by $1.9 million, or 32%, from $6.0 million for the six months ended June 30, 2018 to $7.9 million for the six months ended June 30, 2019. The increase was primarily due to higher salary and commission costs of $1.2 million as a result of our sales expansion activities, including hiring of additional sales personnel and expansion of marketing activities costs of $0.7 million, consistent with our growth in revenue.

General and Administrative

General and administrative expenses increased by $0.6 million, or 29%, from $2.0 million for the six months ended June 30, 2018 to $2.5 million for the six months ended June 30, 2019. The increase was primarily due to higher personnel costs of $0.6 million to support our expansion activities.

Research and Development

Research and development expenses increased by $0.4 million, or 17%, from $2.3 million for the six months ended June 30, 2018 to $2.7 million for the six months ended June 30, 2019. The increase in research and development expense primarily relates to a $0.5 million license fee payment made to Aroa during the six months ended June 30, 2019 to extend certain rights under the Aroa License.

Interest Expense

Interest expense increased by $1.1 million, or 151%, from $0.7 million for the six months ended June 30, 2018 to $1.8 million for the six months ended June 30, 2019. The increase was primarily due to having a larger principal balance outstanding with a higher interest rate during the six months ended June 30, 2019 compared to the prior year period.

Loss on Extinguishment of Debt

We recorded a loss on the extinguishment of debt of $0.6 million during the six months ended June 30, 2018 related to the refinancing of our credit facility with Hercules Capital, Inc., or Hercules, in April 2018. The loss was primarily composed of the write-off of unamortized debt discounts and prepayment penalties at the time of extinguishment.

Change in Fair Value of Preferred Stock Warrant Liability

The fair value of our preferred stock warrant liability increased during the six months ended June 30, 2019, primarily attributable to an increase in the fair value of our Series B preferred stock. As a result, we recognized a loss on the change in the fair value of our preferred stock warrant liability of $38,000 during the six months ended June 30, 2019.

Other Income

Other income increased by $83,000, which was primarily attributable to having a larger cash balance which earned more interest income during the six months ended June 30, 2019 as compared to the prior year period.

Comparison of the Years Ended December 31, 2017 and 2018

	Year Ended December 31,		Change	
	2017	2018	Dollar	Percentage
	(in thousands, except percentages)			
Revenue	$ 4,245	$ 8,274	$ 4,029	95%
Cost of revenue (excluding amortization of intangible assets)	1,713	4,547	2,834	165%
Amortization of intangible assets	—	785	785	—%
Gross profit	2,532	2,942	410	16%
Gross margin	60%	36%		
Operating expenses:				
Sales and marketing	8,712	13,646	4,934	57%
General and administrative	4,958	4,899	(59)	(1)%
Research and development	5,786	4,339	(1,447)	25%
Gain on litigation settlement	—	(2,160)	(2,160)	—%
Total operating expenses	19,456	20,724	1,268	7%
Loss from operations	(16,924)	(17,782)	(858)	5%
Other (expense) income:				
Interest expense	(4,558)	(1,802)	2,756	(60)%
Loss on extinguishment of debt	—	(1,822)	(1,822)	—%
Change in fair value of preferred stock warrant liability	54	244	190	352%
Other income	94	70	(24)	(26)%
Total other (expense) income	(4,410)	(3,310)	1,100	(25)%
Net loss	$ (21,334)	$ (21,092)	$ 242	(1)%

Revenue

Revenue increased by $4.0 million, or 95%, from $4.2 million for the year ended December 31, 2017 to $8.3 million for the year ended December 31, 2018. The increase in revenue was primarily driven by an increase in unit sales of our products due to the expansion of our commercial organization and increased penetration within the market. During 2018, we sold 2,110 units of OviTex as compared to 1,027 units of OviTex during 2017, a 105% increase in unit sales volume.

Cost of Revenue

Cost of revenue (excluding amortization of intangible assets) increased by $2.8 million, or 165%, from $1.7 million for the year ended December 31, 2017 to $4.5 million for the year ended December 31, 2018. The increase in cost of revenue was primarily the result of an increase in revenue as well as a $1.8 million increase in our excess and obsolete inventory reserve recognized during the year ended December 31, 2018 as compared to the same period in the prior year, primarily due to Aroa reducing the shelf life of a certain product line.

Amortization of Intangible Assets

Amortization of intangible assets was $0.8 million for the year ended December 31, 2018. In May 2018, we determined that certain milestone targets under our licensing agreement with Aroa became probable of being met and recorded the payment obligation as an intangible asset. There were no intangible assets or related amortization expense during the year ended December 31, 2017.

Gross Margin

Gross margin decreased from 60% for the year ended December 31, 2017 to 36% for the year ended December 31, 2018. The decrease was primarily due to a $1.8 million increase in excess and obsolete inventory adjustments recognized during 2018 as compared to the prior year period, primarily due to Aroa reducing the shelf life of a certain product line during 2018. We also recognized $0.8 million in amortization of intangible assets in 2018. There was no such expense in 2017.

Sales and Marketing

Sales and marketing expenses increased by $4.9 million, or 57%, from $8.7 million for the year ended December 31, 2017 to $13.6 million for the year ended December 31, 2018. The increase was primarily due to higher salary and commission costs of $2.6 million as a result of our sales expansion activities, including hiring of additional sales personnel and expansion of marketing activity costs of $2.3 million, consistent with our growth in revenue.

General and Administrative

General and administrative expenses remained flat for the year ended December 31, 2017 compared to the year ended December 31, 2018.

Research and Development

Research and development expenses decreased by $1.4 million, or 25%, from $5.8 million for the year ended December 31, 2017 to $4.3 million for the year ended December 31, 2018. The decrease in research and development expense was primarily attributable to a decrease in licensing payments of $0.5 million, a decrease in external testing and analysis costs of $0.2 million and a decrease of $0.7 million in overall research and development efforts as we shifted our focus to the commercialization of our approved products.

Gain on Litigation Settlement

In 2018, we recognized a gain on litigation settlement of $2.2 million related to a litigation claim that we had brought against the former carrier for our directors and officer and employment practices liability insurance for breach of contract and failure to reimburse us for defense costs incurred in litigation against LifeCell that was fully settled in 2016.

Interest Expense

Interest expense decreased by $2.8 million, or 60%, from $4.6 million for the year ended December 31, 2017 to $1.8 million for the year ended December 31, 2018. The decrease was primarily due to a decrease of $1.4 million related to non-cash accretion expense, and a decrease of $1.4 million related to the recognition of a beneficial conversion feature recognized in 2017.

Loss on Extinguishment of Debt

We recorded a loss on the extinguishment of debt of $1.8 million during the year ended December 31, 2018 related to the repayment of borrowings and cancellation of refinancing of our credit facilities with Hercules and MidCap Financial Trust, or MidCap, in April and November, respectively. The losses were primarily comprised of the write-off of unamortized debt discounts and prepayment penalties at the time of extinguishment.

Change in Fair Value of Preferred Stock Warrant Liability

The fair value of our preferred stock warrant liability decreased during each of the years ended December 31, 2017 and 2018, primarily attributable to the decrease in the remaining contractual term of the outstanding warrants. As a result, we recognized a gain on the change in the fair value of our preferred stock warrant liability of $54,000 and $0.2 million during the years ended December 31, 2017 and 2018, respectively.

Liquidity and Capital Resources

Overview

As of June 30, 2019, we had cash and cash equivalents of $15.9 million and an accumulated deficit of $153.8 million compared to cash and cash equivalents of $17.3 million and an accumulated deficit of $137.9 million as of December 31, 2018. 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 expand our sales and marketing initiatives to support our growth in existing and new markets and invest funds in additional research and development activities. Our primary sources of capital to date have been from private placements of our preferred stock, issuance of convertible promissory notes, borrowings under our credit facilities and sales of OviTex. Through June 30, 2019, we raised approximately $107.0 million from private placements of our preferred stock. As of June 30, 2019, we had $30.0 million of borrowings outstanding under our credit facility, or the OrbiMed Credit Facility, with OrbiMed Royalty Opportunities IP, LP, or OrbiMed. This credit facility matures in November 2023 and has $5.0 million of additional capacity through December 31, 2019, provided that our consolidated revenue on a trailing six-month basis equals or exceeds $7.5 million. This facility requires that we maintain a minimum cash balance of $2.0 million.

Following the completion of this offering, we will incur additional costs of operating as a public company. Based on our current business plan, we believe that our existing cash resources, availability under our credit facility and estimated net proceeds from this offering will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. 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. 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, including the shares of common stock sold in this offering. 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. 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:

	Year ended December 31,		Six months ended June 30,	
(in thousands)	2017	2018	2018	2019
Cash used in operating activities	$ (16,368)	$ (19,924)	$ (10,847)	$ (12,982)
Cash used in investing activities	(101)	(1,558)	(31)	(589)
Cash provided by financing activities	26,335	27,414	4,787	12,166
Net increase (decrease) in cash and cash equivalents	$ 9,866	$ 5,932	$ (6,091)	$ (1,405)

Operating Activities

During the six months ended June 30, 2018, we used $10.8 million of cash in operating activities, resulting from our net loss of $10.9 million and the change in operating assets and liabilities of $3.1 million, offset by non-cash charges of $3.1 million. Our non-cash charges were comprised of depreciation of $0.3 million, loss on extinguishment of debt of $0.5 million, interest expense of $0.3 million, amortization of intangible assets of $0.6 million and our excess and obsolete inventory charge of $1.4 million. We also had stock-based compensation expense of $0.1 million and a change in the fair value of our warrants of $0.2 million. The change in our operating assets was primarily related to a $0.5 million increase in our accounts receivable, a $2.6 million increase in inventory, and a $0.4 million decrease in our accrued expenses and other liabilities. These uses of cash were offset by increases in accounts payable of $0.3 million and a decrease in prepaid expenses and other of $0.1 million.

During the six months ended June 30, 2019, we used $13.0 million of cash in operating activities, resulting from our net loss of $11.2 million and the change in operating assets and liabilities of $3.4 million, offset by non-cash charges of $1.6 million. Our non-cash charges were comprised of depreciation of $0.1 million, amortization of intangibles of $0.2 million, interest expense of $0.2 million, our excess and obsolete inventory charge of $0.9 million and stock-based compensation expense of $0.1 million. The change in our operating assets was primarily related to a $0.6 million increase in our accounts receivable, a $1.2 million increase in inventory, a $0.2 million increase in prepaid expenses and other assets, and a $1.4 million decrease in our accounts payable, accrued expenses and other liabilities.

During the year ended December 31, 2017, we used $16.4 million of cash in operating activities, resulting from our net loss of $21.3 million offset by non-cash charges of $4.9 million and the change in operating assets and liabilities of $75,000. Our non-cash charges were comprised of depreciation of $0.8 million, interest expense of $2.1 million, the recognition of a beneficial conversion feature of $1.4 million, and an excess and obsolete inventory charge of $0.5 million. We also had stock-based compensation expense of $0.2 million and a change in the fair value of our warrants of $54,000. The change in our operating assets was primarily related to a $0.6 million increase in accounts receivable, a $0.1 million increase in inventory, a $58,000 increase in prepaid and other assets and a decrease in accounts payable of $0.7 million. These amounts were offset by a $1.6 million increase in accrued expenses and other current liabilities.

During the year ended December 31, 2018, we used $19.9 million of cash in operating activities, resulting from our net loss of $21.1 million and the change in operating assets and liabilities of $4.5 million offset by non-cash charges of $5.6 million. Our non-cash charges were comprised of depreciation of $0.5 million, the amortization of intangibles of $0.8 million, interest expense of $0.7 million, the recognition of a loss on extinguishment of debt of $1.8 million, and our excess and obsolete inventory charge of $2.2 million. We also had stock-based compensation expense of $0.2 million and a change in the fair value of our warrants of $0.2 million. The change in our operating assets was primarily related to a $4.8 million increase in inventory, a $0.5 million increase in accounts receivable, and a decrease in accrued expenses and other liabilities of $1.2 million. These amounts were slightly offset by a $1.9 million increase in accounts payable.

Investing Activities

During the six months ended June 30, 2018, cash used in investing activities was $31,000 for the purchases of property and equipment.

During the six months ended June 30, 2019, cash used in investing activities was $0.6 million, consisting of payments made for our intangible asset of $0.5 million and purchases of property and equipment of $0.1 million.

During the year ended December 31, 2017, cash used in investing activities was $0.1 million for the purchases of property and equipment.

During the year ended December 31, 2018, cash used in investing activities was $1.6 million, consisting of payments made for our intangible assets of $1.5 million, and purchases of property and equipment of $0.1 million.

Financing Activities

During the six months ended June 30, 2018, cash provided by financing activities was $4.8 million, consisting of $8.0 million in proceeds received from the issuance of long-term debt, $1.3 million in net borrowings under our revolver, and $1.4 million in net proceeds received from the issuance of our Series B preferred stock. These amounts were partially offset by $5.0 million in repayments of long-term debt and $0.8 million in payments of issuance costs.

During the six months ended June 30, 2019, cash provided by financing activities was $12.2 million, consisting of proceeds received from the issuance of our Series B preferred stock.

During the year ended December 31, 2017, cash provided by financing activities was $26.3 million, consisting of $14.7 million in net proceeds received from the issuance of our Series B preferred stock, $7.4 million in proceeds from the issuance of our convertible promissory notes, and $5.0 million in proceeds received from the issuance of long-term debt, partially offset by $0.6 million in payments of issuance costs and $0.2 million in repayments of capital lease obligations.

During the year ended December 31, 2018, cash provided by financing activities was $27.4 million, consisting primarily of $30.0 million in proceeds received from the issuance of long-term related party debt with OrbiMed, $8.0 million in proceeds from the issuance of long-term debt with MidCap, $4.0 million in net proceeds received from the issuance of our Series B preferred stock, partially offset by $13.0 million in repayments made on our long-term debt with MidCap and Hercules and $1.6 million in payments of issuance costs related to our debt financings.

Indebtedness

In November 2018, we entered into the OrbiMed Credit Facility, which consists of $35.0 million in term loans, or the OrbiMed Term Loans. The OrbiMed Term Loans consist of two tranches, a $30.0 million Tranche 1, or Tranche 1, and a $5.0 million Tranche 2, or Tranche 2. Upon closing, we borrowed $30.0 million of Tranche 1 and used a portion of the proceeds to repay borrowings under our credit facility with MidCap and intend to use the remaining proceeds to fund operations and capital expenditures. We will be eligible to borrow Tranche 2 until December 31, 2019, provided that our consolidated revenue on a trailing six-month basis equals or exceeds $7.5 million.

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 event, (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 would be required to pay interest on principal 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. We are also required to pay 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, 2018 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by Period				
(in thousands)	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[1]	17,820	3,039	9,117	5,664	—
Operating lease commitments[2]	518	209	309	—	—
LifeCell litigation settlement obligations	1,000	1,000	—	—	—
Purchase commitments with Aroa	12,971	721	10,750	1,500	—
Projected future milestone payments deemed probable	2,500	2,500	—	—	—
Total[4]	$ 64,809	$ 7,469	$ 20,176	$ 37,164	$ —

(1) Interest payable reflects the rate in effect as of December 31, 2018. 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 2021.

(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, (b) any royalty payments to third parties as the amounts, timing and likelihood of such payments are not known, and (c) 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.

Quantitative and Qualitative Disclosures about Market Risk

Our cash is held on deposit in demand accounts at a large financial institution in amounts in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance coverage limit of $250,000 per depositor, per FDIC-insured bank, per ownership category. We have reviewed the consolidated financial statements of this institution and believe it has sufficient assets and liquidity to conduct its 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 prospectus 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 a result, we are exposed to risks from changes in interest rates. A 1.0% increase in interest rates would have resulted in a $0.1 million increase to our interest expense for the year ended December 31, 2018.

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 United States, or 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 prospectus, 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 Committee Topic 606, *Revenue from Contracts with Customers*, or ASC 606, which was adopted on January 1, 2019 using the modified retrospective method. The adoption of this guidance had no cumulative adjustment to our consolidated financial statements. 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.

Prior to the adoption of ASC 606 in January 2019, revenue was recognized when persuasive evidence of an arrangement exists, the price was fixed and determinable, delivery has occurred, and there was reasonable assurance of collection of the sales proceeds. Revenue for products sold to a customer was recognized when the product was shipped to the customer, at which time title passed to the customer. Fees charged to customers for shipping were recognized as revenue. In the case of consigned inventory, revenue was recognized when the product was utilized in a surgical procedure.

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 Restella 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.

Stock-Based Compensation

The following table summarizes stock-based compensation expense resulting from stock options:

(in thousands)	Year ended December 31, 2017	Year ended December 31, 2018	Six months ended June 30, 2018	Six months ended June 30, 2019
Sales and marketing	$ 44	$ 68	$ 30	$ 30
General and administrative	116	115	58	72
Research and development	37	33	20	17
Total stock-based compensation	$ 197	$ 216	$ 108	$ 119

We measure stock options and other stock-based awards based on their estimated fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award, while awards containing a performance condition are recognized when the achievement of the performance criteria is considered probable. We apply the straight-line method of expense recognition to all awards with service-based vesting conditions.

We estimate the fair value of stock options using the Black-Scholes option-pricing model, which requires subjective assumptions, including the fair value of our common stock, volatility, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, and our expected dividend yield. Certain assumptions used in our Black-Scholes option-pricing model represent management's best estimates and involve a number of variables, uncertainties and assumptions and the application of management's judgment, as they are inherently subjective. If any assumptions change, our stock-based compensation expense could be materially different in the future.

These assumptions are estimated as follows:

- *Risk-free interest rate.* The risk-free interest rate was based on the yields of U.S. Treasury securities with maturities commensurate with the expected term of the stock option.

- *Expected dividend yield.* We have not paid dividends on our common stock nor do we expect to pay dividends in the foreseeable future.

- *Expected term.* The expected term represents the period that our stock options are expected to be outstanding. We calculated the expected term using the simplified method based on the average of each option's vesting term and the contractual period during which the option can be exercised, which is typically 10 years following the date of grant.

- *Expected volatility.* The expected volatility was based on the historical stock volatility of several of our comparable publicly traded companies over a period of time equal to the expected term of the options, as we do not have any trading history to use the volatility of our own common stock.

- *Fair value of common stock.* As our common stock has not historically been publicly traded, we have periodically estimated the fair value of common stock. See "— Estimating the Fair Value of Common Stock."

Stock Options Granted

The following table summarizes by grant date the number of shares subject to stock options granted from January 1, 2018 through the date of this prospectus, the per share exercise price of the options, the fair value of common stock underlying the options on each grant date, and the per share estimated fair value of the options:

Grant Date	Number of Shares Subject to Options Granted	Exercise Price Per Share of Common Stock	Estimated Fair Value per Share of Common Stock	Estimated Grant-date Fair Value per Stock Option
January 8, 2018	20,500	$ 0.24	$ 0.09	$ 0.03
February 21, 2018	60,000	$ 0.24	$ 0.09	$ 0.03
February 28, 2018	2,440,006	$ 0.24	$ 0.09	$ 0.03
April 2, 2018	495,000	$ 0.24	$ 0.09	$ 0.03
April 3, 2018	28,810	$ 0.24	$ 0.09	$ 0.03
June 18, 2018	20,000	$ 0.24	$ 0.20	$ 0.10
July 23, 2018	20,000	$ 0.24	$ 0.20	$ 0.10
September 14, 2018	20,000	$ 0.24	$ 0.20	$ 0.10
October 3, 2018	20,000	$ 0.24	$ 0.20	$ 0.10
October 26, 2018	42,500	$ 0.24	$ 0.20	$ 0.10
November 5, 2018	530,000	$ 0.24	$ 0.20	$ 0.10
November 30, 2018	60,000	$ 0.24	$ 0.20	$ 0.10
January 15, 2019	958,000	$ 0.24	$ 0.20	$ 0.10
February 4, 2019	20,000	$ 0.24	$ 0.20	$ 0.10
May 14, 2019	20,000	$ 0.24	$ 0.43	$ 0.29
May 20, 2019	2,500	$ 0.24	$ 0.43	$ 0.29
May 31, 2019	400,000	$ 0.24	$ 0.43	$ 0.29
August 13, 2019	755,000	$ 0.43	$ 0.43	$ 0.23

Based on an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, the intrinsic value of vested and unvested stock options outstanding as of June 30, 2019 was $ and $, respectively.

Estimating the Fair Value of Common Stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuation of common stock, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our commercialization efforts;
- the progress of our research and development programs, including the status and results of preclinical studies for our product candidates;
- our stage of development and our business strategy;

- external market conditions affecting the medical device industry and trends within the medical device industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

In determining the estimated fair value of common stock, our board of directors considered the subjective factors discussed above in conjunction with the most recent valuations of our common stock that were prepared by an independent third-party. The independent valuation prepared as of December 31, 2017 was utilized by our board of directors when determining the estimated fair value of common stock for the awards granted on January 8, 2018, February 21, 2018, February 28, 2018, April 2, 2018 and April 3, 2018. The independent valuation prepared as of December 31, 2018 was utilized by our board of directors when determining the estimated fair value of common stock for the awards granted on June 30, 2018, July 23, 2018, September 14, 2018, October 3, 2018, October 26, 2018, November 5, 2018, November 30, 2018, January 15, 2019 and February 4, 2019. The independent valuation prepared as of June 30, 2019 was utilized by our board of directors when determining the estimated fair value of common stock for the awards granted on May 14, 2019, May 20, 2019, May 31, 2019 and August 13, 2019. These third-party valuations resulted in a valuation of our common stock of $0.09, $0.20 and $0.43 per share as of December 31, 2017, December 31, 2018 and June 30, 2019, respectively.

Following the closing of this offering, the fair value of our common stock will be the closing price of our common stock on the Nasdaq Global Market as reported on the date of the grant.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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 prospectus.

Internal Controls over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements in accordance with GAAP. As a result of becoming a public company, we will be required, under Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ending December 31, 2020. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. The SEC defines a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim consolidated financial statements will not be detected or prevented on a timely basis.

In accordance with the provisions of the Sarbanes-Oxley Act, neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period included in this prospectus.

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.

BUSINESS

Overview

We are a commercial stage medical technology company focused on designing, developing and marketing a new category of tissue reinforcement materials to address unmet needs in soft tissue reconstruction. We offer a portfolio of advanced bioscaffolds that improve clinical outcomes and reduce overall costs of care in hernia repair, abdominal wall reconstruction and plastic and reconstructive surgery. Our products are an innovative solution that integrate multiple layers of minimally-processed biologic material with interwoven polymers in a unique embroidered pattern, which we refer to as a bioscaffold. These products have been implanted by surgeons in more than 5,700 patients with no reported explantations due to failure of the product.

Our first portfolio of products, the OviTex Reinforced Bioscaffold, or 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, or FDA, which clearance was obtained and is currently held by Aroa Biosurgery Ltd., or Aroa, our exclusive manufacturer and supplier and have demonstrated safety and clinical effectiveness in our ongoing prospective, single arm, multicenter post-market clinical study, which we refer to as our BRAVO study. The first 32 patients who reached one year follow-up in the BRAVO study experienced no ventral hernia recurrences, no explantations and no surgical site occurrences requiring follow-up surgery. Our second portfolio of products, the OviTex PRS — Restella Reconstructive Bioscaffold, or Restella, addresses unmet needs in plastic and reconstructive surgery. In April 2019, our Restella products received 510(k) clearance from the FDA, which clearance was obtained and is currently held by Aroa.

We began commercialization of our OviTex products in the United States in July 2016, and they are now sold to more than 200 hospital accounts. Hernia repair is one of the most common surgeries performed in the United States, representing approximately 1.2 million procedures annually. Based upon the volume weighted average selling price, we estimate the total annual addressable market opportunity for our OviTex products to be $1.5 billion. 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.

Restella 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 Restella 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 United States is approximately $500 million. We commenced a limited launch in May 2019 and expect to fully launch our Restella products in the United States through our direct sales force in the first half of 2020. We also intend to engage in discussions with the FDA regarding an Investigational Device Exemption, or IDE, protocol to study the safety and effectiveness of our Restella product for an indication in breast reconstruction surgery.

We have a broad portfolio of intellectual property protecting our products, which 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, or 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 infilteration. 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 United States. We have invested in our direct sales and marketing infrastructure in order to expand our presence and to promote awareness and adoption of our products. As of June 30, 2019, we had 22 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, business managers and administrative support staff in order to cover the top 500 hospitals that we believe perform approximately 55% of our targeted soft tissue reconstruction procedures. We plan to continue to contract with group purchasing organizations, or GPOs, and integrated delivery networks, or IDNs, to increase access to and penetration of hospital accounts.

Our revenue for the years ended December 31, 2017 and 2018 was $4.2 million and $8.3 million, respectively, which represents an increase of $4.0 million, or 95%. Our net loss for the same time periods was $21.3 million and $21.1 million, respectively. Our revenue for the six months ended June 30, 2018 and 2019 was $3.6 million and $6.6 million, respectively, which represents an increase of $3.0 million, or 82%. Our net loss for the same time periods was $10.9 million and $11.2 million, respectively. As of June 30, 2019, we had an accumulated deficit of $153.8 million. The vast majority of our revenue to date has been generated from sales of our OviTex products in the United States, with the remainder generated from sales of our OviTex products in Europe and sales of our Restella products in the United States.

Overview of Soft Tissue Reconstruction

We are focused on the development and commercialization of bioscaffolds for use in soft tissue reconstruction. We offer bioscaffold products for a variety of reconstruction procedures, including hernia repair, abdominal wall reconstruction and plastic and reconstructive surgery.

Soft Tissue Reconstruction Surgical Procedures

Hernia Repair and Abdominal Wall Reconstruction Overview

A hernia occurs when pressure causes an organ, intestine or fatty tissue to squeeze through a hole caused by a defect or weak area in the surrounding muscle or connective tissue. Sometimes the muscle weakness is present at birth, but more often it occurs later in life. Anything that causes an increase in abdominal pressure can cause a hernia, including obesity, lifting heavy objects, diarrhea or constipation, or persistent coughing or sneezing. Prior abdominal surgery, poor nutrition, smoking, and overexertion can weaken muscles and contribute to the likelihood and complexity of a hernia. Many hernias are asymptomatic, but some become incarcerated or strangulated, causing pain and requiring immediate surgery. Hernia pain can quickly intensify, become chronic in nature, be excruciating and debilitating and cause nausea or vomiting.

Hernias can be broadly classified depending on whether they develop in the upper abdomen, referred to as ventral hernias, or in the groin, which primarily consist of inguinal hernias. Hiatal hernias occur when the upper part of the stomach bulges through the hiatus, the small opening where the esophagus passes through the diaphragm before connecting to the stomach. Ventral hernias that develop at the site of a previous surgical scar, referred to as incisional hernias, present in up to one-third of patients who have had abdominal surgery. Inguinal hernias can be caused by a birth defect or develop later in life and are more common in males. Hernia is predominantly a disease of the middle aged and elderly. Hernias vary in complexity based on the size of the hernia defect, patient co-morbidities, such as obesity and diabetes, patient history of prior hernia repair and the degree of contamination in the surgical wound at the time of the hernia repair surgery. For patients who have had multiple prior hernia surgeries that have failed, the anatomy of their abdominal wall is often compromised and surgeons must perform more advanced techniques to repair the abdomen, known as abdominal wall reconstruction.

Plastic and Reconstructive Surgery Overview

Plastic and reconstructive surgery is performed to treat structures of the human body that are affected aesthetically or functionally due to defects, abnormalities, trauma, infection, burns, tumors or disease. Plastic and reconstructive surgery is generally performed to improve function and ability, but may also be performed to achieve a more typical appearance of the affected anatomical structure. Clinical practice of plastic and reconstructive surgery includes: excision of tumors of the skin, vasculature, chest, oral and oropharyngeal cavities, extremities, and reconstructions of the same; debridement, skin grafting and skin flaps for burn reconstructions; trauma surgery for the hands, upper and lower limbs and facial region; congenital or acquired malformations related to the hands, face, skull and jaw; surgical removal of vascular abnormalities; reconstructions of the breast and pelvic regions; and a range of aesthetic surgeries.

To date, the most studied application of biologic matrices in plastic and reconstructive surgery is breast reconstruction surgery. Surgeons use biologic matrices in the vast majority of their implant-based breast reconstruction procedures and the use of these materials is well-characterized in the clinical literature and recommended by recent U.S. and European consensus guidelines for certain surgical techniques, from the ecancer Global Foundation. However, no biologic matrix or any other soft tissue reinforcement material, including Restella, is approved or cleared by the FDA specifically for use in breast reconstruction surgery. As such, we intend to engage in discussions with the FDA regarding an IDE protocol to study the safety and effectiveness of our Restella product for an indication in breast reconstruction surgery. Mastectomy is a method of tumor removal for breast cancer in which all breast tissue, including the cancerous cells, is surgically removed. Single (or unilateral) mastectomy is the removal of one breast while double (or bilateral) mastectomy is the removal of both breasts and represent 35% and 65% of procedures, respectively. Breast reconstruction surgery is a surgical procedure generally used to restore a breast to near normal shape and appearance following a mastectomy and can be performed using either a prosthetic breast implant, referred to as implant-based reconstruction, or the patient's own tissue, referred to as autologous reconstruction. Additional reconstructive surgeries may be required following the initial breast reconstruction, including breast lift (mastopexy) or breast revision surgery in which the surgeon adjusts the position and shape of the breast.

Market Opportunity

OviTex

Hernia repair is one of the most common surgeries performed in the United States. There are an estimated 1.2 million hernia repairs annually in the United States including recurrences, which we categorize as approximately (i) 65,000 complex/moderate ventral hernia repairs and abdominal wall reconstructions, (ii) 362,000 simple ventral hernia repairs and (iii) 789,900 inguinal hernia repairs. We estimate that there are approximately 44,400 hiatal hernia repairs annually in the United States. Approximately 90% of all hernia repairs are treated with a tissue reinforcement material.

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 persist for years.

In addition, for third-party payors, the costs related to hernia are significant. The number of annual physician office visits in the United States related to hernia were approximately 2.5 million in 2016 according to the National Ambulatory Medical Care Survey. Hernia repair and abdominal wall reconstruction inpatient per procedure costs in the United States ranged from approximately $6,117 to $29,615 in 2018

according to the national average Medicare Severity Diagnosis Related Groups, or MS-DRG rate, which does not account for surgeon fees involved with such procedures. Hernias are prone to recurrence, which often require multiple repair procedures and additional healthcare expenditures. In the United States, the economic burden of hernia repair accounts for approximately $48 billion of healthcare expenditures annually.

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	58,000	$ 350 million	Biologic Matrices and Resorbable Synthetic Mesh
Simple Ventral Hernia Repair	326,000	$ 500 million	Permanent Synthetic Mesh
Inguinal Hernia Repair	711,000	$ 650 million	Permanent Synthetic Mesh
Hiatal Hernia Repair	40,000	$ 40 million	Biologic Matrices and Resorbable Synthetic Mesh
Total	**1,135,000**	**$ 1.5 billion**	

Restella

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.

Breast reconstructions can be performed either using a sub-pectoral or pre-pectoral technique. In a sub-pectoral technique, the upper portion of the breast implant is placed below the pectoralis muscle and a biologic matrix is placed around the lower portion of the breast implant. In a pre-pectoral technique, the

entire breast implant is placed above the pectoralis muscle and the full top surface of the breast implant is covered. The pre-pectoral technique utilizes a larger biologic matrix compared to that needed with the sub-pectoral technique. For patients who undergo autologous reconstruction, the donor site of the autologous tissue, typically the abdomen, may require soft tissue reinforcement.

Based on the current sales of biologic matrices in the United States we estimate the annual U.S. current addressable market opportunity for our Restella products to be approximately $500 million. This market continues to grow as surgeon and patient preferences shift from sub-pectoral to pre-pectoral techniques.

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 Restella 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 repair 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.

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 the abdominal wall. Based on longitudinal data from the Danish Hernia Database, in an analysis of approximately 2,900 patients who received a mesh hernia repair, 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 643 in 2016, 2,464 in 2017, to more than 6,400 in 2018 through October. Synthetic mesh products have been the subject of more than 6,000 lawsuits in the United States.

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, in part as a result of being commonly used in complex hernia repairs or abdominal wall reconstructions. The RICH study, a multicenter, prospective study sponsored by LifeCell Corporation, or LifeCell that evaluated the performance of Strattice, the current market-leading biologic matrix, in open ventral incisional hernia repair in contaminated abdominal wall defects, demonstrated post operative hernia recurrence rates of 22% and 33% 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 recently published, multicenter, prospective study sponsored by C.R. Bard, Inc. 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 12% at 18-months 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.

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, or PGA. The embroidering pattern varies between our OviTex and Restella 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 Restella 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.

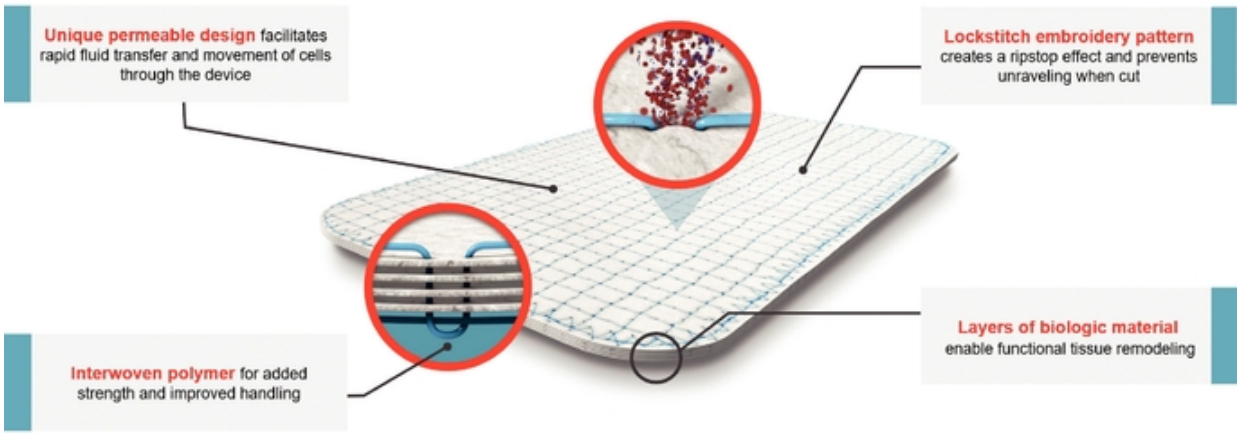
Our capabilities in polymer science, biologics, textile engineering and analytical testing enable us to quickly design, manufacture and develop innovative products. These competencies also allow our technical team to tailor the degree of stretch, direction of stretch, overall strength, handling properties,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

Our bioscaffolds 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

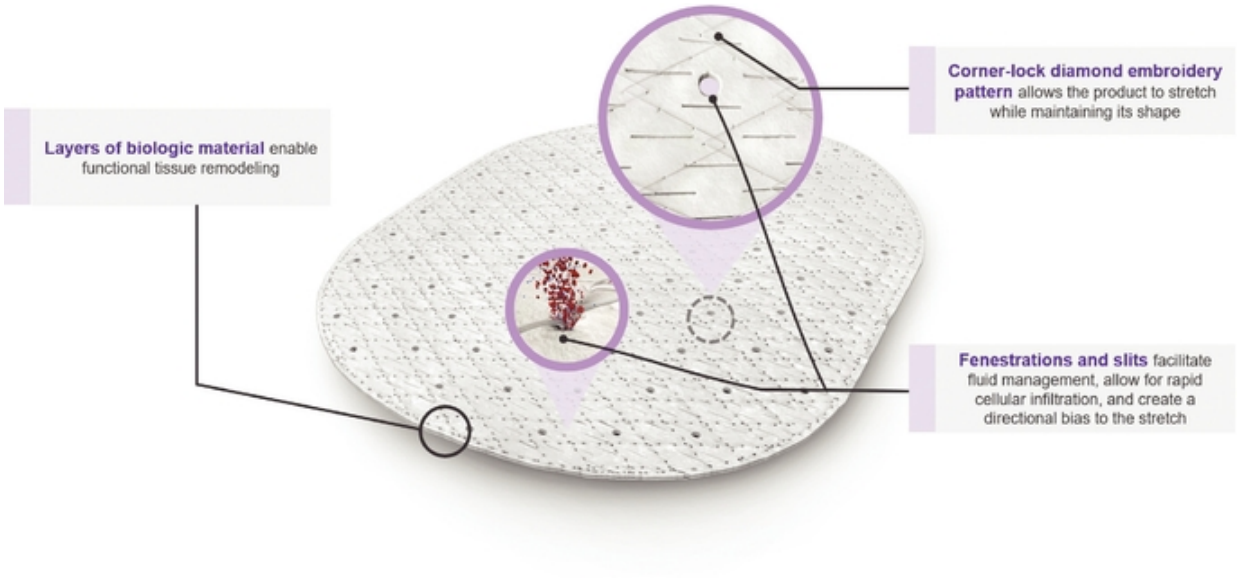
compliance. Each of our products is designed to exhibit a degree of compliance appropriate for its intended clinical application.

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

OviTex



Restella



We believe the principal benefits of our bioscaffolds are:

§ ***Reduced foreign body inflammatory response.*** The biologic material utilized in our bioscaffolds 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 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 bioscaffolds 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 was reminiscent of 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 bioscaffolds are engineered to create hundreds of micro-channels to promote fluid exchange to allow host cells and new blood vessels to penetrate the bioscaffold. In our non-human primate comparative study, at four weeks our OviTex products had host cells between and within the layers of the bioscaffold. We believe this early cell infiltration may reduce the potential for bacterial colonization and the risk for infection. In our OviTex BRAVO study, there were no wound infections that required surgical intervention or device removal in the first 32 patients who reached one year follow-up.

- ***Highly engineered biomechanical properties with durability of results.*** Our bioscaffolds 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 no hernia recurrences in the first 32 patients who reached one year follow-up, despite 80% of these patients having one or more factors known to increase the risk of recurrence. Based on this interim data, we believe that this 0% 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 bioscaffolds 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, of 26 subjects who received minimally invasive surgery, 100% of the surgeons who operated on those subjects cited 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 addition, we have designed an OviTex product for use in laparoscopic and robotic-assisted surgery.

- ***Lower upfront cost products.*** Our bioscaffolds provide our customers with meaningful cost savings over leading competitive products, while maintaining clinical efficacy 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 Restella 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 Restella 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 bioscaffold that is optimized for soft tissue reconstruction. Our OviTex and Restella 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 device is designed in an ellipse shape, with specific thickness and handling properties optimized for use in laparoscopic and robotic-assisted surgery.

- ***Disruptive technology supported by compelling clinical evidence.*** The safety, efficacy and durability of our OviTex products are supported by compelling clinical evidence that includes studies in more than 200 non-human primates, and our BRAVO study. Our non-human primate data demonstrated that use of our OviTex products resulted in more rapid tissue integration and revascularization compared to biologic matrices and lower inflammatory response and better functional tissue remodeling compared to permanent and resorbable synthetic mesh. In our BRAVO study, the first 32 patients who reached one year at follow-up had demonstrated no ventral hernia recurrence, no explantations and no surgical site occurrences requiring follow-up surgery.

- ***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 Restella 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 Restella 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 Restella products are priced below leading biologic matrices, and as we launch our Restella 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 Medicare Severity Diagnosis Related Groups, or 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 our exclusive license, product development and

supply and manufacturing agreement with Aroa, 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 bioscaffold 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, Integra LifeSciences, 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 United States. As of June 30, 2019, we had approximately 200 active hospital accounts, which are supported by 44 employees in our United States based commercial organization. We plan to continue to invest in our commercial organization by adding account managers, clinical development specialists, business managers and administrative support staff in order to cover the top 500 hospitals that we believe perform approximately 55% of our targeted soft tissue reconstruction procedures.

- ***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. We plan to continue to drive awareness of our products through these programs, while expanding their geographic reach and increasing the number of surgeon interactions. In addition, surgeons frequently use DocMatter, an online peer-to-peer community for surgeons to share experiences, share clinical cases, pose clinical questions, present the latest clinical data and develop best practices. DocMatter maintains more than 300 general surgeons in its OviTex peer-to-peer community. We believe a significant peer-to-peer community will develop for our Restella products on this platform.

- ***Increase access to group purchasing organizations and integrated delivery networks.*** We continue to pursue contracts with several large GPOs and IDNs. GPO and IDN contracts enable greater access to geographies with high procedural volumes and provide prioritized status within a hospital's procurement department. We believe that the addition of multiple contracts with national GPOs and high-volume IDNs will materially increase our access to surgeon customers, broaden awareness of our products and help drive utilization of our products within a larger number of hospitals and healthcare 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. We plan to publish 90-day, 12-month and 24-month follow-up data from our BRAVO study over the next several years. In addition, we are tracking the health economic outcomes within our BRAVO study. We also plan to initiate a post-market study of our OviTex products for robotic-assisted ventral hernia repair surgery in 2020. We also intend to support independent investigator-led post-market clinical studies on the effectiveness and safety of our Restella products.

- ***Advance our portfolio of bioscaffolds 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. New product features and designs that we plan to introduce, subject to receiving any required regulatory approval or clearance, include:

— additional sizes and shapes of our OviTex LPR product line;

— a self-grip technology designed to enhance the use of our OviTex products in robotic-assisted surgery for inguinal and ventral hernia repair and enhancements to our Restella products to assist with surgical placement and tissue integration;

— larger OviTex sizes in our resorbable product line; and

— the use of additional polymers, including for instance a longer-acting resorbable and high strength permanent synthetic, to incorporate into our OviTex and Restella products.

Our Products

Our Technology Platform

Our advanced bioscaffold 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 bioscaffold 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 profile. 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 bioscaffold 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 can 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 Bioscaffolds

Our OviTex Reinforced Bioscaffolds have received 510(k) clearance from the FDA, which clearance was obtained and is currently held by Aroa, and are 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.

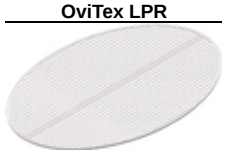
Our OviTex products are sterile bioscaffolds derived from ovine rumen with either polypropylene or PGA. The product is provided in a dry and hydratable form and packaged in a double pouched configuration. The product can be stored at room temperature and only needs five minutes from rehydration to use. 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 bioscaffold 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

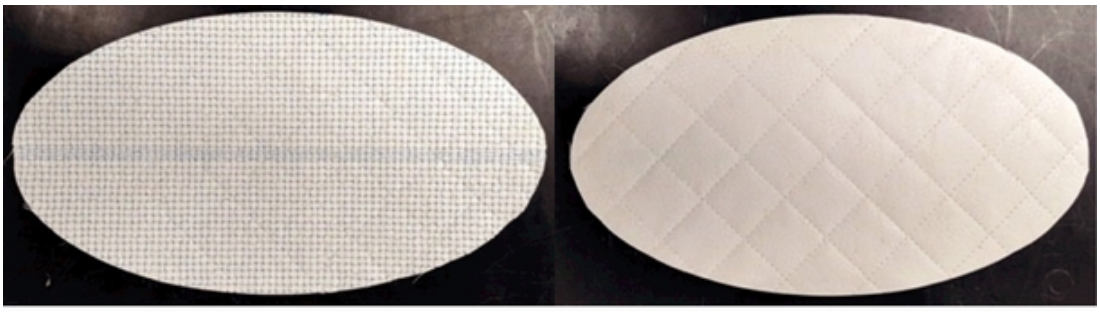
Our OviTex for Laparoscopic and Robotic Procedures, or OviTex LPR, is a sterile bioscaffold derived from ovine rumen with polypropylene fiber intended to be used in laparoscopic and robotic-assisted hernia surgical repairs. OviTex LPR was designed for use with a trocar and requires the same rehydration 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 shape to minimize trimming.

	OviTex	**OviTex 1S**	**OviTex 2S**	**OviTex LPR**
				
Size and Shape	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)
Strength	+	++	+++	+
Layers of Ovine Rumen	Four	Six	Eight	Four

	OviTex	OviTex 1S	OviTex 2S	OviTex LPR
Common Procedures	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
Polymer	Resorbable (PGA) or Permanent (Polypropylene)	Resorbable (PGA) or Permanent (Polypropylene)	Resorbable (PGA) or Permanent (Polypropylene)	Permanent (Polypropylene)
Shelf Life		Resorbable-18 months Permanent-24 months		24 months
Configuration	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
Commercial Availability	§ United States § Europe (up to 20 × 20 cm)	§ United States § Europe (up to 20 × 20 cm)	§ United States § Europe (up to 20 × 20 cm)	United States

* 25 x 30 cm and 25 x 40 cm sizes currently only available with permanent (polypropylene) polymer.
† Denotes relative level of strength

OviTex LPR



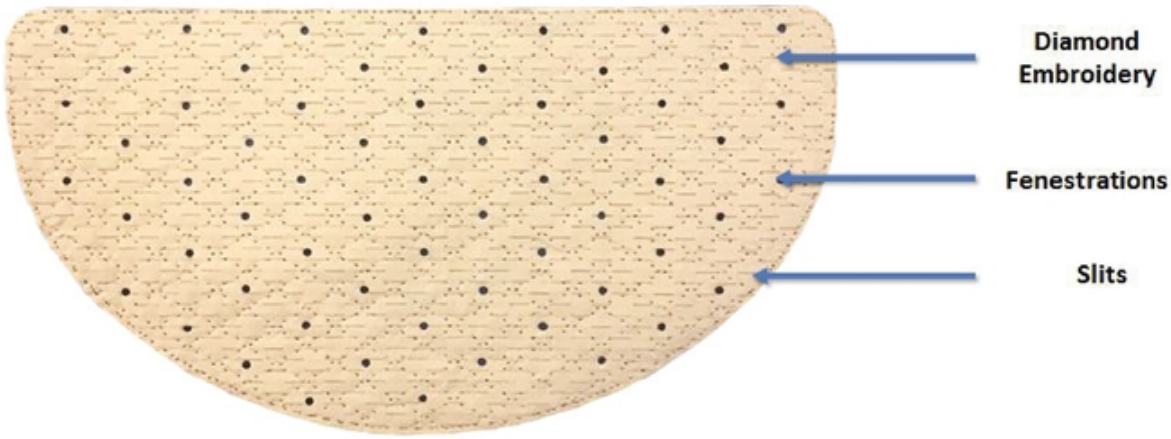
OviTex Plastic and Reconstructive Surgery — Restella

OviTex PRS — Restella Reconstructive Bioscaffold, or Restella, has received 510(k) clearance from the FDA, which clearance was obtained and is currently held by Aroa, 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 Restella 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 Restella product is a sterile reconstructive bioscaffold 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 Restella product is available in arced rectangle, half-moon and oval shapes in a range of sizes (8 × 15 cm through 20 × 25 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 shelf life of permanent Restella is 24 months and the shelf life of resorbable Restella is 12 months.

Restella



Product Pipeline and Research and Development

We continue to expand our product pipeline and the treatment capabilities of our products through innovation, which we believe will expand the patient population that can benefit from our products to maximize their utility across surgical techniques and clinical applications for soft tissue reinforcement. New product features and designs that we plan to introduce, subject to receiving any required regulatory approval or clearance, include:

- additional sizes and shapes of our OviTex LPR product line;
- a self-grip technology designed to enhance the use of our OviTex products in robotic-assisted surgery for inguinal and ventral hernia repair and enhancements to our Restella products to assist with surgical placement and tissue integration of our Restella products;
- larger OviTex sizes in our resorbable product line; and
- the use of additional polymers, including for instance a longer-acting resorbable and high strength permanent synthetic, to incorporate into our OviTex and Restella products.

Clinical Results and Studies

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 bioscaffolds for additional indications for use in the future.

We believe we have completed the largest non-human primate preclinical studies conducted in soft tissue reconstruction surgery. Non-human primates are considered the most suitable animal model to predict the human immune and inflammatory response to a soft tissue reconstruction device. Although not required for FDA clearance of our bioscaffolds, we completed these preclinical studies prior to implantation of our products in human patients. In these studies, we compared our OviTex and Restella products to market leading competitive materials. In these studies, our bioscaffolds exhibited a minimal inflammatory response, rapid cellular infiltration and revascularization and allowed for earlier and complete remodeling into functional tissue.

We are currently sponsoring our BRAVO study. An analysis of the first 32 patients who underwent surgery and completed the twelve-month follow-up visit showed a 0% rate of hernia recurrence, no device explantations and no predefined surgical site complications or wound-related events requiring surgical intervention. This clinical study included patients with a range of comorbidities, prior hernia repairs and history of surgical infections, predisposing them to complications. These patients were treated using either an open or minimally invasive surgical approach. These findings are generally corroborated by similar clinical data from multiple published retrospective studies in a variety of hernia repairs utilizing our OviTex products.

Our Restella products, designed for plastic and reconstructive surgery, utilize the same ovine rumen biologic material and interwoven polymer fibers as our OviTex products, but differ in their overall design. Our Restella bioscaffolds have also been evaluated in a non-human primate model and demonstrated less inflammation and earlier remodeling into functional tissue than the leading biologic matrix used in plastic and reconstructive surgical procedures. Surgeons are beginning to utilize our Restella bioscaffolds in their surgeries and we plan to continuously collect, analyze and support the presentation of clinical data to characterize the performance of our reconstructive bioscaffolds.

Our BRAVO Study

We are sponsoring our BRAVO study, a prospective, single arm, multicenter study evaluating the clinical outcomes of 91 patients with simple and complex ventral hernias repaired with our OviTex 1S with permanent polymer. The study recently completed enrollment of 91 adult patients who underwent open, laparoscopic or robotic-assisted ventral hernia repair at seven centers in the United States between April 2017 and June 2019. The study was designed to test the hypothesis that the strong preclinical biologic performance and predictable biomechanics of our OviTex bioscaffolds would translate into better clinical performance than that of biologic or synthetic devices for hernia repair. No study center contributed more than 19% of patients enrolled.

The primary endpoints of this study are the incidence of early postoperative surgical site occurrences or wound-related events noted at the hernia repair site and the incidence of other postoperative complications, in each case occurring within the first three months of the ventral hernia repair. These include deep or superficial wound infection, seroma, hematoma, wound dehiscence, skin necrosis and fistulas. Hernia recurrence is evaluated at each follow-up visit. In the case of a clinical suspicion by the surgeon of a recurrence, imaging studies are performed. Patients enrolled in the study are evaluated at 30 days, three months, 12 months and 24 months, with interim analysis of patients being conducted for each 25 patient cohort that reaches the three- and twelve-month follow-up period after implantation of our OviTex product. Patients presenting with a primary or recurrent ventral hernia were eligible for the study, with the exception of those with a Body Mass Index, or BMI, of over 40 kg/m^2, a Center for Disease Control, or CDC, Class IV/Dirty-Infected wound, or defects requiring devices larger than 20 × 20 cm or 18 × 22 cm, and other typical exclusion criteria. The secondary endpoints of this study are incidence of late postoperative surgical site occurrences or wound-related events noted at the hernia repair site and occurring more than three months after surgery, incidence of other late postoperative complications occurring more than three months after surgery or true hernia recurrence at the site of surgery at three months, 12 months or 24 months after the hernia repair.

The first 32 patients who have undergone surgery and completed the one-year follow-up visit have been evaluated. Excluded were two patients who withdrew from the study, one patient who is still active but has missed their one-year visit, and three subjects who died within three weeks of surgery due to causes unrelated to our OviTex product or the study procedure.

While many factors can influence surgical wound healing and postoperative infection, bacterial burden is the most significant risk factor. The CDC wound class is a surgical wound classification system designed by the CDC to help clinicians preemptively identify patients at risk of surgical site infection and assess the degree of bacterial contamination of a surgical wound at the time of operation. The CDC identifies four surgical wound classification categories: Class I/Clean; Class II/Clean-Contaminated; Class III/Contaminated; and Class IV/Dirty-Infected. The Ventral Hernia Working Group, or VHWG, grade is a hernia grading system based on risk factor characteristics of the patient and the wound that helps surgeons develop patient assessment strategies, including the selection of appropriate repair material, the appropriate surgical technique and overall clinical approach based on each patient's risk for developing a surgical site occurrence and postoperative complications. This surgical site occurrence-risk grading system consists of four grades: Grade 1/Low Risk; Grade 2/Co-Morbid; Grade 3/Potentially Contaminated; and Grade 4/Infected. This grading system represents salient points along a continuum of risk from low risk (healthy patients with uncomplicated wounds) to high-risk (patients with multiple comorbidities and uncontrolled infection). The demographics of the 32 patients, as well as the number of previous hernia repairs, history of surgical infection, wound status, VHWG classification, obesity classification approach and self-reported patient and surgeon satisfaction are presented in the table below.

BRAVO Study Data

	N[(1)]	%
Comorbidities		
Diabetes Mellitus	6	18.8%
Hypertension	16	50.0%
Previous Ventral Hernia Repair	14	43.8%
Obesity	21	65.6%
COPD/Asthma	4	12.5%
Smoking History	9	28.1%
Prior Hernia Repairs		
Yes	14	43.8%
No	18	56.3%
History of Surgical Infection		
Yes	6	18.8%
No	26	81.3%
Wound Status		
Class I	27	84.4%
Class II	3	9.4%
Class III	2	6.3%
VHWG Grade		
Grade 1	5	15.6%
Grade 2	21	65.6%
Grade 3	6	18.8%
Obesity Classification		
Not Obese	11	34.4%
Obese	15	46.9%
Morbidly Obese	6	18.8%

	N[1]	%
Approach		
Open	24	75.0%
Robotic-assisted	6	18.8%
Laparoscopic	2	6.3%

(1) Represents the number of patients out of the first 32 patients

	Month 12 Average	Range
Satisfaction		
Patient	9.3 (n=27)	2-10
Surgeon	9.8 (n=32)	8-10

The table below presents publicly available recurrence data for other biological matrix and resorbable synthetic mesh products in prospective clinical studies in ventral hernia repair presented in published clinical literature and conference presentations. Recurrence rates are calculated as the number of hernia recurrence at the time of follow-up divided by the number of patients who completed follow-up at the same time period.

Product Name	Tissue Reinforcement Material	Hernia Recurrence Rate[1]	Number of Hernia Recurrence[1]	Number of Patients who Completed Follow-up[1]	Follow-up Period in Months
Phasix[1]	Resorbable Synthetic Mesh	5%	5	95	12
Phasix[1]	Resorbable Synthetic Mesh	12%	11	95	18
Phasix[1]	Resorbable Synthetic Mesh	23%	19	82	36
Strattice[1]	Biologic Matrix	22%	15	69	12
Strattice[1]	Biologic Matrix	33%	22	67	24

(1) Hernia Recurrence Rate based on number of hernia recurrences reported in patients who completed follow up and patients who reported recurrent hernia before the specified follow up period. Clinical literature and conference presentations included hernia recurrence rates based on number of hernia recurrences in patients who comprised the initial intent-to-treat population (including those who did not complete the follow up period and did not report a hernia recurrence).

The table below presents the recurrence rate for the first 32 patients who reached 12-month follow-up in our BRAVO study.

Product Name	Tissue Reinforcement Material	Hernia Recurrence Rate	Number of Hernia Recurrence	Number of Patients who Completed Follow-up	Follow-up Period in Months
OviTex	**Reinforced Bioscaffold**	**0%**	**0**	**32**	**12**

None of the first 32 patients who reached the one-year follow-up period had experienced a recurrence at that time (0 of 32; 0%). In this study, nine patients experienced surgical site occurrences, of which five were considered possibly related to the device (5 of 32; 15.6%). Of these five surgical site occurrences, four were infections (abdominal wall abscesses), and one was a seroma. None of the surgical site occurrences required further surgery or removal of the device, and all surgical site occurrences had resolved by the time of the 90-day follow-up visit. All nine patients had comorbidities that are known to increase the risks of surgical site occurrences, including obesity in seven, diabetes mellitus in one, chronic obstructive pulmonary disease in one, hypertension in five, one to five previous ventral hernia repairs in seven (average of 2.7 prior ventral hernia repairs) and previous surgical infections in three. Patient satisfaction for the completed patients was 9.3 out of 10 at the one-year follow-up and surgeon satisfaction at that time was 9.8 out of 10. Our OviTex product was considered easy or very easy to use in all cases, whether open or minimally invasive.

The first planned 12-month analysis of this study showed no device failures requiring explantation, reoperation or recurrences, thereby demonstrating the strong biologic and biomechanical performance of our OviTex bioscaffolds. Our 0% 12-month recurrence rate compares favorably to the reported 12-month recurrence rates in published prospective studies for Phasix, and Strattice, which were 5.0%, and 22%, respectively. We believe that our OviTex bioscaffolds better tolerate an infected environment as demonstrated by our 0% explantation rate.

Preclinical In Vivo Evaluation of our OviTex Product in Non-Human Primates

We evaluated the biologic performance of two configurations of our OviTex bioscaffolds in comparison to five currently available reconstruction materials and two other reconstruction materials that are no longer commercially available, including permanent synthetic mesh, resorbable synthetic mesh and biologic matrices in non-human primate studies, with 73 non-human primates. We selected the African Green monkeys for use in this study because this primate is closely related to and shares greater than 98% of their genetic code with humans. This non-human primate model has been used extensively to evaluate clinical and immune responses to pathogens, vaccines, and pharmaceuticals, and to predict xenograft biocompatibility for abdominal wall repair.

In accordance with the study protocol, the animals were anesthetized and a 7 × 3 cm full thickness "window" defect was created in the midline of the abdominal wall. The defect was then repaired with a reconstruction material of equal size, which was sutured in place to repair the defect and the skin was then sutured closed. Next the animals were euthanized at four, 12 or 24 weeks and the skin of the abdomen was dissected back to expose the site of the device. The graft site was evaluated for signs of herniation, inflammation, adhesions, contractions or other abnormalities. Then the length and width of the grafts were measured and the entire grafts and surrounding tissues were removed and photographed. Samples of the grafts were then prepared for analysis by an independent histopathologist. The most relevant data from this study came from the 24 week analysis.

Test Articles, Material Classification, Source Materials and Explant Time Points

Material	Manufacturer	Classification	Source Materials	Explant Time Point (weeks)
OviTex PGA 1S	TELA Bio	Reinforced Biologic	Ovine rumen embroidered with polyglycolic acid	4, 12, 24
OviTex PP 1S	TELA Bio	Reinforced Biologic	Ovine rumen embroidered with polypropylene	4, 12, 24
Strattice Firm	LifeCell Corporation (now Allergan)	Biologic	Porcine dermis	4, 12, 24
Phasix	C.R. Bard, Inc. (now BD)	Resorbable Synthetic	Poly-4-hydroxybutyrate (P4HB)	4, 12, 24
Ventralight ST	C.R. Bard, Inc. (now BD)	Permanent Synthetic	Polypropylene with hydrogel barrier	4, 12, 24

OviTex

At 24 weeks, our OviTex bioscaffolds best preserved their original geometry and exhibited limited contraction, had minimal inflammation, had rapid cellular infiltration and vascularization, and the grafts fully remodeled into host tissue (fastest rate of remodeling) with a higher degree of organized collagen than synthetics and biologics (on average).

Biologic Matrices

At 24 weeks, the biologics significantly contracted in length and expanded in width, had minimal inflammation, slow cellular infiltration and vascularization, and the grafts fully remodeled into host tissue (slower rate of remodeling than our OviTex product) and exhibited varying degrees of organized remodeled collagen.

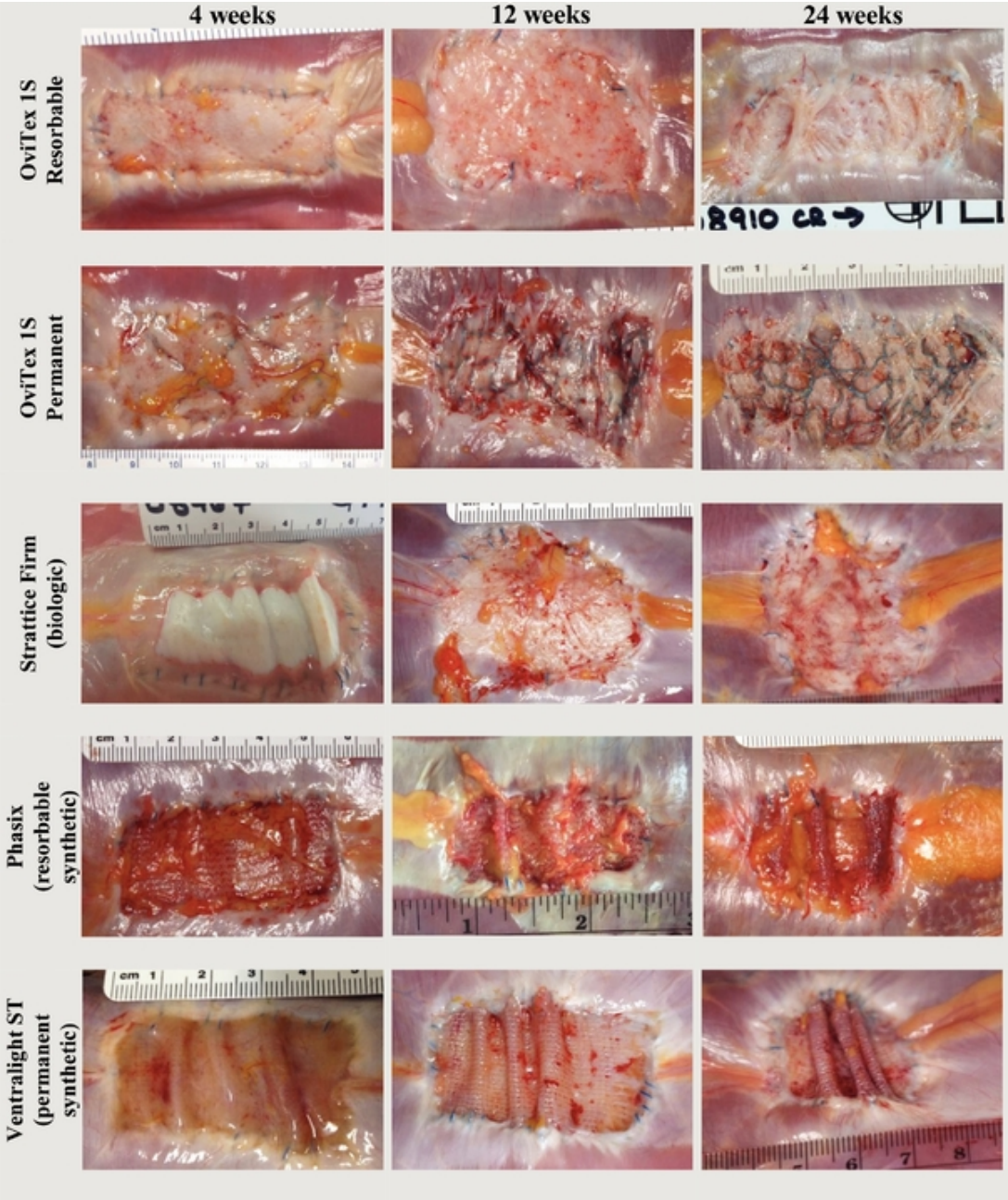
Resorbable Synthetics

At 24 weeks, the resorbable synthetic material exhibited significant contraction, had mild to moderate inflammation (which persisted at elevated levels throughout the study), showed a substantial layer of early amorphous inflamed tissue adjacent to the device, and given that they contain no biologic material that can be remodeled, the scar-like collagen formed adjacent to the persistent synthetic mesh material, separated by a layer of loose connective and adipose tissue, which was also present between the mesh fibers.

Permanent Synthetics

At 24 weeks, the permanent synthetics exhibited a high degree of contraction in length and width, had mild to moderate inflammation (which persisted at elevated levels throughout the study), showed substantial layers of

early amorphous tissue formed next to the device, and given that they have no biologic that can be remodeled, they exhibited disorganized and scar-like collagen surrounding the persistent synthetic mesh material.



* Illustrative samples.

Figure: Our OviTex product exhibited less contraction over time compared to other materials

The outcome of this preclinical study to evaluate our OviTex product in a non-human primate model confirms the utility of our reinforced bioscaffolds for hernia repair as a viable alternative to available biologic and synthetic hernia repair materials.

Other Clinical Studies Using Our OviTex Products

Clinical experience with ventral hernias and abdominal wall reconstruction

A growing body of clinical evidence supports the safety, durability and effectiveness of our OviTex products for use in ventral hernia repair and abdominal wall reconstruction procedures.

An independent investigator-initiated, observational, retrospective cohort study on a consecutive series of 23 adult patients was conducted to evaluate the clinical outcomes of abdominal wall reconstruction in complex incisional ventral hernias repaired with our OviTex 1S and OviTex 2S with both permanent polymer and resorbable polymer. These patients underwent open ventral hernia repair with our OviTex products at a single center in the United States between June 2016 and June 2018. The primary endpoints of this study include rates of recurrence, surgical site infections and surgical site occurrences. The majority of patients were female (56.5%), mean age of 60.8 ± 11.1 years, and mean body mass index of 33.1 ± 5.3. Comorbidities included obesity (60.9%), hypertension (56.5%), previous wound infection (39.1%), diabetes mellitus (34.8%), and recent smoking history (26.1%). The mean comorbidities per patient were 3.4. Mean VHWG Grade was 2.8 ± 0.8. There were eight Grade 3 (34.8%) and five Grade 4 (21.7%) patients. Concomitant procedures were performed in twelve patients (52.1%). These included small bowel resection in four, enterocutaneous fistula resection with associated small bowel in three, colon resection in one, gastric bypass reversal in one, and panniculectomy in three. Fifteen patients presented with recurrent hernias (65.2%). During the abdominal wall reconstruction procedure, twelve patients had a previous synthetic mesh removed (52.2%) and three patients had a previous biologic removed (13.0%). These 23 patients completed follow-up visits at nine to 33 months and were evaluated. Two of the 23 patients experienced a recurrence (8.7%) at the mean 18.7 ± 8.2 months follow-up. Postoperative surgical site occurrences at the hernia repair site occurred in seven patients (30.4%), including four superficial infections, two seromas, and one superficial wound necrosis. All were effectively treated without the need for removal of the device. Patient satisfaction with the repair was excellent. We believe the results of this study demonstrate that our OviTex products have an acceptably low rate of recurrence in this challenging patient population. The results of this study were presented at the American Hernia Society Annual Meeting in March 2019.

Another independent investigator-initiated, observational, retrospective study of 100 patients in two cohorts of 50 consecutive adult patients was conducted to evaluate the clinical outcomes of abdominal wall reconstruction in ventral hernias classified as VHWG Grade 2 and Grade 3 and CDC Wound Class I through IV repaired with our OviTex 1S and OviTex 2S or synthetic mesh. These patients underwent open ventral hernia repair at multiple hospitals within a university hospital system in the United States in 2017. The primary endpoints of this study include rates of recurrence, surgical site infections and surgical site occurrences at six months follow-up. Fifty patients underwent ventral hernia repair with our OviTex product. The majority of patients were female (58%), mean age of 55 ± 14 years, and body mass index of 34 ± 6. Comorbidities included obesity, hypertension, diabetes mellitus, and recent smoking history. VHWG Grade distribution included Grade 2 (32%) and Grade 3 (68%) and CDC Wound Class distribution included CDC Class I (30%), 2 (44%), 3 (10%), and 4 (16%). Concomitant procedures were performed in 70% of patients. Fifty patients completed follow-up visits at six months and were evaluated. Hernia recurrence was 8%. Postoperative surgical site occurrences at the hernia repair site occurred in 18 patients (36%), including eight infections, five seromas, and five wound drainage or dehiscence, or disruption of the wound closure. In the fifty patients who underwent ventral hernia repair with synthetic mesh, the majority of patients were male (54%), mean age of 52 ± 12 years, and body mass index of 33 ± 7. These patients had similar comorbidities. VHWG Class distribution included Grade 2 (94%) and Grade 3 (6%) and CDC Wound Class distribution included CDC Class I (94%), II (4%), III (2%), and IV (0%). Concomitant procedures were performed in 10% of patients. Fifty patients completed follow-up visits at six months and were evaluated. Hernia recurrence was 12%. Postoperative surgical site occurrences at the hernia repair site occurred in 11 patients (22%). This study demonstrated that patients treated with our OviTex product experienced a lower hernia recurrence rate at six months follow-up compared to those treated with synthetic

mesh, despite our OviTex product being implanted in a much higher risk patient population. These results are in contrast with prior clinical results published in peer-reviewed clinical literature that demonstrate that higher risk patients exhibit higher recurrence rates compared to those exhibited in low risk patients. We believe the results of this study demonstrate that our OviTex products may be better suited for definitive hernia repair in higher risk patients in place of synthetic mesh. The results of this study were presented at the Western Surgical Association Scientific Session Annual Meeting in November 2018.

Clinical experience with inguinal hernias

An independent investigator-initiated, observational, retrospective study on a consecutive series of 31 adult patients was conducted to evaluate the clinical outcomes of inguinal hernia repaired with our OviTex product with permanent polymer and its role in reducing chronic postoperative inguinal pain. These patients underwent open inguinal hernia repair at a single center in the United States from 2016 to 2017. The primary endpoints of this study include rates of recurrence, surgical site infections, surgical site occurrences, device explantation, chronic postoperative inguinal pain, and refill of narcotic pain medications during the follow-up period. The vast majority of patients were male (94%), mean age of 56 years (range 27 to 83), and mean body mass index of 27 (range 21 to 33). Six patients presented with recurrent hernias (19%). These 31 patients completed follow-up visits at three to 18 months and were evaluated. No patients experienced a recurrence (0%) and no patients required explantation (0%) of the device for infection, chronic pain, meshoma, which is a complication of mesh implantation in which the mesh shrinks in the form of a rounded mass manifestation, or any other reason at the mean 12.6 months follow-up. There were no postoperative surgical site occurrences at the hernia repair site that required surgical intervention. There were no reported surgical site infections during the initial 30 days postoperatively. All patients were prescribed standard postoperative narcotics for pain control. There were no requests for refills for pain medication. There was no reported incidence of chronic postoperative inguinal pain, a common problem with synthetic mesh products. This study demonstrated that our OviTex product is effective and a viable alternative to synthetic mesh in inguinal hernia repair. We believe the results of this study demonstrate that our OviTex products may lead to less postoperative pain and potentially help minimize the inflammatory response seen in hernia patients treated with synthetic mesh in this most common hernia type. The results of this study were published in the *International Journal of Surgery Open* in June 2018.

Clinical experience with hiatal hernias

Hiatal hernias are a type of hernia in the diaphragm through which the esophagus passes to the stomach. Repair of hiatal hernias is preferentially done using biologic matrices due to a rare but serious complication seen when permanent synthetic mesh is used. However, most surgeons prefer to use robotic or laparoscopic techniques, which are challenging with biologics due to limitations with their thickness and flexibility, which make them difficult to shape, handle, and fixate.

An independent investigator-initiated, observational, retrospective cohort study on a consecutive series of 25 adult patients was conducted to evaluate the clinical outcomes of hiatal hernias repaired with our OviTex and OviTex 1S with resorbable polymer. These patients underwent laparoscopic or open hiatal hernia repair with our OviTex products at a single center in the United States between August 2016 and May 2017. The primary endpoints of this study include rates of recurrence and complications and symptom control or resolution. The majority of patients were female (72%%), mean age of 59.8 ± 14.8 years, and mean body mass index of 29.6 ± 7.3. Comorbidities included hypertension (64%), obesity (44%), hyperlipidemia (32%), diabetes mellitus (20%), obstructive sleep apnea (20%), chronic obstructive pulmonary disease or asthma (20%), coronary artery disease (16%), and prior heart attack (12%). Three patients presented with recurrent hernias (12%). Laparoscopic repair was completed in 23 of 24 patients and one case was straight open due to strangulation and perforation of the hernia. These patients completed follow-up visits at one to 20 months and were evaluated. No patients experienced a recurrence (0%) at the mean 14.2 ± 4.7 months follow-up. Most preoperative symptoms resolved or were significantly improved, specifically

heartburn in 20 of 21 (95%) patients, dysphagia, or difficulty swallowing, in 18 of 19 (95%) patients, regurgitation in all 10 (100%) patients, nausea and vomiting in all three (100%) patients, dyspnea, or shortness of breath, in all four (100%) patients, and chest discomfort or pain in six of seven (86%) patients. One of one patient did not achieve symptom relief for abdominal bloating which was also present preoperatively. There were no intraoperative complications and specifically no complications attributable to the use of our OviTex products. The products were found to be easy to shape, handle, and fixate. We believe the results of this study demonstrate that our OviTex products provide a viable treatment alternative for patients with hiatal hernias and that our OviTex products can be shaped, handled and fixated with ease using laparoscopic techniques. The results of this study were published in the *Journal of the Society of Laparoendoscopic Surgeons* in October-December 2018.

Preclinical Animal Testing of Restella

Our resorbable and permanent Restella products were evaluated in a non-human primate study, in which our Restella product was compared to AlloDerm at two, four, 12 and 24 weeks for differences in healing kinetics, as evidenced through inflammatory response, cellular infiltration, and the morphological quality of the newly remodeled tissue associated with each device. The inflammatory response for both the Restella groups and AlloDerm was minimal, though when comparing the two the response was slightly lower in our resorbable Restella product at all time points, including the last 24 weeks. At four weeks, the highly permeable nature of our Restella product design enhanced fluid exchange evidenced by more effective and rapid infiltration of host cells in the collagen network. In comparison, the collagen network of AlloDerm developed a superficial layer of fibroblasts, covering the device, which macroscopically appeared white and largely inert. The earlier infiltration and faster recruitment of fibroblasts and host cells in our Restella product helped "jump start" the remodeling process into host tissue. At 12 weeks, our Restella product was fully remodeled and the maturation of the product was slightly ahead of that of AlloDerm at all time points. At 24 weeks, significant contraction was seen in all AlloDerm devices, as well as calcifications. The collagen in the AlloDerm specimens showed signs of maturation, much like our Restella products, which remodeled into mature collagen, consistent of compact lamellar bundles of low cellularity, occupying the entire defect site with functional tissue. After 24 weeks our Restella product was associated with a favorable tissue response, demonstrating rapid infiltration, earlier and more rapid tissue integration and slightly more advanced tissue remodeling in comparison to AlloDerm.

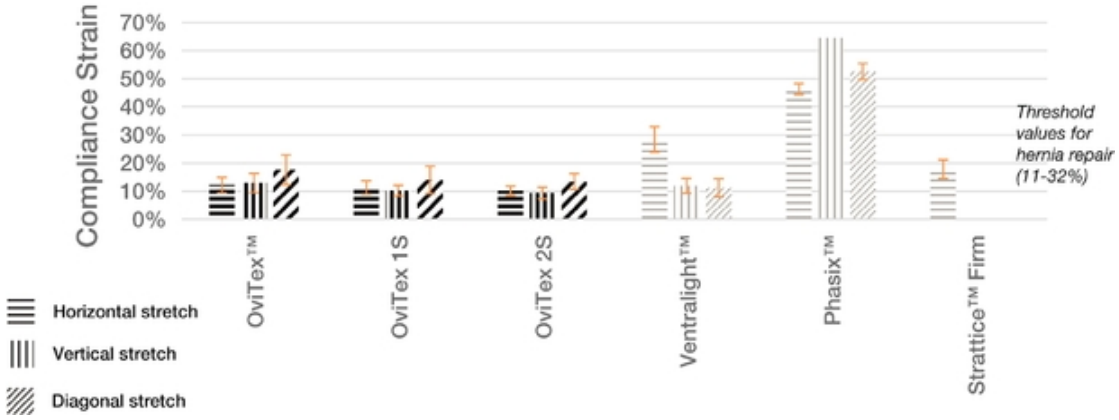
OviTex Tensile Testing Studies

While strength of a soft tissue reconstruction material is important, the degree to which it stretches, known as compliance, is also critical. These materials must offload the tension of the repaired soft tissue in order for the repaired tissue to heal properly and allow for the most durable repair. We utilize ASTM, or American Society for Testing and Materials, tensile testing techniques and standards to evaluate the biomechanical characteristics of our products. ASTM is an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials. Compliance is a key measurement for our products, under these standards compliance is defined as the percentage change in length of material per unit of tensile load applied. A high compliance product means that little tensile load, or force per unit area, is required to stretch a high percentage. The compliance requirements of the abdominal wall have been well characterized with an ability to stretch between 11% and 32% when subjected to typical anatomical loads.

We utilize tensile machines to test our products and those of our competitors to the same anatomical loads as the abdominal wall structure to determine their compliance. An ideal hernia repair and abdominal wall reconstruction product would trend or match the compliance of the native abdominal wall structure at typical anatomical loads. Based on our ASTM tensile testing studies, OviTex, OviTex 1S and OviTex 2S all exhibited compliance of approximately 11%, within the ideal compliance range that mirrors that of the native abdominal wall structure. Most of our competitors' products do not meet this biomechanical target compliance range, which means they are subject to excessive stretching, resulting in the inability to offload the forces of the hernia or abdominal wall defect. We believe our OviTex products exhibit compliance

characteristics that most closely match those of the native abdominal wall structure, compared to our competitors' products. The chart below summarizes the compliance measurements of our OviTex products compared to those of other commercially available soft tissue reconstruction products.

Average Uniaxial Compliance Strain per Direction



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 products.

Pursuant to the terms of the Aroa License we made upfront payments to Aroa totaling $2.3 million and granted Aroa 1,834,867 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 are obligated to pay Aroa up to an aggregate of $4 million in revenue-based milestone payments upon our achievement of certain net sales thresholds for sales of our products within the Licensed Territory, of which we have already paid $1.0 million.

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 July 30, 2029, 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 June 30, 2019, we exclusively license two issued U.S. patents that will expire in 2029 and 2031. We own six U.S. issued or allowed patents which will expire between 2035 and 2037 and six pending U.S. patent applications, which subject to issuance, are projected to expire between 2035 and 2040, without taking into account potential patent term extensions or adjustments. In addition to our U.S. intellectual property, we also own four 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 United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States 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®, OviTex® and Restella® are registered trademarks of ours in the United States.

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

Research and Development

We invest in research and development to advance our bioscaffold 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 bioscaffolds in various stages of development that are expected to enhance our current products and increase surgeon adoption of our products. In addition, we intend to engage in discussions with the FDA regarding an IDE protocol to study the safety and effectiveness of our Restella portfolio for an indication in breast reconstruction surgery. Our research and development efforts are based at our facility in Malvern, Pennsylvania.

Commercial Strategy

We have established strong relationships in the United States 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. There are currently more than 200 active hospital accounts in the United States that have incorporated our products into their practices.

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 June 30, 2019, we had 44 employees in our United States based commercial organization in 22 sales territories, which includes account managers and administrative support staff. We intend to expand our commercial organization to approximately 60 employees by December 31, 2019. We plan to continue to invest in our commercial organization by adding account managers, clinical development specialists, business managers and administrative support staff in order to cover the top 500 hospitals that we believe perform approximately 55% of our targeted soft tissue reconstruction procedures.

Manufacturing

All of 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, with approximately 100 employees. This facility is currently undergoing a short-term expansion to increase capacity with additional process equipment and work shifts, and a further intermediate-term expansion is planned, with approximately 15,000 square feet of additional manufacturing space available. Expansions are mutually agreed between us and Aroa, and under the terms of the Aroa License we share 50% of the expansion cost, which we may later offset against our revenue share payment to Aroa. 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 of 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 bioscaffold products are then manufactured by Aroa at its facility in Auckland, New Zealand.

Distribution

All 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 Davol Inc., a subsidiary of C.R. Bard, Inc., which produces Phasix and Ventralight ST, and LifeCell, a subsidiary of Allergan, which produces Strattice. In the plastic and reconstructive surgery market, our primary competitor is LifeCell, a subsidiary of Allergan, 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 United States 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 United States. 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 United States

All of our medical devices sold in the United States are subject to the Federal Food, Drug, and Cosmetic Act, or 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 United States 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 Premarket Approval application, also referred to as a PMA. 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 is currently considering proposals to reform its 510(k) marketing clearance process, and such proposals could include increased requirements for clinical data and a longer review period. In November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it plans to develop proposals to drive manufacturers using the 510(k) pathway toward the use of newer predicates. These proposals include plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA also announced that it intends to finalize guidance to establish a premarket review pathway for "manufacturers of certain well-understood device types" as an alternative to the 510(k) clearance pathway and that such premarket review pathway would allow manufacturers to rely on objective

safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. These proposals have not yet been finalized or adopted, and the FDA announced that it would seek public feedback prior to publication of any such proposals, and may work with Congress to implement such proposals through legislation.

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 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 provide adequate directions for use and that all claims are substantiated;
- complying with new requirements for Unique Device Identifiers (UDI) on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database (GUDID);
- 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, or MDR, 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, or the EU, and the European Economic Area, or the EEA (which is comprised of the 28 Member States of the EU plus Norway, Liechtenstein and Iceland) has a coordinated system for the authorization of medical devices. The European Union Medical Devices Directive, or MDD, sets out the basic regulatory framework for medical devices in the European Union. This directive has been separately enacted in more detail in the national legislation of the individual member states of the European Union.

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 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. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-certify compliance with the MDD 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 European Union without further conformance tests being required in other member states.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the MDD 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, among other things, is intended to 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

Medical Devices Regulation will, however, only become applicable three years after publication (in 2020). Once applicable, the new regulations will 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;
- set up 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, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

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, or HITECH, 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, or 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, or CCPA, which creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA goes 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.

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.

European Union member states, the United Kingdom, Switzerland and other jurisdictions have also adopted data protection laws and regulations, which impose significant compliance obligations. In the EEA and the United Kingdom, the collection and use of personal data, including clinical trial data, is governed by the provisions of the General Data Protection Regulation, or GDPR. The GDPR became effective on May 25, 2018, repealing its predecessor directive and increasing responsibility and liability of pharmaceutical and

medical device companies in relation to the processing of personal data of EU data subjects. The GDPR, together with national legislation, regulations and guidelines of the EU member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. 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. Those who structure their business arrangements to satisfy all of the criteria of a safe harbor are protected from liability under the statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the Department of Health and Human Services Office of Inspector General. 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, or the Sunshine Act, which was enacted as part of the Patient Protection and Affordable Care Act, or the 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 ranging from $1,128 to $11,278 for each payment or other transfer of value that is not reported (up to a maximum per annual report of $169,170) and from $11,278 to $112,780 for each knowing failure to report (up to a maximum per annual report of $1.128 million). Additionally, there are 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 prohibit 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. Similar to 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, or 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 United States 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. The scope of the FCPA includes interactions with certain healthcare professionals in many countries.

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

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our products. By way of example, the Patient Protection and Affordable Care Act, or PPACA substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the medical device industry. PPACA, among other things, imposed a 2.3% excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions. Although the excise tax was suspended from 2016 through 2019, absent further legislative action, the tax will be reinstated starting January 1, 2020.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which eliminated the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the PPACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the PPACA are invalid as well. While the Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA.

There will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge and/or patients' willingness to pay for our products. While in general it is too early to predict what effect, if any, any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

Pricing and Reimbursement

In the United States 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 efforts are underway by the current U.S. administration and 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 United States has increased and will continue to increase the pressure on medical product and service pricing.

Employees

As of August 30, 2019, we had 83 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.

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 15,000 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.

Legal Proceedings

On November 18, 2016, we entered into a Settlement and Release Agreement, or the Settlement Agreement with Antony Koblish, Maarten Persenaire and LifeCell, to settle litigation initiated by LifeCell in 2015. The Agreement governs the terms of the release of claims and non-exclusive license arising out of litigations initially brought by LifeCell in the Superior Court of New Jersey, Chancery Division, Somerset County, and the U.S. District Court for the District of New Jersey, collectively, the Litigations. The Litigations alleged that we misappropriated LifeCell's trade secrets, hired various former LifeCell employees in violation of their noncompetition covenants and nonsolicitation agreements and infringed a LifeCell patent.

Under the terms of the Agreement, LifeCell granted us a non-exclusive, irrevocable, worldwide, fully paid up, perpetual license to LifeCell's patent to make, have made, use, sell and import our products in the United States that would otherwise infringe upon such patent and agreed not to sue us with respect to our

OviTex products. Under the terms of the Agreement, we agreed to pay LifeCell $4.0 million as full payment of all amounts owing under the Agreement. Through December 31, 2018, we have paid $3.0 million to LifeCell. The remaining $1.0 million is due upon achievement of certain OviTex sales milestones.

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.

MANAGEMENT

The following table sets forth information regarding our executive officers and directors, including their ages as of August 30, 2019:

NAME	AGE	POSITION(S)
Executive Officers		
Antony Koblish	53	President and Chief Executive Officer and Director
Nora Brennan	51	Chief Financial Officer
Maarten Persenaire, MD	62	Chief Medical Officer
E. Skott Greenhalgh, PhD	52	Chief Technology Officer
Non-Employee Directors		
Kurt Azarbarzin	57	Chairman of the Board of Directors
Vince Burgess	55	Director
Ronald Ellis	48	Director
Ashley Friedman	41	Director
Adele Oliva	53	Director
Matt Zuga	54	Director

(1) Member of our audit committee.
(2) Member of our compensation committee.
(3) Member of our nominating and corporate governance committee.

Executive Officers

Antony Koblish. Mr. Koblish is one of our co-founders and has served as our President and Chief Executive Officer and as a member of the board of directors since our founding in April 2012. Previously, Mr. Koblish was President and Chief Executive Officer of Orthovita, Inc., a publicly traded orthobiologics and biosurgery medical device company. Mr. Koblish co-founded and currently serves as Chairman of the Board of Onkos Surgical, a surgical oncology company, and is an operating partner with 1315 Capital, a private investment firm that provides expansion and growth capital to commercial-stage specialty pharmaceutical, medical technology, and health care services companies. Mr. Koblish also serves as the Chairman of the Board of Cerapedics, a private ortho-biologics company. As Chairman of the Board of Cerapedics and Onkos Surgical Mr. Koblish attends one board meeting per quarter, respectively, and as an operating partner for 1315 Capital Mr. Koblish attends one to two meetings per quarter. The remainder of Mr. Koblish's time is dedicated to serving as our Chief Executive Officer. Mr. Koblish earned a Master of Science in Engineering degree in Mechanical Engineering and Applied Mechanics from the University of Pennsylvania, and holds a Bachelor of Science degree in Mechanical Engineering from Worcester Polytechnic Institute.

Mr. Koblish's knowledge of our business, as well as his extensive leadership experience and successful record of commercial operation and product pipeline development provide him with the qualifications and skills to serve on our board of directors.

Nora Brennan. Ms. Brennan has served as our Chief Financial Officer since January 2019. Previously, Ms. Brennan performed consulting services from April 2018 until January 2019 and served as Chief Financial Officer at Xeris Pharmaceuticals, Inc., a specialty pharmaceutical company, from June 2017 until April 2018. From 2006 to June 2017, she was employed at Integra Lifesciences Corporation, a global medical device company, where she held various senior leadership roles, including Senior Vice President, Investor Relations and Corporate Treasurer. Prior to joining Integra, Ms. Brennan worked at Citigroup and JP

Morgan in various finance and investment banking roles. Ms. Brennan holds a Master of Business Administration degree from the University of Chicago Booth School of Business and a Bachelor of Arts from the University of Illinois.

Maarten Persenaire, MD. Dr. Persenaire is one of our co-founders and has served as our Chief Medical Officer since December 2012. From 1999 to 2011, Dr. Persenaire was Chief Medical Officer at Orthovita, Inc. Dr. Persenaire received his Doctor of Medicine degree at Groningen University in The Netherlands.

E. Skott Greenhalgh, PhD. Dr. Greenhalgh has served as our Chief Technology Officer since December 2016, and as our Vice President of Research and Development from January 2013 through November 2016. Previously, Dr. Greenhalgh served as Chief Technology Officer at Stout Medical Group LP and US Biodesign Inc. Dr. Greenhalgh received his Doctor of Philosophy degree in Fiber and Polymer Science and his Master's degree in Textile Engineering from North Carolina State University, and his Bachelor of Science degree in Mechanical Engineering is from Drexel University.

Non-Employee Directors

Kurt Azarbarzin. Mr. Azarbarzin has been a member of our board of directors since November 2018. Mr. Azarbarzin has served as Chief Executive Officer and a member of the board of directors of Verb Surgical Inc., a robotic surgery company, since July 2019. Mr. Azarbarzin previously served as Chief Technology Officer for CONMED Corporation, a global, publicly-traded medical device company dedicated to helping customers improve patient outcomes, from 2016 to July 2019. Mr. Azarbarzin is the former Founder of SurgiQuest, Inc., a medical device company focused on advancing minimally invasive surgery, and served as its Chief Executive Officer from 2005 until June 2016. Mr. Azarbarzin is a member of the executive board at Center for Biomedical Innovation and Technology at Yale University. Mr. Azarbarzin previously held leadership roles in Research and Development at U.S. Surgical & Tyco Healthcare. He earned a Bachelor of Science from the University of Bridgeport and completed advanced graduate studies in mechanical design at Bridgeport Engineering Institute and manufacturing engineering at Bradley University.

Mr. Azarbarzin's expertise in the medical device industry and experience as an executive officer in the medical device field provide him with the qualifications and skills to serve on our board of directors.

Vince Burgess. Mr. Burgess has been a member of our board of directors since June 2014. Mr. Burgess has served as President, Chief Executive Officer and member of the board of directors of Acutus Medical, a medical device company, since October 2017 and he has served as a Venture Partner with OrbiMed Advisors, LLC, a healthcare investment firm, since September 2011. Prior to joining OrbiMed, Mr. Burgess was a member of the initial executive team at Volcano Corporation, where he served as President of Advanced Imaging Systems. He also led marketing and business development at Volcano from 2002 to 2010. He currently serves as a member of the board of directors of NeuroPace, Inc., Sonendo Inc. and Ornim Medical. He has previously served on the boards of Keystone Heart, Inc., Vessix Vasular, Cryterion Medical and CardiAQ, Inc. He earned his Bachelor of Science degree in Business Administration from the University of South Carolina and his Masters of Business Administration from the University of California, Los Angeles.

Mr. Burgess' expertise in marketing and business development, as well as his operational and board experience in the surgical tool field provide him with the qualifications and skills to serve on our board of directors.

Ronald Ellis. Dr. Ellis has been a member of our board of directors since February 2018. Dr. Ellis has served as Vice President of Corporate Strategy & Business Development at Pacira Pharmaceuticals, since October 2016. Dr. Ellis was a Managing Director at Leerink Partners, a boutique health care investment bank, from January 2013 to September 2016. Prior to working at Leerink Partners, Dr. Ellis was the Healthcare Trading Specialist at Citigroup Global Markets and Deutsche Bank Securities. He previously

served as a Biotechnology Analyst in Equity Research at Prudential and Leerink Swann. Dr. Ellis also worked as an associate on the specialty pharmaceuticals equity research team at ING Barings, which was subsequently acquired by ABN AMRO. Dr. Ellis did his post-doctoral work in pharmacoeconomics and health outcomes, as a Wyeth-Ayerst fellow. He earned his medical degree from the Philadelphia College of Osteopathic Medicine and a Masters of Business Administration with a concentration in Medical Management from St. Joseph's University, where he also studied pharmaceutical marketing.

Dr. Ellis' extensive experience in the health care industry and health care investment investing as well as the leadership positions he has served in over his 20 years of experience provide him with the qualifications and skills to serve on our board of directors.

Ashley Friedman. Mr. Friedman has been a member of our board of directors since October 2014. Mr. Friedman has served as a Managing Director at Signet Healthcare Partners, a private equity firm focused on growth-stage health care investments, since March 2016 and a Venture Partner at Signet Healthcare Partners from June 2014 to March 2016. From June 2003 until February 2015, Mr. Friedman worked for Investor Growth Capital, a venture capital firm focused on health care investments. He began his career as a health care investment banker at Lehman Brothers. Mr. Friedman holds a Bachelor of Science from Yale University in both Economics and Molecular, Cellular & Developmental Biology, with a concentration in biotechnology.

Mr. Friedman's insight into life science investing and finance matters and his extensive experience in health care venture capital and private equity provide him with the qualifications and skills to serve on our board of directors.

Adele Oliva. Ms. Oliva has been a member of our board of directors since 2012. Ms. Oliva co-founded 1315 Capital, a firm focused on health care — growth investing, in 2014. Since 2007, Ms. Oliva has served as a partner of Quaker Partners, a healthcare investment firm. Prior to joining Quaker Partners, she was Co-Head of US Healthcare at Apax Partners, a global private equity firm. Ms. Oliva serves a member of the board of directors of Novasom, Inc., Onkos Surgical, Innovative Health, Greenbrook TMS Inc., ColorScience and Sprout Pharmaceuticals. She received a Bachelor of Science degree from St. Joseph's University and a Masters of Business Administration from Cornell University, where she was awarded the Albert Fried fellowship.

Ms. Oliva's extensive finance and health care experience, as well as her insight into commercial-stage specialty medical technology companies provide her with the qualifications and skills to serve on our board of directors.

Matt Zuga. Mr. Zuga has been a member of our board of directors since May 2019. Mr. Zuga is co-founder of HighCape Partners, a growth equity fund, where he has served as a Partner since 2013. Mr. Zuga served as Managing Director of Syngenta Ventures, an investment vehicle of Syngenta Corp, from 2012 to 2013. Prior to that, he was a founder and managing member of Red Abbey Venture Partners, where he is currently a member of the Investment Committee. His current board memberships include Aziyo Biologics and Alba Therapeutics (Co-Chairman). He has previously served as a Board member for Arginetix, Inc. and Board observer at Advanced BioHealing, Aegerion Pharmaceutical, Sirtris Pharmaceuticals and Stromedix, Inc. Prior to RAVP, Mr. Zuga was Head of Life Sciences investment banking at Legg Mason. Mr. Zuga received a Masters of Business Administration from the Kenan-Flagler Business School at the University of North Carolina at Chapel Hill and a Bachelor of Science in Business Administration/Finance from The Ohio State University.

Mr. Zuga's insight into financial and investment matters from his life sciences investment and banking experience, his financial and corporate governance experience from serving on numerous boards of directors, provide him with the qualifications and skills to serve on our board of directors.

Family Relationships

There are no family relationships among our directors and executive officers.

Board Composition and Election of Directors

Our board of directors is currently composed of seven members. In accordance with our fourth amended and restated certificate of incorporation, which will be filed immediately prior to the completion of this offering, our directors will be divided into three classes serving staggered three-year terms. At each annual meeting of stockholders, our directors will be elected to succeed the class of directors whose terms have expired. Our current directors will be divided among the three classes as follows:

- the Class I directors will consist of , and , and their terms will expire at the annual meeting of stockholders to be held in 2020;
- the Class II directors will consist of , and , and their terms will expire at the annual meeting of stockholders to be held in 2021; and
- the Class III directors will consist of , and , and their terms will expire at the annual meeting of stockholders to be held in 2022.

The classification of our board of directors, together with the ability of the stockholders to remove our directors only for cause and the inability of stockholders to call special meetings, may have the effect of delaying or preventing a change in control or management. See "Description of Capital Stock — Anti-Takeover Provisions of Delaware Law and our Charter Documents" for a discussion of other anti-takeover provisions that are included in our fourth amended and restated Certificate of Incorporation.

Board Leadership Structure

Role of Board in Risk Oversight

One of the key functions of our board of directors is to oversee our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address the risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. While our board of directors maintains the ultimate oversight responsibility for the risk management process, its committees oversee risk in certain specified areas. For example:

- Our audit committee oversees management of financial reporting, compliance and litigation risks, including risks related to our insurance, information technology, human resources and regulatory matters, as well as the steps management has taken to monitor and control such exposures.
- Our compensation committee is responsible for overseeing the management of risks relating to our executive compensation policies, plans and arrangements and the extent to which those policies or practices increase or decrease risks for our company.
- Our nominating and corporate governance committee manages risks associated with the independence of our board of directors, potential conflicts of interest and the effectiveness of our board of directors.

Director Independence

Under the Nasdaq Marketplace Rules, or the Nasdaq Listing Rules, each committee of our board of directors must be comprised of at least one independent member at the time of listing, a majority of independent directors no later than 90 days after such date and solely independent directors within one year after such date.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information provided by each director, our board of directors has determined that none of our directors, with the exception of Mr. Koblish, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and is independent under applicable Nasdaq rules. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Party Transactions."

Director Compensation

Upon completion of this offering, directors who are also full-time officers or employees of our company will receive no additional compensation for serving as directors, and directors who are not full-time officers or employees of our company, or non-employee directors, will receive the following compensation.

In connection with this offering, we expect to implement a compensation policy for our non-employee directors.

Board Committees

Audit Committee

Our audit committee consists of , and . Our board of directors has determined that each of , and are independent under the Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, or the Exchange Act. The chair of our audit committee is . Our board of directors has determined that is an "audit committee financial expert" as such term is currently defined in Item 407(d)(5) of Regulations S- K. This designation does not impose any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is directly responsible for, among other things:

- selecting a firm to serve as the independent registered public accounting firm to audit our consolidated financial statements;
- ensuring the independence of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm and reviewing, with management and that firm, our interim and year-end operating results;
- establishing procedures for employees to anonymously submit concerns about questionable accounting or audit matters;
- considering the adequacy of our internal controls and internal audit function;
- monitoring compliance with the code of business and conduct and ethics for financial management;
- reviewing material related party transactions or those that require disclosure; and
- approving or, as permitted, pre-approving all audit and non-audit services to be performed by the independent registered public accounting firm.

Our audit committee will operate under a written charter, to be effective prior to the completion of this offering, that satisfies the applicable rules of the Securities and Exchange Commission, or the SEC, and the Nasdaq Listing Rules.

Compensation Committee

Our compensation committee consists of , and . Each member of this committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act and meets the requirements for independence under the current Nasdaq Listing Rules. The chair of our compensation committee is . The compensation committee is responsible for, among other things:

- reviewing and approving, or recommending that our board of directors approve, the compensation of our executive officers;
- reviewing and recommending to our board of directors the compensation of our directors;
- administering our stock and equity incentive plans;
- reviewing and approving, or making recommendations to our board of directors with respect to, incentive compensation and equity plans; and
- reviewing our overall compensation philosophy.

Our compensation committee will operate under a written charter, to be effective prior to the completion of this offering.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of , and . The chair of our nominating and corporate governance committee is . Each member of the nominating and corporate governance committee meets the requirements for independence under the current Nasdaq Listing Rules. The nominating and corporate governance committee is responsible for, among other things:

- identifying and recommending candidates for membership on our board of directors;
- reviewing and recommending our corporate governance guidelines and policies;
- reviewing proposed waivers of the code of conduct for directors and executive officers;
- overseeing the process of evaluating the performance of our board of directors; and
- assisting our board of directors on corporate governance matters.

Our nominating and corporate governance committee will operate under a written charter, to be effective prior to the completion of this offering.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or on our compensation committee.

Code of Business Conduct and Ethics

In connection with this offering, our board of directors will adopt a written code of business conduct and ethics that will apply to all of our directors, officers and employees. The code of business conduct and ethics will cover fundamental ethics and compliance-related principles and practices such as accurate accounting records and financial reporting, avoiding conflicts of interest, the protection and use of our property and information and compliance with legal and regulatory requirements. Our code of business conduct and ethics will be posted on the investor relations section of our website at www.telabio.com. We intend to disclose any amendments to our code of business conduct and ethics, or waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements.

Limitations on Liability and Indemnification Matters

Our fourth amended and restated certificate of incorporation, which will be effective immediately prior to the completion of this offering, and our second amended and restated bylaws, which will become effective immediately prior to the completion of this offering, limits our directors' liability, and may indemnify our directors and officers to the fullest extent permitted under the DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

The DGCL and our second amended and restated bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to payment or reimbursement of reasonable expenses, including attorneys' fees and disbursements, in advance of the final disposition of the proceeding.

We have entered or intend to enter into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these provisions in our fourth amended and restated certificate of incorporation and second amended and restated bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy, as expressed in the Securities Act and is therefore unenforceable.

The limitation of liability and indemnification provisions in our fourth amended and restated certificate of incorporation and second amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.

EXECUTIVE AND DIRECTOR COMPENSATION

Our "named executive officers" for the year ended December 31, 2018, which consists of our principal executive officer and our two other most highly compensated executive officers, are:

- Antony Koblish, our President and Chief Executive Officer
- Maarten Persenaire, our Chief Medical Officer; and
- E. Skott Greenhalgh, our Chief Technology Officer.

Summary Compensation Table

The following table sets forth information regarding the compensation of our named executive officers for the year ended December 31, 2018.

Name and Principal Position	Year	Salary ($)	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)[2]	All Other Compensation ($)	Total
Antony Koblish	2018	375,000	29,840	164,063	—	568,903
President and Chief Executive Officer						
Maarten Persenaire	2018	280,000	7,510	122,500	—	410,010
Chief Medical Officer						
E. Skott Greenhalgh	2018	275,000	7,638	120,312	—	402,950
Chief Technology Officer						

(1) Amounts shown in this column do not reflect dollar amounts actually received by our named executive officers. Instead, these amounts reflect the aggregate grant date fair value of each stock option granted in 2018 computed in accordance with the provisions of FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 8 to our audited consolidated financial statements included in this prospectus. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Our named executive officers will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.

(2) Amounts for Mr. Koblish and Drs. Persenaire and Greenhalgh represent 2018 earned annual bonuses paid in February 2019 under our corporate bonus program of $164,063, $122,500 and $120,312, respectively.

Narrative Disclosure to Summary Compensation Table

Elements of Compensation

The compensation of our named executive officers generally consists of base salary, annual cash bonus opportunities, long term incentive compensation in the form of equity awards and other benefits, as described below.

Base Salary

The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, responsibilities, and contributions. Mr. Koblish and Dr. Persenaire have had no increase in their base salary since our inception in 2012. In 2018, the compensation committee approved a 12% merit-based increase for Dr. Greenhalgh's base salary (from $250,000 to $280,000), effective March 15, 2018, in recognition of his efforts in developing OviTex, the identification of future product inventions (including Restella) and to increase his base salary to equal the base salary of Dr. Persenaire, our only other management-level executive officer at that time.

Annual Cash Bonus Opportunities

Each of our named executive officers' performance-based cash bonus opportunity is expressed as a percentage of base salary that can be achieved at a target level by meeting predetermined corporate and

individual performance objectives. Our compensation committee annually sets each executive's target bonus for the year. The 2018 annual bonus for Mr. Koblish and Drs. Persenaire and Greenhalgh were targeted at 43.8% of their respective base salaries.

For 2018, all named executive officers were eligible to earn their annual bonuses pursuant to the achievement of corporate and/or individual performance goals. These goals primarily included the achievement of revenue targets, the development and launch of large size OviTex products, the technology transfer of Restella to Aroa and progress made in gaining market acceptance of OviTex with integrated delivery networks and group purchasing organizations. Following a review of the corporate goals attained in 2018, our compensation committee recommended, and our board of directors approved, 2018 annual bonus payments to each of Mr. Koblish and Drs. Persenaire and Greenhalgh in an amount equal to 95.5% of their respective target bonus amounts, totaling $164,063, $122,500 and $120,312, respectively. Such amounts represented approximately 43.8% of each named executive officer's annual base salary for the year ended December 31, 2018. The employment agreements of Mr. Koblish and Drs. Persenaire and Greenhalgh do not contain bonus percentage targets. The bonus percentage and bonus percentage targets were determined by the compensation committee of the board of directors and approved by the full board of directors.

Long Term Equity Incentives

Our equity-based incentive awards are designed to align our interests and the interests of our stockholders with those of our employees and consultants, including our named executive officers. Our board of directors or compensation committee approves equity grants. All of our named executive officers received options to purchase shares of our common stock in 2018. See "— Outstanding Equity Awards at Fiscal Year End" for more information regarding equity awards made in 2018 to our named executive officers.

Stock option awards to our named executive officers in 2018 vest 25% on the first anniversary of the grant date, with the remaining 75% vesting in equal monthly installments on the last day of each of the 36 calendar months immediately following the first anniversary of the grant date, subject to the named executive officer's continuous service through the relevant vesting dates; provided, however, that such stock options will vest in full upon a change in control if the named executive officer remains in service through the date of that transaction.

Such stock options allow for exercise prior to vesting in exchange for restricted shares of common stock subject to the same vesting schedule as the original option. With respect to stock option awards granted prior to 2018, our named executive officers have utilized these early exercise provisions from time to time.

Other Benefits

We currently provide broad-based welfare benefits that are available to all of our employees, including our named executive officers, including health, dental, life, vision and disability insurance.

In addition, we maintain, and the named executive officers participate in, a 401(k) plan that provides eligible employees with an opportunity to save for retirement on a tax advantage basis and under which we are permitted to make discretionary employer contributions. Employees' pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code. Since inception of the 401(k) plan, we have not made any discretionary employer contributions.

We do not maintain any defined benefit pension plans or nonqualified deferred compensation plans.

Executive Officer Employment Agreements

We have entered into employment agreements with each of our named executive officers, the key terms of which are described below. The following is a summary of the material terms of each agreement. For

complete terms, please see the respective agreements attached as exhibits to the registration statement of which this prospectus forms a part.

Mr. Koblish

We entered into an employment agreement, or the Koblish Employment Agreement, with Mr. Koblish, dated December 3, 2012, providing for his position as President and Chief Executive Officer, which was subsequently amended on April 11, 2013. The Koblish Employment Agreement provides for an initial base salary of $375,000 and eligibility to participate in the employee benefit plans, policies or arrangements maintained by us for our senior executive employees generally.

If Mr. Koblish's employment is terminated by us without "cause," as defined below, or by Mr. Koblish for "good reason," as defined below, Mr. Koblish will be eligible to receive, subject to Mr. Koblish's execution and nonrevocation of a general release of claims and continued compliance with his restrictive covenant obligations:

- 12 months of base salary continuation; and
- 12 months continued provision of health, dental, and vision insurance.

In addition, upon the occurrence of a "change in control," as defined below, the vesting of all of Mr. Koblish's outstanding equity awards will be fully accelerated immediately prior to the change in control unless (a) the acquiror honors, assumes or substitutes new rights, terms, conditions, and value for the award that are substantially equivalent or better than the rights, terms, conditions of the rights existing at the change in control, and (b) immediately after the change in control, Mr. Koblish is an employee of us or our successor entity; provided that, in such case, if Mr. Koblish's employment is thereafter terminated by us or our successor without cause or by Mr. Koblish for good reason within 12 months following the change in control, the vesting of all of Mr. Koblish's outstanding equity awards will be fully accelerated as of the termination date.

The Koblish Employment Agreement contains non-competition and non-solicitation covenants that apply during the term of Mr. Koblish's employment and for one year following termination of employment.

Dr. Persenaire

We entered into an amended and restated employment agreement, or the Persenaire Employment Agreement, with Dr. Persenaire, dated January 29, 2013, providing for his position as Chief Medical Officer, which was subsequently amended on April 11, 2013. The Persenaire Employment Agreement provides for an initial base salary of $280,000 and eligibility to participate in the employee benefit plans, policies or arrangements maintained by us for our senior executive employees generally.

If Dr. Persenaire's employment is terminated by us without "cause," as defined below, or by Dr. Persenaire for "good reason," as defined below, Dr. Persenaire will be eligible to receive, subject to Dr. Persenaire's execution and nonrevocation of a general release of claims and continued compliance with his restrictive covenant obligations, severance benefits that are substantially similar to the severance benefits provided to Mr. Koblish under such circumstances, with the exception that the continuation period for salary and health, dental and vision insurance would be nine months rather than 12 months.

The Persenaire Employment Agreement contains non-competition and non-solicitation covenants that apply during the term of Dr. Persenaire's employment and for one year following termination of employment.

Dr. Greenhalgh

We entered into an employment agreement, or the Greenhalgh Employment Agreement, with Dr. Greenhalgh, dated December 16, 2016, providing for his position as Chief Technology Officer. The Greenhalgh Employment Agreement provides for an initial base salary of $250,000 (which has subsequently been raised to $280,000) and eligibility to participate in the employee benefit plans, policies or arrangements maintained by us for our senior executive employees generally.

If Dr. Greenhalgh's employment is terminated by us without "cause," as defined below, or by Dr. Greenhalgh for "good reason," as defined below, Dr. Greenhalgh will be eligible to receive, subject to Dr. Greenhalgh's execution and nonrevocation of a general release of claims and continued compliance with his restrictive covenant obligations

- 9 months of base salary continuation; and
- 9 months continued provision of health, dental, and vision insurance.

The Greenhalgh Employment Agreement contains non-competition and non-solicitation covenants that apply during the term of Dr. Greenhalgh's employment and for one year following termination of employment.

For purposes of each of the employment agreements:

- "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 us or our affiliates public disgrace or disrepute, or adversely affects our or our affiliates' operations or financial performance or the relationship we have with our affiliates, customers and suppliers, (ii) commission of an act of gross negligence, willful misconduct, fraud, embezzlement, theft or material dishonesty with respect to us or any of our affiliates, (iii) a breach of the executive's fiduciary duty of loyalty to us or any of our 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 us or any of our affiliates, including the employment agreement, (vi) a material breach of any of our policies regarding employment practices, or (vii) refusal to perform the lawful directives of our board of directors, if not cured within 30 days following receipt by the executive from us of written notice thereof.
- "good reason" means one or more of the following: (i) a material reduction in title, duties, authority or responsibilities, (ii) a material breach by us of the employment agreement, (iii) a material reduction in aggregate compensation, or, except with respect to Dr. Greenhalgh, (iv) any requirement following a change in control that the executive be based 50 miles or more from the facility where the executive is based prior to the change of control.
- "change of control" means: (i) any sale, of all or substantially all of our assets; or (ii) our acquisition by another entity by means of any transaction (including a series of related transactions, but excluding our sale of securities for the purpose of raising additional funds) unless our stockholders of record immediately prior to such transaction hold, immediately after such transactions, at least 50% of the voting power of the surviving or acquiring entity.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth information for each of our named executive officers regarding the number of shares of common stock underlying outstanding equity awards as of December 31, 2018.

Name	Option Awards				
	Grant Date[1]	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Antony Koblish	7/23/2015[2]	2,289,167	390,833	0.24	7/23/2025
	2/28/2018	—	1,004,787	0.24	2/28/2028
Maarten Persenaire	7/23/2015[2]	223,398	38,141	0.24	7/23/2025
	2/28/2018	—	252,867	0.24	2/28/2028
E. Skott Greenhalgh	3/20/2013	93,750	—	0.18	3/20/2023
	5/1/2013	31,250	—	0.18	5/1/2023
	12/11/2013	145,000	—	0.18	12/11/2023
	7/23/2015[2]	440,332	75,179	0.24	7/23/2025
	2/28/2018	—	257,200	0.24	2/28/2028

(1) Each stock option award was granted under our 2012 Plan and has the same vesting schedule, which provides for 25% of the award to vest on the first anniversary of the grant date and the remaining 75% of the award to vest in equal monthly installments on the last day of each of the 36 calendar months immediately following the first anniversary of the grant date, subject to the recipient's continuous service with us through the relevant vesting dates. In addition, the vesting of each stock option is subject to full acceleration in the event of a change in control, subject to the recipient's continuous service with us through the date of such transaction. Each stock option may be exercised prior to vesting in exchange for restricted shares of common stock subject to the same vesting schedule.

(2) Each stock option award granted in 2015 became fully vested and exercisable on July 31, 2019, prior to the completion of this offering.

Equity Compensation Plans

2019 Equity Incentive Plan

Prior to the completion of this offering, we intend to adopt and ask our stockholders to approve the 2019 Plan under which we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain talent for which we compete. The material terms of the 2019 Plan as it is currently contemplated are summarized below. Our board of directors is still in the process of developing, approving and implementing the 2019 Plan and, accordingly, this summary is subject to change.

Administration

The 2019 Plan authorizes our board of directors to appoint a committee to administer and interpret the 2019 Plan; however, in its sole discretion, our board of directors may at any time and from time to time exercise any and all rights and duties of the committee except with respect to matters which under applicable law are required to be determined in the sole discretion of the committee. Our board of directors will designate our compensation committee to administer and interpret the 2019 Plan. Except when limited by the terms of the 2019 Plan, our compensation committee has the authority to, among other things: select the individuals to whom awards are granted; determine the type of award to be granted; determine the number of shares, if any, to be covered by each award; establish the other terms and conditions of each award; approve forms of agreements for use under the 2019 Plan; and modify or amend each award. To the extent permitted by applicable law, our compensation committee may delegate to one or more of our officers the authority to grant awards to participants who are not subject to the requirements of Section 16 of the Exchange Act and the rules and regulations thereunder.

Subject to any stockholder approval that may be required under applicable law, the 2019 Plan may be amended or terminated at any time or from time to time by our board of directors.

Eligibility

Any of our employees, directors, consultants, and other service providers, or those of our affiliates, are eligible to participate in the 2019 Plan and may be selected by our compensation committee to receive an award.

Shares of Our Common Stock Available for Issuance

Subject to certain adjustments, the maximum number of shares of common stock that may be issued under the 2019 Plan in connection with awards, or 2019 Plan Limit, is equal to the sum of: (i) shares of our common stock and (ii) an annual increase on the first day of each year beginning in and ending in , equal to the lesser of (A) shares of our common stock, (B) % of the shares of our common stock outstanding (on an as-converted basis) on the last day of the immediately preceding fiscal year, and (C) such smaller number of shares of our common stock as determined by our board of directors, all of which may be issued in respect of incentive stock options, or ISOs. Any shares of common stock issued under the 2019 Plan may consist, in whole or in part, of authorized and unissued shares of our common stock or treasury shares. Any shares of our common stock issued by us through the assumption or substitution of outstanding grants in connection with the acquisition of another entity will not reduce the 2019 Plan Limit. In the event of any corporate event or transaction such as a merger, consolidation, reorganization, recapitalization, stock split, reverse stock split, split up, spin-off, combination of shares, exchange of shares, stock dividend, dividend in kind, or other like change in capital structure (other than ordinary cash dividends) to our stockholders, or other similar corporate event or transaction that affects our shares of common stock, our compensation committee shall make appropriate adjustments or substitutions in the number and kind of shares that may be issued under the 2019 Plan, the number and kind of shares subject to outstanding awards, the exercise price, or base price applicable to outstanding awards, and/or any other affected terms and conditions of the 2019 Plan or outstanding awards, in each case as it determines appropriate and equitable. Shares of our common stock subject to awards that expire, terminate, or are cancelled or forfeited for any reason, as well as shares of our common stock withheld in settlement of a tax withholding obligation associated with an award or in satisfaction of the exercise price payable upon exercise of a stock option, will again be available for grant under the 2019 Plan.

Non-employee directors (in their capacity as such) may not be granted awards under the 2019 Plan with an aggregate grant date fair value in excess of $ in any single calendar year.

Types of Awards

The 2019 Plan provides for the grant of the following equity-based and cash-based incentive awards to participants: (i) stock options, (ii) stock appreciation rights, (iii) restricted stock, (iv) restricted stock units, or RSUs, and (v) cash or other stock based awards.

Stock Options

An option entitles the holder to purchase from us a stated number of shares of our common stock. An ISO may only be granted to an employee of ours or our eligible affiliates. Our compensation committee will specify the number of shares of our common stock subject to each option, the vesting conditions, and the exercise price for such option, provided that the exercise price may not be less than the fair market value of a share of our common stock on the date the option is granted. Notwithstanding the foregoing, if ISOs are granted to any 10% stockholder, the exercise price shall not be less than 110% of the fair market value of our common stock on the date the option is granted.

Generally, options may be exercised in whole or in part through a cash payment. Our compensation committee may, in its sole discretion, permit payment of the exercise price of an option in the form of previously acquired shares of our common stock based on the fair market value of such shares on the date the option is exercised or through means of "net settlement", which involves the cancellation of a portion of the option to cover the cost of exercising the balance of the option.

All options shall be exercisable in accordance with the terms of the applicable award agreement. Our compensation committee may provide in the terms of the applicable award agreement that the participant

may exercise the unvested portion of an option in whole or in part in exchange for restricted stock subject to the same vesting terms as the portion of the option so exercised and such additional terms and conditions as determined by our compensation committee. The maximum term of an option shall be determined by our compensation committee on the date of grant but shall not exceed 10 years (5 years in the case of ISOs granted to any 10% stockholder). In the case of ISOs, the aggregate fair market value (determined as of the date of grant) of our common stock with respect to which such ISOs become exercisable for the first time during any calendar year cannot exceed $100,000. ISOs granted in excess of this limitation will be treated as non-qualified stock options.

Stock Appreciation Rights

A stock appreciation right represents the right to receive, upon exercise, any appreciation in a share of our common stock over a particular time period. The base price of a stock appreciation right shall not be less than the fair market value of a share of our common stock on the date the stock appreciation right is granted. The maximum term of a stock appreciation right shall be determined by our compensation committee on the date of grant but shall not exceed 10 years. Distributions with respect to stock appreciation rights may be made in cash, shares of our common stock, or a combination of both, at our compensation committee's discretion.

Unless otherwise provided by our compensation committee, any portion of an option or stock appreciation right that is not exercisable at the time of termination of service shall expire and automatically be forfeited on the termination date. If a participant terminates service with us (or our affiliates) due to death or disability, the participant's unexercised options and stock appreciation rights may be exercised, to the extent they were exercisable on the termination date, for a period expiring (i) at such time as may be specified by our compensation committee at or after grant, (ii) if not specified by our compensation committee at or after grant, twelve months from the termination date, or (iii) if sooner, the expiration of the stated term. If a participant terminates service with us (or our affiliates) for cause (as defined in the 2019 Plan) or if a participant resigns at a time that there was a cause basis for the participant's termination, (a) all unexercised options and stock appreciation rights (whether vested or unvested) shall expire and automatically be forfeited on the termination date, and (b) any shares of our common stock in respect of exercised options or stock appreciation rights for which we have not yet delivered share certificates will be forfeited and we will refund to the participant the option exercise price paid for those shares, if any. If a participant terminates service with us (or our affiliates) for any other reason, any vested but unexercised options and stock appreciation rights may be exercised by the participant, to the extent exercisable at the time of termination, for a period expiring (x) at such time as may be specified by our compensation committee at or after grant, (ii) if not specified by our compensation committee at or after grant, 90 days from the termination date, or (iii) if sooner, the expiration of the stated term.

Restricted Stock

A restricted stock award is a grant of shares of our common stock, which are subject to forfeiture restrictions during a restriction period. Our compensation committee will determine the price, if any, to be paid by the participant for each share of our common stock subject to a restricted stock award. If the specified vesting conditions are not attained, the participant will forfeit the portion of the restricted stock award with respect to which those conditions are not attained, and the underlying shares of our common stock will be forfeited to us. At the end of the restriction period, if the vesting conditions have been satisfied, the restrictions imposed will lapse with respect to the applicable number of shares. During the restriction period, a participant will have the right to vote shares of restricted stock and receive dividends with respect to restricted stock, provided that our compensation committee may specify that any such dividends are subject to the same vesting schedule as restricted stock in respect of which the dividends are paid. Unless otherwise provided in an award agreement or determined by our compensation committee, upon a termination of service, a participant will forfeit any portion of the participant's restricted stock awards that then remains subject to forfeiture restrictions.

Restricted Stock Units

An RSU represents a right to receive, on the achievement of specified vesting conditions, an amount equal to the fair market value (at the time of distribution) of one share of our common stock . An RSU may be settled in shares of our common stock, cash, or a combination of both, at the discretion of our compensation committee. Unless otherwise provided in an award agreement or determined by our compensation committee, upon a termination of service, a participant will forfeit all of the participant's RSUs that then remain subject to forfeiture.

Cash or Other Stock Based Awards

Cash or other stock based awards (including awards to receive unrestricted shares of our common stock or immediate cash payments) may be granted to participants. Our compensation committee will determine the terms and conditions of each such award, including, as applicable, the term, any exercise or purchase price, performance goals, vesting conditions and other terms and conditions. Payment in respect of a cash or other stock based award may be made in cash, shares of our common stock, or a combination of both, at the discretion of our compensation committee.

Change in Control

Upon or in anticipation of a change in control (as defined in the 2019 Plan), our compensation committee may, on a participant-by-participant basis: (i) cause any or all outstanding awards to become vested and immediately exercisable (as applicable), in whole or in part; (ii) cause any outstanding option or stock appreciation right to become fully vested and immediately exercisable for a reasonable period in advance of the change in control and, to the extent not exercised prior to that change in control, cancel that option or stock appreciation right upon closing of the change in control; (iii) cancel any unvested award or unvested portion thereof, with or without consideration; (iv) cancel any award in exchange for a substitute award; (v) redeem any restricted stock or RSU for cash and/or other substitute consideration with value equal to the fair market value of an unrestricted share of our common stock on the date of the change in control; (vi) cancel any outstanding option or stock appreciation right with respect to all shares of our common stock for which the award remains unexercised in exchange for a cash payment equal to the excess (if any) of the fair market value of the shares of our common stock subject to the option or stock appreciation right over the exercise or base price of the option or stock appreciation right (and if the fair market value does not exceed the exercise or base price of the award, cancel the award without payment of any consideration); and/or (vii) take such other action as our compensation committee shall determine to be reasonable under the circumstances. In the discretion of our compensation committee, any cash of substitute consideration payable upon cancellation of an award may be subject to vesting terms substantially identical to those that applied to the cancelled award immediately prior to the change in control, or earn-out, escrow, holdback or similar arrangements, to the extent such arrangements are applicable to any consideration paid to stockholders in connection with the change in control.

Repricing

Neither our board of directors nor our compensation committee may, without obtaining prior approval of our stockholders: (i) implement any cancellation/re-grant program pursuant to which outstanding options or stock appreciation rights under the 2019 Plan are cancelled and new options or stock appreciation rights are granted in replacement with a lower exercise or base price per share; (ii) cancel outstanding options or stock appreciation rights under the 2019 Plan with an exercise or base price per share in excess of the then current fair market value per share for consideration payable in our equity securities; or (iii) otherwise directly reduce the exercise or base price in effect for outstanding options or stock appreciation rights under the 2019 Plan.

Miscellaneous

Generally, awards granted under the 2019 Plan shall be nontransferable except by will or by the laws of descent and distribution. No participant shall have any rights as a stockholder with respect to shares of our common stock covered by options, stock appreciate rights or RSUs, unless and until such awards are settled in shares of our common stock of common stock. No option shall be exercisable, no shares of our common

stock shall be issued, no certificates for shares of our common stock shall be delivered and no payment shall be made under the 2019 Plan except in compliance with all applicable laws. The awards will be subject to our stock ownership and clawback policies, as may be in effect from time to time. The 2019 Plan will expire ten years after it becomes effective.

2012 Stock Incentive Plan

The 2012 Plan was originally adopted our board of directors and approved by our stockholders on December 3, 2012. The 2012 Plan has been amended from time to time to increase the number of shares available for issuance pursuant to plan awards and was most recently amended on April 5, 2019. The 2012 Plan permits the grant of stock options, stock appreciation rights, restricted stock, restricted stock units and other awards from time to time to selected employees, officers, directors and consultants. Subject to adjustment, the maximum number of shares that may be granted under the 2012 Plan is 17,040,673. It is expected that the 2012 Plan will terminate immediately prior to the consummation of this offering and we will not grant any additional awards under our 2012 Plan. Thereafter, however, our 2012 Plan will continue to govern the outstanding awards previously granted under the 2012 Plan.

Administration

The 2012 Plan is currently administered by a committee appointed by our board of directors. At the discretion of our board of directors, the 2012 Plan may be administered directly by our board of directors. To the extent permitted by applicable law, our board of directors may delegate to one or more of our executive officers the power to grant awards to employees or officers and to exercise other powers under the 2012 Plan as our board of directors may determine, provided that the Board shall fix the terms of the award and the maximum number of shares subject to awards that the executive officers may grant.

Transferability

A participant in the 2012 Plan may not sell, assign, transfer, or pledge an award under the 2012 Plan other than by will or the laws of descent and distribution or, except in the case of an incentive stock option, pursuant to a domestic relations order, provided however that the committee may (but need not) permit other transfers where the committee concludes that the such transfer (i) would not result in accelerated taxation, (ii) would not cause an incentive stock option to no longer qualify as an incentive stock option or (iii) is otherwise appropriate and desirable.

Changes in Capital Structure

In the event of a corporate event or transaction (including, without limitation, any stock dividend, stock split, extraordinary cash dividend, recapitalization, reorganization, merger, consolidation, split-up, spin-off, combination or exchange of shares), the committee in its sole discretion may:

- adjust the number and kind of shares which may be delivered under the 2012 Plan;
- adjust the number and kind of shares subject to outstanding awards;
- adjust the exercise price of outstanding awards or the measure to be used to determine the amount of the benefit payable under the terms of an award; or
- make any other adjustments determined appropriate.

In addition, upon the occurrence or in anticipation of a change in control, the committee may in its sole discretion provide that:

- awards be settled in cash rather than stock;
- awards become immediately vested and exercisable for a designated period of time;
- awards will be assumed by another party to transaction or otherwise be equitably converted or substituted in connection with such transaction;
- outstanding awards may be settled by payment of cash or cash equivalents equal to the excess of the fair market value of the underlying stock over the exercise or base price of the award; or
- any combination any of the foregoing.

Amendment, Modification and Termination

Our board of directors may, at any time and from time to time, amend, modify or terminate the 2012 Plan without stockholder approval; provided, however, our board of directors may condition any other amendment or modification on the approval of stockholders for any reason, including by reason of such approval being necessary or deemed advisable to satisfy any other tax, securities or other applicable laws, policies or regulations.

Director Compensation

We have not historically provided any compensation to any member of our board of directors who has been designated to serve on our board by one of our significant investors. Mr. Koblish, our President and Chief Executive Officer, did not receive additional compensation for his services as a director. We additionally reimburse our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of directors and committee meetings.

Our board of directors intends to adopt a non-management director compensation policy following the completion of this offering.

Director Compensation Table

The table below sets forth information for the fiscal year ended December 31, 2018 regarding the compensation awarded to, earned by or paid to our non-employee directors. Other than Messrs. Azarbarzin, Burgess, and Touhey, none of our non-employee directors received compensation for the year ended December 31, 2018.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1][2][3]	Total ($)
Kurt Azarbarzin	5,727	54,696	60,423
Vincent Burgess	24,000	7,660	31,661
Paul Touhey[4]	45,000	7,660	52,661

(1) Amounts shown in this column do not reflect dollar amounts actually received by our directors. Instead, these amounts reflect the aggregate grant date fair value of each stock option granted in 2018 computed in accordance with the provisions of FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 8 to our audited consolidated financial statements included in this prospectus. Our directors will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.

(2) As of December 31, 2018, Messrs. Azarbarzin, Burgess, and Touhey held options to purchase 530,000, 467,205, and 263,432 shares of our common stock, respectively. No directors other than Messrs. Azarbarzin, Burgess, and Touhey held outstanding equity awards as of December 31, 2018.

(3) These options have exercise prices equal to $0.24, which our board of directors has determined to be the fair value of our common stock on the date of grant, and vest 25% on the first anniversary of the grant date and the remaining 75% vests ratably in equal monthly installments on the last day of each of the thirty-six calendar months following the first anniversary of the grant date, subject to the director's continuous service with us through the relevant vesting dates.

(4) Mr. Touhey resigned from our board of directors in November 2018.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

We describe below transactions and series of similar transactions, during our last three fiscal years or currently proposed, to which we were a party or will be a party, in which:

- the amounts involved exceeded $120,000; and
- any of our directors, executive officers or beneficial holders of more than 5% of any class of our capital stock had or will have a direct or indirect material interest.

Other than as described below, there have not been, nor are there any currently proposed, transactions or series of similar transactions meeting this criteria to which we have been or will be a party other than compensation arrangements, which are described where required under the sections titled "Management — Board Leadership Structure" and "Executive and Director Compensation."

January 2017 Convertible Promissory Note Financing

On January 18, 2017, we issued a total of $7.4 million in aggregate principal amount of convertible promissory notes to holders of our preferred stock, which advanced loans to us in the aggregate amount of $7.4 million. The convertible notes accrued interest at a rate of 12% per year and matured on October 20, 2017, and $8.1 million of convertible notes, which included $0.7 million of interest thereon, converted into 6,951,175 shares of our Series B Preferred Stock.

In connection with the January 18, 2017 issuance of convertible promissory notes, we issued warrants the investors to purchase a total of 1,591,864 shares of our Series B Preferred Stock at a weighted exercise price of $1.16 per share. The shares of Series B Preferred Stock that are issuable upon exercise of the warrants issued January 18, 2017 are referred to herein as warrant shares. Upon completion of this offering, the warrants will automatically convert into warrants to purchase shares of our common stock at an exercise price of $ per share.

The table below sets forth the aggregate principal amount of convertible promissory notes issued to, and the number of warrant shares underlying the warrants issued to, our executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members.

NAME[1]	Aggregate Principal Amount of Notes	Warrant Shares
OrbiMed Private Investments IV, LP[2]	$ 3,520,015.09	758,623
Quaker Bioventures II, L.P.[3]	2,073,213.23	446,813
Entities associated with HighCape Partners QP, L.P.[4]	581,481.00	125,318
Entities associated with Signet Healthcare Partners QP[5]	833,663.37	179,667
Antony Koblish[6]	50,000.00	10,775
Maarten Persenaire, MD[7]	60,000.00	12,931
E. Skott Greenhalgh[8]	9,170.39	1,976
Paul Touhey[9]	57,020.38	12,288

(1) Additional details regarding these participants and other equity holders are provided in the section titled "Principal Stockholders."
(2) Vince Burgess, a member of our board of directors, was designated to our board of directors by OrbiMed Private Investments IV, LP.
(3) Adele Oliva, a member of our board of directors, was designated to our board of directors by Quaker Bioventures II, L.P.
(4) Matt Zuga, a member of our board of directors, was designated to our board of directors by HighCape Partners QP, L.P.
(5) Ashley Friedman, a member of our board of directors, was designated to our board of directors by Signet Healthcare Partners QP Partnership III LP and Signet Healthcare Partners Accredited Partnership III, LP.
(6) Antony Koblish is our President and Chief Executive Officer and a member of our board of directors.
(7) Maarten Persenaire, MD is our Chief Medical Officer.

(8) E. Skott Greenhalgh is our Chief Technology Officer.
(9) Paul Touhey resigned from our board of directors in November 2018.

2019 Series B Preferred Stock Offerings

In June and July 2019, we issued an aggregate of 11,587,439 shares of our Series B Preferred Stock in two closings at a price per share of $1.16. The first closing occurred on June 28, 2019, at which time we issued 10,123,480 shares of our Series B Preferred Stock for gross cash proceeds of $11.7 million. The second closing occurred on July 31, 2019, at which time we issued an additional 1,463,959 shares of our Series B Preferred Stock for gross cash proceeds of approximately $1.7 million.

In August 2019, we issued an aggregate of 509,483 shares of our Series B Preferred Stock at a price per share of $1.16. The closing occurred on August 30, 2019, for gross cash proceeds of approximately $0.6 million.

The table below sets forth the number of shares of Series B Preferred Stock purchased by our executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members in such 2019 Series B Preferred Stock offerings. Each share of Series B Preferred Stock in the table below will automatically convert into shares of our common stock immediately prior to the completion of this offering. The Series A and Series B preferred stock are entitled to receive non-compounding cumulative dividends at a rate per year of 8% of the original issuance price of $1.00 and $1.16, respectively.

NAME	Series B Preferred Stock (#)	Aggregate Cash Purchase Price for Series B Preferred Stock ($)
OrbiMed Private Investments IV, LP(1)	3,588,383	$ 4,162,523.70
Quaker Bioventures II, L.P.(2)	2,191,660	2,542,325.23
Entities associated with HighCape Partners QP, L.P.(3)	592,774	687,617.92
Entities associated with Signet Healthcare Partners QP(4)	849,855	985,831.94
Pacira Pharmaceuticals, Inc.(5)	1,398,018	1,621,701.22
Nora Brennan(6)	86,200	99,992.00
Antony Koblish(7)	88,700	102,196.00
Maarten Persenaire, MD(8)	86,207	100,000.12
Paul Touhey(9)	105,369	122,228.04

(1) Vince Burgess, a member of our board of directors, was designated to our board of directors by OrbiMed Private Investments IV, LP.
(2) Adele Oliva, a member of our board of directors, was designated to our board of directors by Quaker Bioventures II, L.P.
(3) Matt Zuga, a member of our board of directors, was designated to our board of directors by HighCape Partners QP, L.P.
(4) Ashley Friedman, a member of our board of directors, was designated to our board of directors by Signet Healthcare Partners QP Partnership III LP and Signet Healthcare Partners Accredited Partnership III, LP.
(5) Ronald Ellis, a member of our board of directors, was designated to our board of directors by Pacira Pharmaceuticals, Inc.
(6) Nora Brennan is our Chief Financial Officer.
(7) Antony Koblish is our President and Chief Executive Officer and a member of our board of directors.
(8) Maarten Persenaire, MD is our Chief Medical Officer.
(9) Paul Touhey resigned from our board of directors in November 2018.

Stockholders Agreement

We are party to the Stockholders Agreement with each holder of our common stock and each holder of our preferred stock. The Stockholders Agreement, including all rights thereunder, will automatically terminate immediately prior to the completion of this offering.

Investors' Rights Agreement

We are party to an amended and restated investors' rights agreement, or the Investors' Rights Agreement, with each holder of our common stock and each holder of our preferred stock, which includes each holder of more than 5% of our capital stock and certain of our directors (or, in some cases, entities affiliated therewith). The Investors' Rights Agreement imposes certain affirmative obligations on us, including with respect to financial reporting, option vesting restrictions and investor inspections, and also grants certain rights to the holders, including demand and piggyback registration rights and, if we are eligible, Form S-3 registration rights, with respect to the registrable securities held by them. See the section titled "Description of Capital Stock — Registration Rights" for additional information. Certain provisions of the Investors' Rights Agreement, including our affirmative obligations and pre-emptive rights held by the holders of our preferred stock, will terminate upon completion of this offering, while the registration rights set forth in the investors' rights agreement will continue in effect after the completion of this offering until they expire in accordance with their terms.

Other Transactions

We have entered into various employment-related agreements with our executive officers that, among other things, provide for compensatory and certain change in control benefits. For a description of these agreements and arrangements with our named executives, see the section titled "Executive and Director Compensation — Executive Officer Employment Agreements."

We have also granted stock options to our executive officers and directors. For a description of these stock options, see the section titled "Executive and Director Compensation."

Indemnification Agreements

We have entered or intend to enter into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. For more information regarding these indemnification agreements, see "Management — Limitations on Liability and Indemnification Matters."

Policies and Procedures for Related Party Transactions

Our board of directors will adopt a written related party transaction policy, to be effective upon the completion of this offering, setting forth the policies and procedures for the review and approval or ratification of related-party transactions. This policy will cover any transaction, arrangement or relationship or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant and a related party had or will have a direct or indirect material interest, as determined by the audit committee of our board of directors, including, without limitation, purchases of goods or services by or from the related party or entities in which the related party has a material interest, and indebtedness, guarantees of indebtedness or employment by us of a related party.

All related party transactions described in this section occurred prior to adoption of this policy and as such, these transactions were not subject to the approval and review procedures set forth in the policy. However, these transactions were reviewed and approved by our board of directors.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock as of August 30, 2019 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current executive officers and directors as a group.

In accordance with the rules of the SEC, beneficial ownership includes voting or investment power with respect to securities and includes the shares issuable pursuant to stock options that are exercisable within 60 days of August 30, 2019. Shares issuable pursuant to stock options are deemed outstanding for computing the percentage of the person holding such options but are not outstanding for computing the percentage of any other person. The percentage ownership information under the column titled "Before Offering" is based on shares of common stock outstanding as of August 30, 2019 and includes shares of common stock subject to repurchase by us, assuming the automatic conversion of all our preferred stock outstanding into an aggregate of shares of our common stock and the conversion of all outstanding warrants to purchase shares of our Series B Preferred Stock into warrants to purchase 2,186,693 shares of our common stock, in each case immediately prior to the completion of this offering, but does not give effect to the accrued dividends to be paid in shares of our common stock in connection with the automatic conversion of our preferred stock into common stock. The percentage ownership information under the column titled "After Offering" is based on the sale of shares of common stock in this offering (assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus) and gives effect to the accrued dividends to be paid in shares of our common stock in connection with the automatic conversion of our preferred stock into common stock. The percentage ownership information assumes no exercise of the underwriters' option to purchase additional shares.

Except as indicated in the footnotes to this table, (i) the persons or entities named have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them, and (ii) the address for each person or entity listed in the table is c/o TELA Bio, Inc., 1 Great Valley Parkway, Suite 24, Malvern, PA 19355.

	NUMBER OF SHARES BENEFICIALLY OWNED BEFORE OFFERING	PERCENTAGE OF SHARES BENEFICIALLY OWNED BEFORE OFFERING	NUMBER OF SHARES BENEFICIALLY OWNED AFTER OFFERING	PERCENTAGE OF SHARES BENEFICIALLY OWNED AFTER OFFERING
Greater than 5% Stockholders:				
OrbiMed Private Investments IV, LP[1]	36,779,291	34.6%		
Quaker BioVentures II, L.P.[2]	22,463,516	21.2%		
HighCape Partners QP, L.P.[3]	6,075,663	5.8%		
Signet Healthcare Partners Accredited Partnership III, LP[4]	8,710,627	8.2%		
Pacira Pharmaceuticals, Inc.[5]	14,329,052	13.6%		
Directors and Named Executive Officers:				
Antony Koblish[6]	6,491,175	6.0%		
Maarten Persenaire, MD[7]	1,937,879	1.8%		
E. Skott Greenhalgh, PhD[8]	1,059,994	1.0%		
Kurt Azarbarzin	—	—		
Vince Burgess[9]	422,225	*		
Ronald Ellis[5]	14,329,052	13.6%		
Ashley Friedman[4]	8,710,627	8.2%		
Adele Oliva[2]	22,463,516	21.2%		
Matt Zuga[3]	6,075,663	5.8%		
All current executive officers and directors as a group (10 persons)	61,576,331	55.5%		

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 11,878,249 shares of common stock issuable upon conversion of Series A Preferred Stock; (ii) 24,142,419 shares of common stock issuable upon conversion of Series B Preferred Stock; and (iii) 758,623 shares of common stock issuable upon exercise of warrants to purchase common stock resulting from the automatic conversion of warrants to purchase 758,623 shares of Series B Preferred Stock held by OrbiMed Private Investments IV, LP ("OPI IV"). OrbiMed Capital GP IV LLC ("GP IV") is the general partner of OPI IV. OrbiMed Advisors LLC ("OrbiMed Advisors") is the managing member of GP IV. By virtue of such relationships, GP IV and OrbiMed Advisors may be deemed to have voting and investment power with respect to the shares held by OPI IV. Both GP IV and OrbiMed Advisors may be deemed to directly or indirectly, including by reason of their mutual affiliation, to be the beneficial owners of the shares held by OPI IV. OrbiMed Advisors exercises this investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein. Each of GP IV, OrbiMed Advisors, Carl L. Gordon, Sven H. Borho, and Jonathan T. Silverstein disclaims beneficial ownership of the shares held by OPI IV, except to the extent of its or his pecuniary interest therein if any. The business address for OPI IV is c/o OrbiMed Advisors LLC, 601 Lexington Avenue, 54th Floor, New York, NY 10022.

(2) Consists of (i) 8,530,145 shares of common stock issuable upon conversion of Series A Preferred Stock; (ii) 12,763,434 shares of common stock issuable upon conversion of Series B Preferred Stock; (iii) 723,124 shares of common stock; and (iv) 446,813 shares of common stock issuable upon exercise of warrants to purchase common stock held upon conversion of warrants to purchase 446,813 shares of Series B Preferred Stock held by Quaker BioVentures, II, L.P. Quaker BioVentures Capital II, L.P. serves as the partner of Quaker BioVentures, II, L.P. Quaker BioVentures Capital II, LLC serves as the general partner of Quaker BioVentures Capital II, L.P and Quaker BioVentures Capital II, LLC may be deemed to have beneficial ownership of the shares held by Quaker BioVentures II, L.P. Quaker Bioventures Capital II, LLC exercises this investment and voting power through a management committee comprised of Adele C. Oliva, Richard S. Kollender, P. Sherrill Neff, and Ira M. Lubert. Each of Quaker Bioventures II, LLC, Adele C. Oliva, Richard S. Kollender, P. Sherrill Neff, and Ira M. Lubert disclaims beneficial ownership of the shares held by Quaker BioVentures , II, L.P., except to the extent of its or his pecuniary interest therein. The address for Quaker BioVentures II, L.P. is 150 Monument Road, Suite 207, Bala Cynwyd, PA 19004.

(3) Consists of (i) 493,357 shares of common stock issuable upon conversion of Series A Preferred Stock held by HighCape Partners QP, L.P.; (ii) 6,643 shares of common stock issuable upon conversion of Series A Preferred Stock held by HighCape Partners, L.P.; (iii) 5,377,928 shares of common stock issuable upon conversion of Series B Preferred stock held by HighCape Partners QP, L.P.; (iv) 72,417 shares of common stock issuable upon conversion of Series B Preferred Stock held by HighCape Partners, L.P.; (v) 123,653 shares of common stock issuable upon exercise of warrants to purchase common

stock resulting from the automatic conversion of warrants to purchase 123,653 shares of Series B Preferred Stock held by HighCape Partners QP, L.P.; and (vi) 1,665 shares of common stock issuable upon exercise of warrants to purchase common stock resulting from the automatic conversion of warrants to purchase 1,665 shares of Series B Preferred Stock held by HighCape Partners, L.P. Voting and investment decisions with respect to these shares are made by an investment committee comprised of Matt Zuga and Kevin Rakin, each of whom may be deemed to have beneficial ownership over these shares. The address for HighCape Partners, QP, L.P. is 10751 Falls Road, Suite 300, Baltimore, MD 21093.

(4) Consists of (i) 1,479,951 shares of common stock issuable upon conversion of Series B Preferred Stock held by Signet Healthcare Partners Accredited Partnership III, LP; (ii) 7,051,009 shares of common stock issuable upon conversion of Series B Preferred Stock held by Signet Healthcare Partners QP Partnership III, LP; (iii) 31,168 shares of common stock issuable upon exercise of warrants to purchase common stock held upon conversion of warrants to purchase 31,168 shares of Series B Preferred Stock held by Signet Healthcare Partners Accredited Partnership III, LP; and (iv) 148,499 shares of common stock issuable upon exercise of warrants to purchase common stock resulting from the automatic conversion of warrants to purchase 148,499 shares of Series B Preferred Stock held by Signet Healthcare Partners QP Partnership III, LP. Signet Healthcare GP III, LP is the general partner of Signet Healthcare Partners QP Partnership III LP and Signet Healthcare Partners Accredited Partnership III, LP, and as a result may be deemed to have beneficial ownership of such shares. James C. Gale exercises voting and dispositive power over the shares held by Signet Healthcare Partners Accredited Partnership II, LP and Signet Healthcare Partners QP Partnership II, LP. Each of Signet Healthcare GP III, LP and Mr. Gale disclaims beneficial ownership of the shares held by each of Signet Healthcare Partners Accredited Partnership II, LP and Signet Healthcare Partners QP Partnership II, LP, except to the extent of it or his pecuniary interest therein. The address for Signet Healthcare Partners Accredited Partnership III, LP is 152 West 57th Street, 19th Floor, New York, NY 10019.

(5) Consists of 14,329,052 shares of common stock issuable upon conversion of Series B Preferred Stock. Voting and investment decisions with respect to these shares are made by Ronald Ellis. The address for Pacira Pharmaceuticals, Inc. is 5 Sylvan Way, Suite 300, Parsippany, NJ 07054.

(6) Consists of (i) 2,871,717 shares of common stock; (ii) 179,685 shares of common stock issuable upon conversion of Series A Preferred Stock; (ii) 351,271 shares of common stock issuable upon conversion of Series B Preferred Stock; (iii) 10,775 shares of common stock issuable upon exercise of warrants to purchase common stock resulting from the automatic conversion of warrants to purchase 10,775 shares of Series B Preferred Stock; and (iv) 3,077,727 shares of common stock issuable pursuant to options that are exercisable within 60 days of August 30, 2019.

(7) Consists of (i) 1,050,719 shares of common stock; (ii) 197,511 shares of common stock issuable upon conversion of Series A Preferred Stock; (ii) 315,086 shares of common stock issuable upon conversion of Series B Preferred Stock; (iii) 12,931 shares of common stock issuable upon exercise of warrants to purchase common stock resulting from the automatic conversion of warrants to purchase 12,931 shares of Series B Preferred Stock; and (iv) 361,632 shares of common stock issuable pursuant to options that are exercisable within 60 days of August 30, 2019.

(8) Consists of (i) 50,000 shares of common stock issuable upon conversion of Series A Preferred Stock; (ii) 120,699 shares of common stock issuable upon conversion of Series B Preferred Stock; (iii) 1,976 shares of common stock issuable upon exercise of warrants to purchase common stock resulting from the automatic conversion of warrants to purchase 1,976 shares of Series B Preferred Stock; and (iv) 999,519 shares of common stock issuable pursuant to options that are exercisable within 60 days of August 30, 2019.

(9) Consists of 422,225 shares of common stock issuable pursuant to options that are exercisable within 60 days of August 30, 2019.

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our fourth amended and restated certificate of incorporation, second amended and restated bylaws, the amended and restated investor rights agreement to which we and certain of our stockholders are parties and of the DGCL. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our fourth amended and restated certificate of incorporation, second amended and restated bylaws and amended and restated investors' rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is part.

General

Upon the completion of this offering and the filing of our fourth amended and restated certificate of incorporation, our authorized capital stock will consist of shares of common stock, par value $0.001 per share, and shares of preferred stock, par value $0.001 per share. All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Common Stock

Outstanding Shares

As of June 30, 2019, there would have been shares of common stock outstanding, held by stockholders of record, after giving effect to the automatic conversion of all our preferred stock outstanding into an aggregate of shares of our common stock immediately prior to the completion of this offering.

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. In addition, the affirmative vote of holders of $66^{2}/_{3}\%$ of the voting power of all of the then outstanding voting stock will be required to take certain actions, including amending certain provisions of our fourth amended and restated certificate of incorporation, such as the provisions relating to amending our second amended and restated bylaws, procedures for our stockholder meetings, the classified board, director liability, and exclusive forum for proceedings.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Preferred Stock

Upon the completion of this offering, all outstanding shares of our preferred stock will be automatically converted into an aggregate of shares of common stock. Under the terms of our fourth amended and restated certificate of incorporation that will become effective immediately prior to the completion of this offering, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock. Upon the completion of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Warrants

As of June 30, 2019, we had warrants to purchase an aggregate of 2,186,693 shares of our Series B Preferred Stock outstanding with an exercise price of $1.16 per share. These warrants may be exercised at any time and from time to time, in whole or in part. Immediately prior to the completion of this offering, these warrants will become exercisable to purchase up to shares of our common stock at an exercise price of $ per share.

Stock Options and Equity Plan Shares

As of June 30, 2019, options to purchase 13,074,180 shares of our common stock were outstanding under our 2012 Plan, of which 7,649,251 options were vested of that date. 1,318,203 shares of our common stock remain available for future issuance under the 2012 plan and shares of our common stock are reserved for future issuance under the 2019 Plan.

Registration Rights

The Investors' Rights Agreement grants the parties thereto certain registration rights in respect of the "registrable securities" held by them, which securities include (1) the shares of our common stock issued upon the conversion of shares of our preferred stock and (2) any shares of our common stock issued as a dividend or other distribution with respect to the shares described in the foregoing clause (1). The registration of shares of our common stock pursuant to the exercise of these registration rights would enable the holders thereof to sell such shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Holders of shares of our common stock (including shares issuable upon the conversion of our preferred stock) are entitled to such registration rights pursuant the Investors' Rights Agreement.

Expenses of Registration

Subject to specified conditions and limitations, we are required to pay all expenses, other than underwriting discounts and commissions and stock transfer taxes incurred in connection with any exercise of these registration rights.

Expiration of Registration Rights

These registration rights will expire on the earlier to occur of (1) the written agreement of us and 70% of the holders of the preferred stock on an as-converted basis and including any shares of common stock

which shares of preferred stock have been converted or (2) the date in which all registrable securities can be sold pursuant to Rule 144 of the Securities Act during any ninety-day period.

Demand Registration Rights

At any time beginning six months after the completion of this offering, the holders of not less than 70% of the registrable securities then outstanding may, on not more than two occasions, request that we prepare, file and maintain a registration statement on Form S-1 to register the sale of their registrable securities. Once we are eligible to use a registration statement on Form S-3, the stockholders party to the Investors' Rights Agreement may, not more than once in any twelve-month period, request that we prepare, file and maintain a registration statement on Form S-3 covering the sale of their registrable securities, but only if the anticipated offering price, net of underwriting discounts and commissions, would exceed $2.0 million.

Piggyback Registration Rights

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the stockholders party to the Investors' Rights Agreement will be entitled to certain "piggyback" registration rights allowing them to include their registrable securities in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act other than with respect to a demand registration or a registration statement on Form S-8, these holders will be entitled to notice of the registration and will have the right to include their registrable securities in the registration subject to certain limitations.

Indemnification

The Investors' Rights Agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling holders of registrable securities in the event of either material misstatements or omissions in the applicable registration statement attributable to us or our violation of the Securities Act, and the selling stockholders are obligated to indemnify us for material misstatements or omission in the registration statement attributable to them, subject to certain limitations.

Anti-Takeover Provisions of Delaware Law and Our Charter Documents

Some provisions of Delaware law and our fourth amended and restated certificate of incorporation and our second amended and restated bylaws that will become effective immediately prior to the completion of this offering contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits persons deemed "interested stockholders" from engaging in a "business combination" with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did

own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Elimination of Stockholder Action by Written Consent

Our fourth amended and restated certificate of incorporation, which will be in effect immediately prior to the completion of this offering, will provide that all stockholder actions must be effected at a duly called meeting of stockholders and not by consent in writing. A special meeting of stockholders may be called only by a majority of our board of directors, the chair of our board of directors, or our chief executive officer.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Amendment of Charter Provisions

Our fourth amended and restated certificate of incorporation will further provide that the affirmative vote of holders of at least $66^{2}/_{3}\%$ of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend certain provisions of our fourth amended and restated certificate of incorporation, including provisions relating to the size of the board, removal of directors, special meetings, actions by written consent and cumulative voting. The affirmative vote of holders of at least $66^{2}/_{3}\%$ of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend or repeal our second amended and restated bylaws, although our second amended and restated bylaws may be amended by a simple majority vote of our board of directors.

Classified Board; Election and Removal of Directors

Our fourth amended and restated certificate of incorporation will further provide that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms, and will give our board of directors 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.

Choice of Forum

Our fourth amended and restated certificate of incorporation will provide that, unless our board of directors consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the United States District Court for the District of Delaware) will be the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of us; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees or agents to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL or our fourth amended and restated certificate of incorporation and our second amended and restated bylaws; or (iv) any action asserting a claim against us 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.

Limitations on Liability and Indemnification Matters

For a discussion of liability and indemnification, see "Management — Limitation on Liability and Indemnification Matters."

Listing

We have applied to list our common stock on The Nasdaq Global Market under the trading symbol "TELA".

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is .

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock in the public market after this offering, or the perception that those sales may occur, could adversely affect the prevailing market price for our common stock. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after the restrictions lapse could adversely affect the prevailing market price of our common stock as well as our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of June 30, 2019, upon the completion of this offering and assuming (i) the for reverse stock split of all outstanding shares of our common stock, (ii) the automatic conversion of all our preferred stock outstanding as of June 30, 2019 into an aggregate of shares of our common stock immediately prior to the completion of this offering, (iii) no exercise of the underwriters' option to purchase additional shares of common stock, and (iv) no exercise of outstanding options or warrants, we will have outstanding an aggregate of approximately shares of common stock. All of the shares sold in this offering will be freely tradable unless purchased by our "affiliates" as such term is defined in Rule 144 under the Securities Act or purchased by existing stockholders and their affiliated entities that are subject to lock-up agreements. All remaining shares of common stock held by existing stockholders immediately prior to the consummation of this offering will be "restricted securities," as such term is defined in Rule 144. These restricted securities were issued and sold in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701 of the Securities Act, or Rule 701, which rules are summarized below.

As a result of the lock-up agreements referred to below and the provisions of Rule 144 and Rule 701 under the Securities Act, based on the number of shares of our common stock outstanding as of June 30, 2019, the remaining shares of our common stock will generally become for sale in the public market are as follows:

Approximate Number of Shares	First Date Available For Sale on the Public Markets
shares	181 days after the date of this prospectus, upon expiration of the lock-up agreements referred to below, subject in some cases to applicable volume, manner of sale and other limitations under Rule 144 and Rule 701.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes.

In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

In addition, the shares of common stock reserved for future issuance under our 2012 Plan and 2019 Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, a registration statement under the Securities Act or an exemption from registration, including Rule 144 and Rule 701.

Rule 144

In general, pursuant to Rule 144 under the Securities Act, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not an affiliate of ours at any time during the three months preceding a sale and has held their shares for at least six months, including

the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours at any time during the three months preceding a sale and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately following the completion of this offering without regard to whether current public information about us is available.

Beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

- 1% of the number of common shares then outstanding, which will equal approximately shares of common stock upon the completion of this offering; or
- the average weekly trading volume of our common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 held by our "affiliates" are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

Pursuant to Rule 701 under the Securities Act, shares of our common stock acquired upon the exercise of currently outstanding options or pursuant to other rights granted under our stock incentive plans may be resold by:

- persons other than "affiliates," beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject only to the manner-of-sale provisions of Rule 144; and
- Our "affiliates," beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the manner-of-sale and volume limitations, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144

Lock-Up Agreements

We, along with our directors, executive officers and substantially all of our other stockholders and option holders, have agreed with the underwriters that for the period from the date of the lock-up agreement continuing through the date 180 days after the date of this prospectus we and they will not sell, offer to sell, contract to sell or lend, effect any short sale or establish or increase any put equivalent position or liquidate or decrease any call equivalent position, pledge, hypothecate, grant any security interest in or in any other way transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exchangeable for shares of common stock, or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock.

After this offering, certain of our employees, including our executive officers and/or directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under

these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

Registration Rights

Upon the completion of this offering, the holders of shares of our common stock or their transferees will be entitled to various rights with respect to the registration of these shares under the Securities Act, subject to the lock-up agreements described under "— Lock-Up Agreements" above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates, immediately upon the effectiveness of the registration. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See the section titled "Description of Capital Stock — Registration Rights."

Equity Incentive Plans

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock reserved for issuance under our 2012 Plan and our 2019 Plan. The registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to vesting restrictions, Rule 144 volume limitations and the lock-up agreements described above, if applicable.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non- U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies" and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans;
- "qualified foreign pension funds" and entities all of the interests of which are held by qualified foreign pension funds; and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an applicable financial statement.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF

THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation or entity treated as a corporation that is created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section titled "Dividend Policy," we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. However, if we make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "— Sale or Other Taxable Disposition."

Subject to the discussions below on effectively connected income, backup withholding and the Foreign Account Tax Compliance Act, or FATCA, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment or fixed base in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also generally will be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits attributable to such dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussions below regarding backup withholding and FATCA, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment or fixed base in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also generally will be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits attributable to such gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period. If we are a USRPHC and either our common stock is not regularly traded on an established securities market or a Non-U.S. Holder holds more than 5% of our common stock, actually or constructively, during the applicable testing period, such Non-U.S. Holder will generally be taxed on any gain in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the holder either certifies its non-U.S. status by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above or the holder otherwise establishes an exemption. Proceeds of a disposition of our common

stock conducted through a non-U.S. office of a non-U.S. broker that does not have certain enumerated relationships with the United States generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS also may be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (commonly referred to as FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertakes to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies currently to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our common stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2019, among us and Jefferies LLC and Piper Jaffray & Co., as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

Underwriter	Number of Shares
Jefferies LLC	
Piper Jaffray & Co.	
Canaccord Genuity LLC	
JMP Securities LLC	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per share of common stock. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such

amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Per Share		Total	
	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares
Public offering price	$	$	$	$
Underwriting discounts and commissions paid by us	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $. We have agreed to reimburse the underwriters for certain of their expenses incurred in connection with this offering in an amount not to exceed $.

Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

Listing

We have applied to have our common stock approved for listing on The Nasdaq Global Market under the trading symbol "TELA".

Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

No Sales of Similar Securities

We, our officers, directors and holders of all or substantially all our outstanding capital stock and other securities have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer to sell, contract to sell or lend or effect any short sale or establish or increase "put equivalent position" within the meaning of Rule 16a-l(h) under the Exchange Act, pledge, hypothecate or grant any security interest in, enter into a swap;
- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially; or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Jefferies LLC and Piper Jaffray & Co.

This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus.

Jefferies LLC and Piper Jaffray & Co. may, in their sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock

originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on The Nasdaq Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Directed Share Program

At our request, the underwriters have reserved for sale at the initial public offering price up to shares of common stock for our directors, officers and certain employees and other persons with whom we have a relationship who have expressed an interest in purchasing shares in the offering. The number of shares of common stock available for sale to the general public in the offering will be reduced to the extent these persons purchase the directed shares in the program. Any directed shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares. Except for certain participants who have entered into lock-up agreements as contemplated above, each person buying shares through the directed share program has agreed that, for a period of 180 days from and including the date of this prospectus, he or she will not, without the prior written consent of Jefferies LLC and Piper Jaffray & Co., dispose of or hedge any shares of common stock or any securities convertible into or exchangeable for shares of common stock with respect to shares purchased in the program. For those participants who have entered into lock-up agreements as contemplated above, the lock-up agreements contemplated therein shall govern with respect to their purchases of shares of common stock in the program. Jefferies LLC and Piper Jaffray & Co. in their sole discretion may release any of the securities subject to these lock-up agreements at any time. We have agreed to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act, in connection with sales of the directed shares.

Other Activities and Relationships

The underwriter and certain of its affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriter and certain of its affiliates have, from time to time, performed, and may in the

future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriter and certain of its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Notice to Prospective Investors in EEA

In relation to each member state of the European Economic Area which has implemented the Prospectus Regulation (each, a "Relevant Member State"), no offer of shares of our common stock which are the subject of the offering contemplated by this prospectus supplement has been or will be made to the public in that Relevant Member State, except that with effect from and including the Relevant Implementation Date, an offer of such shares of our common stock may be made to the public in that Relevant Member State:

- to any legal entity which is a "qualified investor" as defined in the Prospectus Regulation;
- to fewer than 150, natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), as permitted under the Prospectus Regulation, subject to obtaining the prior consent of the representatives of the underwriters; or
- in any other circumstances falling within Article 3(2) of the Prospectus Regulation, provided that no such offer of shares of our common stock shall require the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 16 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares of our common stock to be offered so as to enable an investor to decide to purchase or subscribe the shares of our common stock, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Regulation in that Relevant Member State, and the expression "Prospectus Regulation" means Prospectus Regulation (EU) 2017/1129 (and amendments thereto, to the extent implemented in the Relevant Member States) and includes any relevant implementing measure in the Relevant Member State.

Notice to Prospective Investors in United Kingdom

In the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together

being referred to as "relevant persons"). Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

Notice to Prospective Investors in Bermuda

Securities may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to Prospective Investors in Australia

This prospectus supplement is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus supplement in Australia, you confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the Company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the shares of our common stock issued to you pursuant to this prospectus supplement for resale in Australia within 12 months of those shares of our common stock being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Notice to Prospective Investors in Hong Kong

No shares of our common stock have been offered or sold, and no shares of our common stock may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32) or the Securities and Futures Ordinance (Cap. 571) of Hong Kong. No document, invitation or advertisement relating to the shares of our common stock has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to shares of our common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

This prospectus supplement has not been registered with the Registrar of Companies in Hong Kong.

Accordingly, this prospectus supplement may not be issued, circulated or distributed in Hong Kong, and the shares of our common stock may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the shares of our common stock will be required, and is deemed by the acquisition of the shares of our common stock, to confirm that he is aware of the restriction on offers of the shares of our common stock described in this prospectus supplement and the relevant offering documents and that he is not acquiring, and has not been offered any shares of our common stock in circumstances that contravene any such restrictions.

Notice to Prospective Investors in Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the underwriters will not offer or sell any shares of our common stock, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means, unless otherwise provided herein, any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from S-30 the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Notice to Prospective Investors in Singapore

This prospectus supplement has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus supplement and any other document or material in connection with the offer or sale, or the invitation for subscription or purchase, of the shares of our common stock may not be issued, circulated or distributed, nor may the shares of our common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of our common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of our common stock pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Notice to Prospective Investors in Switzerland

The shares of our common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This prospectus supplement has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospect supplement nor any other offering or marketing material relating to the shares of our common stock or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus supplement nor any other offering or marketing material relating to the offering, the Company or the shares of our common stock have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with and the offer of shares of our common stock will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA) and the offer of shares of our common stock has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares of our common stock.

Notice to Prospective Investors in Canada

(A) Resale Restrictions

The distribution of shares of our common stock in Canada is being made only in the provinces of Ontario, Quebec, Alberta and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these shares of our common stock are made. Any resale of the shares of our common stock in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the shares of our common stock.

(B) Representations of Canadian Purchasers

By purchasing shares of our common stock in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the shares of our common stock without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106 — Prospectus Exemptions,
- the purchaser is a "permitted client" as defined in National Instrument 31-103 — Registration Requirements, Exemptions and Ongoing Registrant Obligations,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

(C) Conflicts of Interest

Canadian purchasers are hereby notified that each of the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105 — Underwriting Conflicts from having to provide certain conflict of interest disclosure in this document.

(D) Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The

purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

(E) Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

(F) Taxation and Eligibility for Investment

Canadian purchasers of shares of our common stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in the shares of our common stock in their particular circumstances and about the eligibility of the shares of our common stock for investment by the purchaser under relevant Canadian legislation.

LEGAL MATTERS

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Pepper Hamilton LLP, Philadelphia, Pennsylvania. Certain legal matters in connection with this offering will be passed upon for the underwriters by Latham & Watkins LLP, New York, New York.

EXPERTS

The consolidated financial statements of TELA Bio, Inc. as of December 31, 2018 and 2017, and for the years then ended, have been included herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the December 31, 2018 consolidated financial statements contains an explanatory paragraph the states that the Company's recurring losses and negative cash flows from operations raise substantial doubt about the entity's ability to continue as a going concern. The consolidated financial statements do not include any adjustment that might result from the outcome of that uncertainty.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference. You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov.

Upon the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection at the web site of the SEC referred to above. We also maintain a website at www.telabio.com, at which, following the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

TELA BIO, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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 its subsidiary (the Company) as of December 31, 2017 and 2018, the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, 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, 2017 and 2018, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in note 2 to the consolidated financial statements, the Company has incurred recurring losses and negative cash flows from operations, has limited resources available to fund current commercialization and research and development activities, and will require substantial additional financing to continue to fund its commercialization and research and development activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 and in accordance with auditing standards generally accepted in the United States of America. 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. 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 auditors since 2012.

Philadelphia, Pennsylvania
August 16, 2019

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

	December 31, 2017	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 11,346	$ 17,278
Accounts receivable	757	1,298
Inventory	1,815	4,348
Prepaid expenses and other	429	330
Total current assets	14,347	23,254
Property and equipment, net	1,161	758
Intangible assets, net	—	3,215
Restricted cash	24	—
Total assets	$ 15,532	$ 27,227
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Current portion of debt	$ 905	$ —
Accounts payable	1,507	3,421
Accrued expenses	1,801	5,153
Other current liabilities	1,935	985
Total current liabilities	6,148	9,559
Long-term debt	3,610	—
Long-term debt with related party	—	29,733
Preferred stock warrant liability	1,697	1,640
Other long-term liabilities	899	5
Total liabilities	12,354	40,937
Contingencies and commitments (note 11)		
Redeemable convertible preferred stock; $0.001 par value:		
Series A Preferred stock: 22,501,174 shares authorized, 22,501,174 issued and outstanding at December 31, 2017 and 2018; liquidation value of $33,112 at December 31, 2018	30,940	33,112
Series B Preferred stock: 82,891,619 shares authorized, 59,425,431 and 63,032,500 issued and outstanding at December 31, 2017 and 2018, respectively; liquidation value of $91,010 at December 31, 2018	80,409	91,038
Total redeemable convertible preferred stock	111,349	124,150
Stockholders' deficit:		
Common stock; $0.001 par value: 127,157,585 shares authorized; 7,279,084 and 7,323,795 shares issued and 7,253,510 and 7,301,248 shares outstanding at December 31, 2017 and 2018, respectively	7	7
Accumulated deficit	(108,178)	(137,867)
Total stockholders' deficit	(108,171)	(137,860)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 15,532	$ 27,227

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,	
	2017	2018
Revenue	$ 4,245	$ 8,274
Cost of revenue (excluding amortization of intangible assets)	1,713	4,547
Amortization of intangible assets	—	785
Gross profit	2,532	2,942
Operating expenses:		
Sales and marketing	8,712	13,646
General and administrative	4,958	4,899
Research and development	5,786	4,339
Gain on litigation settlement	—	(2,160)
Total operating expenses	19,456	20,724
Loss from operations	(16,924)	(17,782)
Other (expense) income:		
Interest expense	(4,558)	(1,802)
Loss on extinguishment of debt	—	(1,822)
Change in fair value of preferred stock warrant liability	54	244
Other income	94	70
Total other (expense) income	(4,410)	(3,310)
Net loss	(21,334)	(21,092)
Accretion of redeemable convertible preferred stock to redemption value	(5,893)	(8,823)
Net loss attributable to common stockholders	$ (27,227)	$ (29,915)
Net loss per common share, basic and diluted	$ (3.78)	$ (4.11)
Weighted average common shares outstanding, basic and diluted	7,208,547	7,283,167
Pro forma net loss per common share basic and diluted (unaudited)		
Pro forma weighted average shares outstanding, basic and diluted (unaudited)		

See accompanying notes to consolidated financial statements.

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

	Redeemable Convertible Preferred Stock				Stockholders' Deficit				
	Series A		Series B		Common stock		Additional paid-in capital	Accumulated deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at January 1, 2017	22,501,174	$ 28,811	39,543,222	$ 52,452	7,071,676	$ 7	$ —	$ (81,181)	$ (81,174)
Vesting of common stock previously subject to repurchase	—	—	—	—	171,834	—	31	—	31
Exercise of stock options	—	—	—	—	10,000	—	2	—	2
Issuance of Series B redeemable convertible preferred stock upon conversion of promissory notes	—	—	6,951,175	9,462	—	—	—	—	—
Sale of Series B redeemable convertible preferred stock, net of stock issue costs of $269	—	—	12,931,034	14,731	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	197	—	197
Accretion of redeemable convertible preferred stock to redemption value	—	2,129	—	3,764	—	—	(230)	(5,663)	(5,893)
Net loss	—	—	—	—	—	—	—	(21,334)	(21,334)
Balance at December 31, 2017	22,501,174	30,940	59,425,431	80,409	7,253,510	7	—	(108,178)	(108,171)
Vesting of common stock previously subject to repurchase	—	—	—	—	13,627	—	5	—	5
Exercise of stock options	—	—	—	—	34,111	—	5	—	5
Sale of Series B redeemable convertible preferred stock, net of stock issue costs of $206	—	—	3,607,069	3,978	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	216	—	216
Accretion of redeemable convertible preferred stock to redemption value	—	2,172	—	6,651	—	—	(226)	(8,597)	(8,823)
Net loss	—	—	—	—	—	—	—	(21,092)	(21,092)
Balance at December 31, 2018	22,501,174	$ 33,112	63,032,500	$ 91,038	7,301,248	$ 7	$ —	$ (137,867)	$ (137,860)

See accompanying notes to consolidated financial statements.

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

	Year ended December 31,	
	2017	2018
Cash flows from operating activities:		
Net loss	$ (21,334)	$ (21,092)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	761	463
Noncash interest expense	2,113	712
Noncash loss on extinguishment of debt	—	1,469
Amortization of intangible assets	—	785
Inventory excess and obsolescence charge	452	2,224
Beneficial conversion feature upon conversion of promissory notes	1,408	—
Change in fair value of warrants	(54)	(244)
Stock-based compensation expense	197	216
Loss (gain) on sale of property and equipment	14	(2)
Change in operating assets and liabilities:		
Accounts receivable	(578)	(541)
Inventory	(127)	(4,757)
Prepaid expenses and other	(58)	99
Restricted cash	—	24
Accounts payable	(748)	1,914
Accrued expenses and other liabilities	1,586	(1,194)
Net cash used in operating activities	(16,368)	(19,924)
Cash flows from investing activities:		
Payment for intangible asset	—	(1,500)
Purchase of property and equipment	(114)	(62)
Proceeds from sale of property and equipment	13	4
Net cash used in investing activities	(101)	(1,558)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt with related party	—	30,000
Proceeds from issuance of long-term debt and preferred stock warrants	5,000	8,000
Repayment of long-term debt	—	(13,000)
Borrowings under revolving credit facility	—	5,732
Repayments of revolving credit facility	—	(5,732)
Proceeds from issuance of Series B redeemable convertible preferred stock, net of offering costs	14,731	3,978
Proceeds from issuance of convertible promissory notes and preferred stock warrants	7,386	—
Payment of deferred financing costs	(596)	(1,569)
Payment of capital lease obligations	(188)	—
Proceeds from exercise of stock options	2	5
Net cash provided by financing activities	26,335	27,414
Net increase in cash and cash equivalents	9,866	5,932
Cash and cash equivalents, beginning of year	1,480	11,346
Cash and cash equivalents, end of year	$ 11,346	$ 17,278
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 329	$ 1,090
Cash paid on loss on extinguishment of debt	$ —	$ 353
Supplemental disclosures of noncash investing and financing activities:		
Fair value of warrants issued in connection with equity and debt financing	$ 1,751	$ 187
Accretion of redeemable convertible preferred stock	$ 5,893	$ 8,823
Conversion of convertible promissory notes and accrued interest to Series B redeemable convertible preferred stock	$ 8,054	$ —
Intangible assets in accrued expenses and other liabilities	$ —	$ 2,500
Recognition of exit fee for debt discount	$ —	$ 3,400
Issuance of common stock for early exercised stock options	$ 31	$ 5

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 focused on the commercialization and sale of OviTex, which utilizes surgical reconstruction medical device technology licensed from a strategic partner, Aroa Biosurgery (Aroa), as described in note 11, and on the research and development of additional medical devices with Aroa and on other internally developed technologies. In April 2019, the Company received 510(k) clearance from the United States Food and Drug Administration (FDA) for OviTex PRS — Restella Reconstructive Bioscaffold, or Restella, which addresses unmet needs in plastic reconstruction surgery. The Company's principal corporate office and research facility is located in Malvern, Pennsylvania.

(2) Risks and Liquidity

The Company's operations to date have focused on organization and staffing, business planning, raising capital, developing and acquiring technology and assets, and commercializing products. The Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit of $137.9 million as of December 31, 2018. The Company anticipates incurring additional losses until such time, if ever, it can generate sufficient revenue from its products to cover its expenses and has limited resources available to fund current commercialization and research and development activities. As such, additional financings will be needed by the Company to fund its operations and to develop its products. There is no assurance such financing will be available when needed or on acceptable terms. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The accompanying consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Management is currently evaluating different strategies to obtain the required funding of future operations. These strategies may include, but are not limited to, additional funding from current investors, funding from new investors including strategic corporate investors, an initial public offering of the Company's common stock, and/or borrowings of additional debt, among others. There can be no assurance these future funding efforts will be successful.

Management believes that the Company's cash and cash equivalents as of December 31, 2018, along with the $14.0 million in net proceeds received from the sale of Series B in 2019 (note 13), availability of borrowing under the credit facility, and anticipated cash receipts from sales of products are sufficient to fund operations into the second quarter of 2020.

The operations of the Company are subject to certain risks and uncertainties including, among others, uncertainty of product development, 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

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(3) Summary of Significant Accounting Policies (Continued)

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.

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 the fair value of redeemable convertible preferred stock, preferred stock warrant liability and 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 invests in a money market fund. 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. 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 of the investment based on quoted market prices.

Restricted Cash

Restricted cash represented an amount held in an escrow deposit account as of December 31, 2017, securing a letter of credit for the Company's office lease.

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

(3) Summary of Significant Accounting Policies (Continued)

excess of its expected net realizable value based on expected customer demand. As of December 31, 2017 and 2018, the Company had $0.3 million and $0.8 million, respectively, in inventory 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.

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 2018, the Company recorded $4.0 million in intangible assets as it became probable that the Company would make these payments. In 2018, the Company recognized $0.8 million in amortization expense related to intangible assets. At December 31, 2018, the remaining life of intangible assets was 10.6 years. The Company anticipates recognizing amortization expense of $0.3 million for the next five years and $1.7 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 year ended December 31, 2017 or 2018.

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.

Classification and accretion of redeemable convertible preferred stock

The Company has classified redeemable convertible preferred stock outside of stockholders' deficit because the shares contain certain redemption features that are not solely within the control of the Company. The carrying value of the Company's preferred stock is being accreted to redemption value at the end of each reporting period as if the end of the reporting period were the redemption date. Increases to the carrying value of redeemable convertible preferred stock are charged to additional paid-in capital or, in the absence of additional paid-in capital, charged to accumulated deficit.

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, the price is fixed or determinable, delivery has occurred, and there is a reasonable assurance of collection of the sales proceeds.

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(3) Summary of Significant Accounting Policies (Continued)

Revenue for products sold to a customer is recognized when the product is shipped to the customer, at which time title passes to the customer. Fees charged to customers for shipping are recognized as revenue. In the case of consigned inventory, revenue is recognized when the product is utilized in a surgical procedure.

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 payments to Aroa and related supply and manufacturing costs. 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 FASB 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 accounts for stock-based compensation for awards granted to nonemployee consultants by revaluing the award over the vesting period of the awards. 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 FASB 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.

FASB 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

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(3) Summary of Significant Accounting Policies (Continued)

Company's policy on income statement classification of interest and penalties related to income tax obligations is to include such items as part of total interest expense and other expense, respectively.

The recently enacted Tax Cuts and Jobs Act (the Tax Act) significantly revised U.S. corporate income tax law by, among other things, reducing the corporate income tax rate to 21%. See note 10 for a further discussion of the Tax Act.

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, prepaid expenses 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 the 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 include the Company's preferred stock warrants. The warrants are carried at their estimated fair value. The Company follows the provisions of FASB 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)

(3) Summary of Significant Accounting Policies (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, 2017 and 2018 (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)
December 31, 2017:			
Assets:			
Cash equivalents – money market fund	$ 6,854	$ —	$ —
Liability:			
Warrant liability	$ —	$ —	$ 1,697
December 31, 2018:			
Assets:			
Cash equivalents – money market fund	$ 16,002	$ —	$ —
Liability:			
Warrant liability	$ —	$ —	$ 1,640

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

January 1, 2017	$ —
Fair value of warrants issued – Convertible promissory notes	1,408
Fair value of warrants issued – Notes payable	343
Change in fair value of warrants	(54)
December 31, 2017	1,697
Fair value of warrants issued – MidCap Credit Facility	187
Change in fair value of warrants	(244)
December 31, 2018	$ 1,640

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(3) Summary of Significant Accounting Policies (Continued)

The fair value of the warrants at December 31, 2017 was determined using the Black-Scholes option pricing model with the following assumptions:

	Convertible promissory notes	Notes payable
Expected dividend yield	—	—
Expected volatility	70.0%	70.0%
Risk-free interest rate	2.40%	2.40%
Remaining contractual term in years	10.0	10.0

The fair value of the warrants at December 31, 2018 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	58.1%	57.0%	57.4%
Risk-free interest rate	2.69%	2.64%	2.64%
Remaining contractual term in years	9.3	8.1	8.3

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 entitles the holders of such shares to participate in distributions but contractually does not require the holders of such shares to participate in losses of the Company. Accordingly, 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)

(3) Summary of Significant Accounting Policies (Continued)

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of December 31, 2017 and 2018, as they would be antidilutive.

	Years ended December 31,	
	2017	2018
Series A redeemable convertible preferred stock	22,501,174	22,501,174
Series B redeemable convertible preferred stock	59,425,431	63,032,500
Stock options (including shares subject to repurchase)	8,689,716	12,101,704
Series B redeemable convertible preferred stock warrants	1,979,812	2,186,693
Total	92,596,133	99,822,071

The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2018 gives effect to the conversion upon the initial public offering of all outstanding shares of redeemable convertible preferred stock as of December 31, 2018, into shares of common stock as if the conversion had occurred on the later of the beginning of the reporting period or the issuance date of the redeemable convertible preferred stock.

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Year ended December 31, 2018
Numerator:	
Net loss attributable to common stockholders	$
Pro forma adjustments:	
Accretion of redeemable convertible preferred stock	
Change in fair value of preferred stock warrant liability	
Pro forma net loss per common share, basic and diluted	$
Denominator:	
Weighted average shares of common stock outstanding, basic and diluted	
Pro forma adjustments	
Conversion of redeemable convertible preferred stock and related payment of dividends	
Pro forma weighted average common shares outstanding, basic and diluted	
Pro forma net loss per share, basic and diluted	

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(3) Summary of Significant Accounting Policies (Continued)

Recently Issued Accounting Pronouncement

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which outlines a single, comprehensive model for accounting for revenue from contracts with customers and is effective for the Company beginning on January 1, 2019.

The Company adopted the standard on January 1, 2019, using the modified retrospective approach and determined that the new guidance did not have a material impact on its revenue recognition practices as it does not provide customers with price concessions, rebates, volume discounts, or other such reductions for which an estimated transaction price must be determined and then allocated to specific deliverables. 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. Sales commissions are based on revenue recognized in a specific period and are expensed in the period they are earned. The adoption of this guidance had no cumulative adjustment to the Company's consolidated financial statements as of the adoption date.

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, 2020, with early adoption permitted. The Company plans to adopt this standard on January 1, 2020 and is currently evaluating the expected impact that the standard could have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which simplifies certain aspects of the accounting for share-based payment transactions, including impact on income taxes, classification of awards, and classification in the consolidated statement of cash flows. The Company adopted this standard in 2018, and it did not have a material impact on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Consolidated Statement of Cash Flows: Restricted Cash*. The amendments address diversity in practice that exists in the classification and presentation of changes in restricted cash and require that a consolidated statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The standard is effective for the Company beginning January 1, 2019. The Company's adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting*. The amendments in this update expand the scope of Topic 718 to include stock-based payment transactions for acquiring goods and services from nonemployees. Under this ASU, an entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of costs (i.e., the period of time over which stock-based payment awards vest and the pattern of cost recognition over that period). The guidance is effective for the Company beginning January 1, 2020, with early adoption

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(3) Summary of Significant Accounting Policies (Continued)

permitted. The Company is currently evaluating the effect that this guidance will have on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurements,* which changes the fair value measurement disclosure requirements of ASC Topic 820. The goal of the ASU is to improve the effectiveness of ASC Topic 820's disclosure requirements. The standard is effective for the Company beginning January 1, 2020. The Company is currently evaluating the potential impact of the adoption of this standard on its related disclosures.

(4) Property and Equipment

Property and equipment consisted of the following at December 31, 2017 and 2018 (in thousands):

Asset description	Estimated useful lives	December 31, 2017	December 31, 2018
Lab equipment	5 Years	$ 2,200	$ 2,203
Furniture and fixtures	5 Years	107	110
Computer equipment and software	3 Years	363	398
Leasehold improvements	Life of lease	1,276	1,290
Total		3,946	4,001
Less accumulated depreciation and amortization		(2,785)	(3,243)
Property and equipment, net		$ 1,161	$ 758

The cost of property and equipment at both December 31, 2017 and 2018 includes $0.2 million of equipment located at Aroa. Depreciation expense was $0.8 million and $0.5 million for the years ended December 31, 2017 and 2018, respectively.

(5) Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2017	December 31, 2018
Compensation and related benefits	$ 1,116	$ 1,760
Interest	41	42
Professional fees	381	552
Accrued milestone payments	—	2,500
Research and development expenses	51	133
Other	212	166
	$ 1,801	$ 5,153

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(6) Debt

Long-term debt consisted of the following at December 31, 2017 and 2018 (in thousands):

	December 31,	
	2017	2018
OrbiMed Term Loan (related party)	$ —	$ 30,000
Note payable	5,000	—
End of term charge	103	3,000
Unamortized issuance costs	(588)	(3,267)
	4,515	29,733
Current portion	(905)	—
Long-term debt (including with related party)	$ 3,610	$ 29,733

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 $35.0 million in term loans (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). In November 2018, the Company borrowed $30.0 million of Tranche 1 and used a portion of the the proceeds to repay the MidCap Credit Facility (described below) and will use the remaining proceeds to fund operations and capital expenditures. The Company will be eligible to borrow Tranche 2 until December 31, 2019, provided the Company's consolidated revenue on a trailing six-month basis equals or exceeds $7.5 million.

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 event, (xi) regulatory matters, (xii) and key contracts. In addition, the Company must maintain a minimum cash balance of $2.0 million. In the event of default under the OrbiMed Credit Facility, the Company would be required to pay interest on principal 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%. At December 31, 2018, the interest rate was 10.13%. 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).

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(6) Debt (Continued)

The Company is also required to pay 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 $3.3 million of third party and lender fees, which were recorded as the End of Term Charge along with 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 2018 was $0.6 million.

MidCap Credit Facility

In April 2018, the Company entered into a $14.0 million debt financing transaction (MidCap Credit Facility) with MidCap Financial (MidCap), which consisted of a $3.5 million revolving credit facility (Revolver) and $10.5 million in term loans (MidCap Term Loans). The Term Loans consisted of two tranches, an $8.0 million Tranche 1 (MidCap Tranche 1) and a $2.5 million Tranche 2 (MidCap Tranche 2). In April 2018, the Company borrowed $8.0 milion of MidCap Tranche 1 and used the majority of the proceeds to repay the note payable outstanding. In conjunction with the closing of the MidCap Tranche 1 term loans, the Company issued MidCap warrants to purchase 206,897 shares of the Company's Series B redeemable convertible preferred stock at an exercise price of $1.16 per share. The warrants have a contractual term equal to the earlier of a change in control or 10 years. The estimated fair value of the warrants of $0.2 million (determined using the Black-Scholes option pricing model), along with $0.8 million of third-party and lender fees (including $0.4 million of End of Term Charge) incurred with the issuance of the debt, were recorded as the End of Term Charge and debt issuance costs and were being recognized as interest expense over the life of the Tranche 1 term loan using the effective-interest method.

The MidCap Term Loans and the Revolver bore interest at a rate equal to one-month LIBOR plus 7.0% and one-month LIBOR plus 3.75%, respectively, until the aggregate principal, interest, and End of Term Charge totaling $0.4 million were paid with part of the proceeds received from the OrbiMed Credit Facility. As a result of these payments, a $1.2 million loss on extinguishment was recorded during the year ended December 31, 2018. Interest expense associated with the Midcap Credit Facility recorded during 2018 was $0.6 million.

Note Payable

In March 2017, the Company entered into a Loan and Security Agreement (Loan Agreement) and borrowed $5.0 million (Note A). Note A bore interest at 9.45% until the aggregate principal, interest, and other termination fees were paid with part of the proceeds received from the MidCap Credit Facility. As a result of these payments, a $0.6 million loss on extinguishment was recorded during the year ended December 31, 2018. Interest expense associated with Note A recorded during both the years ended December 31, 2017 and 2018 was $0.4 million. In connection with the Loan Agreement, the Company granted 387,932 Series B warrants with an original term of 10 years with an exercise price of $1.16 per share.

Convertible Promissory Note

In January 2017, the Company issued $7.4 million of secured, convertible promissory notes (the Convertible Notes), together with warrants, primarily to holders of the Company's Series B redeemable convertible stock (Series B). The Convertible Notes bore interest at the rate of 12%.

The Convertible Notes were secured by a lien on all assets of the Company, including intellectual property and cash, and were scheduled to mature in October 2017. The principal amount of the Convertible Notes and accrued interest thereon of $0.7 million converted into 6,951,175 shares of the Company's Series B in connection with the sale of Series B to a new investor in October 2017 (note 7).

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(6) Debt

The purchasers of the Convertible Notes also received a 10-year warrant to purchase shares of the Company's Series B, with the number of shares issuable upon warrant exercise equal to 25% of the note principal divided by $1.16, or 1,591,864 warrants. The exercise price of the warrants is $1.16 per share. The estimated fair value of the warrants of $1.4 million (determined using the Black-Scholes option pricing model) was recorded as a debt discount and was fully amortized to interest expense during 2017 over the term of the Convertible Notes. In addition, in accordance with the applicable FASB accounting guidance, after considering the allocation of a portion of the proceeds to the warrants, the Company determined that the Convertible Notes contained a beneficial conversion feature (BCF). The BCF existed at the date of the issuance of the Convertible Notes due to the fact that the original carrying value of the Convertible Notes, after allocation of the proceeds, would be less than the purchase price of the series of preferred stock paid by investors in the next qualified or nonqualified financing, as defined. During the year ended December 31, 2017, the BCF of $1.4 million was fully recognized as additional interest expense.

Debt issuance costs of $0.1 million were incurred and were recorded as a discount on the carrying value of the debt, and was amortized to interest expense in 2017 through the date of conversion of the Convertible Notes.

(7) Redeemable Convertible Preferred Stock and Stockholders' Deficit

Preferred Stock

All of the Company's redeemable convertible preferred stock is classified outside of stockholders' deficit because the shares contain certain redemption features that are not solely within the control of the Company. At the time of issuance, the redeemable convertible preferred stock is recorded at its issuance price, less issuance costs.

In October 2017, the Company entered into a Stock Purchase Agreement (the Stock Purchase Agreement) with a strategic corporate investor (the Investor) pursuant to which the Company sold 12,931,034 shares of the Company's Series B at $1.16 per share for aggregate gross proceeds of $15.0 million. Transaction fees of $0.3 million were recorded as a reduction of the carrying value of the Series B. Concurrent with this financing, a total of 6,951,175 shares of Series B were issued upon conversion of the Convertible Notes plus accrued interest on such notes (note 5).

Pursuant to the Stock Purchase Agreement, the Company had a call option for an additional $10.0 million investment by the investor after the Company achieves an average of $0.8 million in product sales over three consecutive months and there having been no significant negative events for the Company (defined as changes in applicable law, departures of key employees, threat of any pending litigation or actual commencement thereof, or actions by regulators that result in withdrawal of OviTex products from the market). Further, at the request of the investor, the Company's existing stockholders or other third parties reasonably acceptable to the Company's board of directors would be required to invest $10.0 million on the same terms and conditions, including the $1.16 per share price, as sold to the investor. Also, the investor had a put option to invest up to an additional $10.0 million on or before September 15, 2018. Both the put and call option expired unexercised in September 2018. The investor has the same rights of other holders of the Company's Series B. Additionally, the investor was granted one board seat and certain information rights. The Company has also agreed to certain restrictions related to diluting the Company's ownership and soliciting a sale to a third party.

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(7) Redeemable Convertible Preferred Stock and Stockholders' Deficit (Continued)

Throughout 2018, the Company entered into various stock purchase agreements with new and existing investors pursuant to which the Company sold an aggregate 3,607,069 shares of the Company's Series B at $1.16 per share for aggregate gross proceeds of $4.2 million. Transaction fees of $0.2 million were recorded as a reduction of the carrying value of the Series B.

Dividends

The holders of the Series A redeemable convertible stock (Series A) and Series B are entitled to receive cumulative dividends (noncompounding) at a rate per year of 8% of the original issuance price of $1.00 and $1.16, respectively. As of December 31, 2018, no dividends have been declared.

Liquidation Preference

Upon the liquidation, sale, or merger of the Company (collectively, the Liquidation), each holder of Series A and Series B is entitled to receive an amount equal to $1.00 per share for Series A and $1.16 per share for Series B, plus all dividends whether declared or not (Initial Liquidation Payments) with the Series B holding preference to the Series A. If there are additional available assets from the Liquidation after the initial liquidation payments, the remaining available assets will be distributed to common and preferred shareholders' pro rata in proportion to the number of common shares then held by each shareholder with each share of preferred stock treated as the number of shares of common stock into which such share would be converted into assuming conversion immediately prior to the Liquidation, however, that the total amount payable to the holders of the Series A and the Series B upon the Liquidation is capped at an amount equal to five (5) times the original issuance price of the Series A and B, respectively.

Conversion

Each share of Series A and Series B is convertible, at the holder's option, into such number of shares of common stock equal to (i) Series A and Series B issue price divided by the conversion price then in effect (which conversion price is initially equal to $1.00 for Series A and $1.16 for Series B) plus (ii) an amount equal to all accrued but unpaid dividends divided by the fair value of common stock on the day immediately preceding the date of conversion, unless the Company has elected to pay the dividend amount in cash upon conversion. The conversion price of the Series A and Series B is subject to weighted average antidilution protection such that, in the event the Company issues shares of Common stock or securities convertible into shares of Common stock at an effective per-share price less than the conversion price then in effect, the conversion price shall be reduced to the effective price per share for such additional shares of common stock. The Company's redeemable convertible preferred stock will convert automatically into common stock upon the closing of an initial public offering (IPO) offering. Upon the closing of an IPO, the holders of redeemable convertible preferred stock will also be entitled to accrued but unpaid dividends.

Redemption

If so elected by the holders of at least two-thirds of Series A and 90% of Series B of the then outstanding Series A and Series B, at any time on or after October 2, 2019, the Company shall redeem all of the Series A and Series B held by holders who elected to have their stock redeemed. The redemption price per share is the greater of (a) the original issue price of Series A and Series B plus any accrued but unpaid dividends and (b) the fair value for such shares on the redemption date as agreed upon by the Company's board of directors and the holders of at least two-thirds of the then outstanding Series A and 90% of the then outstanding Series B. The shares shall be redeemed in a single cash payment.

Voting Rights

The holders of the Series A and Series B are each entitled to elect two of seven members of the Company's board of directors. Approval of at least two-thirds of the holders of Series A and Series B is required for

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(7) Redeemable Convertible Preferred Stock and Stockholders' Deficit (Continued)

certain significant corporate events (liquidation or sale of the Company, business acquisition, and in-license material intellectual property rights, among other items). Additionally, as part of the Stock Purchase Agreement entered into between the Company and the investor described above, the investor was granted the right to appoint one member to the Company's board of directors and exercised this right in October 2017.

Warrants

The Company had the following warrants outstanding to purchase Series B at December 31, 2018:

	Outstanding	Exercise price	Expiration dates
Preferred stock warrants issued to MidCap	206,897	1.16	2028
Preferred stock warrants issued to note payable holders	387,932	1.16	2027
Preferred stock warrants issued to convertible promissory note holders	1,591,864	1.16	2027
	2,186,693		

The Company accounts for its warrants to purchase shares of redeemable convertible preferred stock issued as liabilities as they are exercisable for a redeemable instrument. The Company will continue to adjust the liability for changes in fair value of these warrants until the earlier of (1) exercise of warrants, (2) expiration of warrants, (3) a change of control of the Company, or (4) the consummation of the Company's initial public offering, at which time the liability will be reclassified to stockholders' deficit.

(8) Stock-Based Compensation

In 2012, the Company adopted the 2012 Stock Incentive Plan (the Plan), which was later amended and restated, pursuant to which 961,781 shares were available for future issuances as of December 31, 2018. The Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock awards, and/or stock appreciation rights to employees, directors, and other persons, as determined by the Company's board of directors. On March 1, 2019, the board of director's increased the numbers of shares available under the plan by 1,400,000 shares. 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 on a straight-line basis over the vesting period of the award. The Company recorded

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(8) Stock-Based Compensation (Continued)

stock-based compensation expense in the following expense categories of its accompanying consolidated statements of operations (in thousands):

	Year ended December 31,	
	2017	2018
Sales and marketing	$ 44	$ 68
General and administrative	116	115
Research and development	37	33
Total stock-based compensation	$ 197	$ 216

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, 2017	6,970,762	$ 0.23	
Granted	2,088,700	0.24	
Exercised	(10,000)	0.21	
Early exercised	(20,500)	0.24	
Canceled/forfeited	(364,820)	0.24	
Outstanding at December 31, 2017	8,664,142	0.24	
Granted	3,753,816	0.24	
Exercised	(34,111)	0.23	
Early exercised	(10,600)	0.24	
Canceled/forfeited	(294,090)	0.24	
Outstanding at December 31, 2018	12,079,157	$ 0.24	7.65
Vested and expected to vest at December 31, 2018	12,079,157	$ 0.24	7.65
Exercisable at December 31, 2018	6,278,779	$ 0.23	6.66

The 2012 Plan provides the holders of stock options an election to early exercise prior to vesting. The Company has 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, 2018, $5,000 of proceeds from early exercised options are recognized as a current liability in accrued expenses in the accompanying consolidated balance sheet.

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(8) Stock-Based Compensation (Continued)

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

	Number of shares
Unvested balance at January 1, 2017	176,908
Early exercised	20,500
Vested	(171,834)
Unvested balance at December 31, 2017	25,574
Early exercised	10,600
Vested	(13,627)
Unvested balance at December 31, 2018	22,547

The weighted average grant-date fair value per share of options granted was $0.02 and $0.04 for the years ended December 31, 2017 and 2018, respectively. The aggregate intrinsic value of options exercised was nominal for the year ended December 31, 2018. As of December 31, 2018, the total unrecognized compensation expense related to unvested employee and nonemployee stock option awards was $0.2 million, which is expected to be recognized in expense over a weighted-average period of approximately 2.26 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 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.

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(8) Stock-Based Compensation (Continued)

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,	
	2017	2018
Expected dividend yield	—	—
Expected volatility	50.0%	56.5%
Risk-free interest rate	2.07%	2.77%
Expected term	6.25 Years	6.25 Years

(9) Employee Benefit Plans

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 profit-sharing contributions made by the Company, if any, are determined annually by the board of directors. To date, the Company has not made discretionary profit-sharing contributions under the 401(k) plan. 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.

(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 as of December 31, 2017 and 2018 consisted of the following (in thousands):

	December 31,	
	2017	2018
Deferred tax assets		
Net operating loss carryforwards	$ 21,660	$ 26,993
Research and development credits	533	701
Depreciation and amortization	706	825
Accrued LifeCell settlement	724	252
Accrued expenses and other	94	191
Inventory reserve	122	425
Gross deferred tax asset	23,839	29,387
Valuation allowance	(23,839)	(29,387)
Net deferred tax asset	$ —	$ —

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(10) Income Taxes (Continued)

The Company does not have unrecognized tax benefits as of December 31, 2017 and 2018. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

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

	December 31,	
	2017	2018
NOL carryforwards		
Federal	$ 79,182	$ 99,939
State	79,484	91,797

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, 2017 and 2018 because of the uncertainty of their realization. The valuation allowance increased by $5.5 million for the year ended December 31, 2018, mainly due to losses incurred, and decreased by $3.2 million for the year ended December 31, 2017, mainly due to the reduction in the tax rate.

In December 2017, the Tax Cuts and Jobs Act (the Tax Act) was enacted. The Tax Act includes a number of changes to existing U.S. tax laws that impact the Company, most notably a reduction of the U.S. corporate income tax rate from 34% to 21% for tax years beginning after December 31, 2017. The Tax Act also provides for a onetime transition tax on certain foreign earnings and the acceleration of depreciation for certain assets placed into service after September 27, 2017 as well as prospective changes beginning in 2018, including repeal of the domestic manufacturing deduction, acceleration of tax revenue recognition, capitalization of research and development expenditures, additional limitations on executive compensation, and limitations on the deductibility of interest.

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.

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(10) Income Taxes (Continued)

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

	Year ended December 31,	
	2017	2018
Rate reconciliation		
Federal tax benefit at statutory rate	(34.0)%	(21.0)%
State rate, net of federal benefit	(5.2)	(4.7)
Permanent differences	5.5	0.5
Change in federal rate	48.0	—
Research and development	—	(0.8)
Change in valuation allowance	(15.1)	26.3
Other	0.8	(0.3)
Total tax provision	—%	—%

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. The Company's 2012 to 2017 tax years remain subject to examination.

(11) Contingencies and Commitments

Legal Proceedings

On November 18, 2016, the Company and LifeCell Corporation (LifeCell) agreed to settle litigation initiated by LifeCell in March 2015 related to LifeCell's complaints alleging (i) that the Company misappropriated LifeCell's trade secrets and proprietary information and hired various former LifeCell employees allegedly in violation of their noncompetition covenants and nonsolicitation agreements and (ii) that the Company infringed U.S. Patent No. 6,143,293, (the 293 patent), which LifeCell had recently purchased from Carnegie Mellon University. Both cases have been dismissed with prejudice. As part of this settlement, LifeCell agreed not to sue the Company, either directly or through a person acting at its request or with its involvement for patent infringement, trade secret misappropriation, breach of an assignment obligation, unfair competition, unjust enrichment, tortious interference with contract and prospective economic advantage, civil conspiracy, or like causes of action with respect to OviTex. Also, as part of this settlement agreement, among other provisions, the Company agreed to pay LifeCell $1.0 million within 30 days of the execution of the settlement agreement and up to an additional $3.0 million based upon the Company achieving set revenue milestones for its OviTex product family. Through December 31, 2018, the Company has paid $3.0 million to LifeCell. The Company will owe the remaining $1.0 million upon achieving a certain amount of cumulative sales of OviTex. The estimated present value of the future revenue milestone payments was $2.8 million and $1.0 million at December 31, 2017 and 2018, respectively. The Company recorded $1.9 million and $0.9 million in other current and other long-term liabilities, respectively, at December 31, 2017, and $1.0 million in other current liabilities at December 31, 2018, in the accompanying consolidated balance sheets, based on when the payments were expected to be made at each respective balance sheet date. Noncash interest expense of $0.3 million and $0.2 million was recorded

(11) Contingencies and Commitments (Continued)

during 2017 and 2018, respectively, for the change in estimated present value of the future revenue milestone payments.

Legal and other costs incurred in defense of the Company was charged to expense as incurred and totaled $0.4 million for the year ended December 31, 2017 and were recorded in general and administrative expenses in the accompanying consolidated statement of operations. No legal defense costs were incurred in 2018.

On February 12, 2016, the Company filed suit against National Union Fire Insurance Company of Pittsburgh, Pennsylvania (National Union), the former carrier for the Company's Directors & Officers and Employment Practices Liability Insurance. The complaint charged National Union with breach of contract and failure to reimburse the Company for defense costs it incurred in the LifeCell litigation discussed above that the Company believes are covered under the insurance policy sold by National Union. The complaint sought reimbursement of $5.0 million, the full limit of the policy, as well as reimbursement of the Company's costs pursuing the action against National Union. In 2018, the Company settled the suit and received $2.4 million and paid its broker $0.2 million and recognized the net amount of $2.2 million as a gain on litigation settlement in the Company's consolidated statement of operations during the year ended December 31, 2018.

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 (Umbrella Agreement) with Aroa. The Umbrella 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 later of August 3, 2022 or expiration of the last patent covering the products (currently July 30, 2029). 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 United States but was subsequently amended in March 2013 to include the European Union and certain former Union of Soviet Socialist Republic satellite nations.

The financial terms of this Umbrella Agreement, as amended, include (i) the payment of $1.0 million and the issuance of 1,834,867 shares of the Company's common stock valued at $0.3 million concurrent with the closing of the December 2012 financing, (ii) the payment of $1.0 million upon the amendment of the Umbrella Agreement in March 2013, and (iii) the payment of $1.0 million upon the approval by the U.S. Food and Drug Administration (FDA) of the use of Aroa's product for certain indications (paid in June 2013). All amounts paid were recorded at the time within in-process research and development expense in the consolidated statements of operations as the Company believes that the technology licensed from Aroa required substantial additional development efforts and had no alternative future uses to the Company. In April 2014, the Company submitted a new 510(k) application to the FDA incorporating the licensed technologies, as well as technology licensed from a second strategic partner. The Umbrella Agreement also

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(11) Contingencies and Commitments (Continued)

requires future payments aggregating up to $4.0 million upon the achievement of U.S. and European cumulative product sales targets.

In 2018, it became probable that the Company would be issued CE Mark approval to sell OviTex in Europe by the European Medical Agency, and the Company recognized a $1.0 million liability and a corresponding developed right intangible asset related to this milestone payment owed to Aroa. Of this amount, $0.5 million was paid in 2018 and the remaining $0.5 million was paid in 2019.

With respect to the sales milestone payments in the North American territory, a payment of $1.0 million and $2.0 million are due when cumulative product sales in the North American territory reach certain amounts. In 2018, it became probable that the Company would achieve the sales milestones in the North American territory, and, as such, the Company recorded a liability of $3.0 million and a corresponding developed technology right intangible asset. The Company paid $1.0 million to Aroa in 2018 related to one of the cumulative product sales targets. 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 Umbrella agreement in addition to those disclosed above are as follows:

- The transfer price for product produced by Aroa was increased from 150% of Aroa's cost of goods sold to 200% of the cost of goods sold, with the quarterly true-up amount continuing to equal 27% of the Company's net sales of the licensed product reduced by transfer price payments previously made for the respective quarter. The purchase commitments aggregate to $11.0 million for the North American territory over a five-year period, consisting of $2.0 million in total in years one and two, $2.0 million in year three, $3.0 million in year four, and $4.0 million in year five. The purchase commitments aggregate to $2.8 million for the European territory over a five-year period, consisting of $0.5 million in total in years one and two, $0.5 million in year three, $0.8 million in year four, and $1.0 million in year five. In addition, the Company continues to be required to pay a make whole payment if the required minimum purchase commitments for each territory for the corresponding contract years are not made. As of December 31, 2018, the Company has met its aggregate North American first two year and year three purchase commitments and no make whole payments are required for those periods. The period for the purchase commitments for the North American territory for years four and five end in June 2020 and June 2021, respectively. 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.

- To avoid losing rights to a licensed product in a specific indication within the North American territory or the European territory, the Company must comply with separate product development goals by indication for each territory. The goal for the abdominal wall reconstruction/hernia repair product for the North American territory was a commercial launch of a product by July 16, 2016. The Company met the North American goal deadline with the successful launch of OviTex in June 2016. The European goal deadline for the abdominal wall reconstruction/hernia repair product was a commercial launch of a product by July 16, 2017. While the Company did not meet the European

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(11) Contingencies and Commitments (Continued)

goal deadline, on August 8, 2017, following negotiations relating to the requirement regarding possible extension payments, the Company paid Aroa $0.5 million to extend the European goal deadline. Concurrent with this extension payment, as Aroa is responsible for the regulatory approval to market OviTex in the European territory, and as such approval is a prerequisite for commercial launch, the Company and Aroa agreed that the Company would only be required to make further payments to extend the European goal deadline if commercial launch of the product is not achieved in the European territory within eight months after the receipt of regulatory approval for the product in the European territory, or on July 16, 2018, whichever is later. The Company commercially launched OviTex in the European territory in 2018 within the necessary timeframe, and no further extension payments will be required.

- Separate product development/launch goals and extension rights exist for a breast reconstruction product, as well as other products in specified indications for use. With respect to the breast reconstruction product, the goal was to file an investigational device exemption with the FDA for the North American territory by December 28, 2017, 18 months after the commercial launch of OviTex in the North American territory. The Company met this deadline with the filing of an investigational device exemption (IDE) application with the FDA on November 22, 2017. The goal for the European territory is to file for a CE Mark by January 16, 2019. The Company extended the European deadline and paid $0.5 million. Concurrent with the extension payment, the Company agreed to assume responsibility in obtaining regulatory approval in Europe with a new regulatory filing deadline of June 30, 2020. The Company expects to meet the filing deadline and that no further extension payments will be required.

- 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.

- The Company is responsible for the payment of 50% of the capital costs of any manufacturing expansion plan agreed upon by the parties, provided that any such payments made by the Company will be offset against future revenue sharing amounts payable (revenue share of 27% of the Company's net sales of the licensed product).

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, 2018, the Company had $0.7 million in purchase commitments with Aroa.

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.

TELA BIO, INC.

Notes to Consolidated Financial Statements (Continued)

(11) Contingencies and Commitments (Continued)

Operating Leases

The Company leases office and laboratory space in Malvern, Pennsylvania under a noncancelable lease, which expires in May 2021. The facility lease agreement has annual scheduled payment increases. Under the lease agreement, the lessor provided $0.2 million of tenant improvements payments to the Company for partial reimbursement of leasehold improvements. The Company is recognizing the rent expense on a straight-line basis over the lease term. The Company recognized rent expense of $0.3 million for both the years ended December 31, 2017 and 2018.

The future minimum lease payments under the facility operating lease agreement as of December 31, 2018 are as follows (in thousands):

2019	$	209
2020		217
2021		92
	$	518

(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.

(13) Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through August 16, 2019, the date at which the consolidated financial statements were available to be issued, and there are no other items requiring disclosure except for the following:

During 2019, the Company sold 12,018,473 shares of Series B to new and existing investors at $1.16 per share in exchange for net proceeds of $14.0 million at the same terms as all other Series B shareholders, which are described in note 7.

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

	December 31, 2018	June 30, 2019	Pro forma June 30, 2019
Assets			
Current assets:			
Cash and cash equivalents	$ 17,278	$ 15,873	
Accounts receivable	1,298	1,897	
Inventory	4,348	4,599	
Prepaid expenses and other	330	384	
Total current assets	23,254	22,753	
Property and equipment, net	758	712	
Intangible assets, net	3,215	3,063	
Deferred offering costs	—	99	
Total assets	$ 27,227	$ 26,627	
Liabilities, redeemable convertible preferred stock, and stockholders' deficit			
Current liabilities:			
Accounts payable	$ 3,421	$ 2,109	
Accrued expenses	5,153	4,533	
Other current liabilities	985	1,007	
Total current liabilities	9,559	7,649	
Long-term debt with related party	29,733	29,977	
Preferred stock warrant liability	1,640	1,678	
Other long-term liabilities	5	7	
Total liabilities	40,937	39,311	
Redeemable convertible preferred stock; $0.001 par value:			
Series A preferred stock: actual: 22,501,174 shares authorized, issued, and outstanding at December 31, 2018 and June 30, 2019; liquidation value of $34,005 at June 30, 2019; pro forma: no shares authorized, issued, or outstanding	33,112	34,005	
Series B preferred stock: actual: 82,891,619 shares authorized, 63,032,500 and 73,587,014 issued and outstanding at December 31, 2018 and June 30, 2019, respectively; liquidation value of $106,165 at June 30, 2019; pro forma: no shares authorized, issued, or outstanding	91,038	107,058	
Total redeemable convertible preferred stock	124,150	141,063	
Stockholders' deficit:			
Common stock; $0.001 par value: actual: 127,157,585 shares authorized; 7,323,795 and 7,372,350 shares issued and 7,301,248 and 7,345,531 shares outstanding at December 31, 2018 and June 30, 2019, respectively; pro forma: shares authorized; shares issued and outstanding at June 30, 2019	7	7	
Additional paid-in capital	—	—	
Accumulated other comprehensive loss	—	(3)	
Accumulated deficit	(137,867)	(153,751)	
Total stockholders' deficit	(137,860)	(153,747)	
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 27,227	$ 26,627	

See accompanying notes to unaudited interim consolidated financial statements.

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

	Six months ended June 30,	
	2018	2019
Revenue	$ 3,635	$ 6,609
Cost of revenue (excluding amortization of intangible assets)	2,455	2,752
Amortization of intangible assets	633	152
Gross profit	547	3,705
Operating expenses:		
Sales and marketing	6,022	7,942
General and administrative	1,967	2,529
Research and development	2,318	2,714
Total operating expenses	10,307	13,185
Loss from operations	(9,760)	(9,480)
Other (expense) income:		
Interest expense	(728)	(1,826)
Loss on extinguishment of debt	(615)	—
Change in fair value of preferred stock warrant liability	174	(38)
Other income	34	117
Total other (expense) income	(1,135)	(1,747)
Net loss	(10,895)	(11,227)
Accretion of redeemable convertible preferred stock to redemption value	(7,948)	(4,787)
Net loss attributable to common stockholders	$ (18,843)	$ (16,014)
Net loss per common share, basic and diluted	$ (2.59)	$ (2.19)
Weighted average common shares outstanding, basic and diluted	7,273,968	7,313,934
Pro forma net loss per common share basic and diluted		
Pro forma weighted average shares outstanding, basic and diluted		
Comprehensive loss:		
Net loss	$ (10,895)	$ (11,227)
Foreign currency translation adjustment	—	(3)
Comprehensive loss	$ (10,895)	$ (11,230)

See accompanying notes to unaudited interim consolidated financial statements.

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

	Redeemable convertible preferred stock				Stockholders' deficit					
	Series A		Series B		Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at January 1, 2018	22,501,174	$ 30,940	59,425,431	$ 80,409	7,253,510	$ 7	$ —	$ —	$ (108,178)	$ (108,171)
Vesting of common stock previously subject to repurchase	—	—	—	—	8,017	—	2	—	—	2
Exercise of stock options	—	—	—	—	25,042	—	5	—	—	5
Sale of Series B redeemable convertible preferred stock, net of stock issue costs of $143	—	—	1,294,069	1,358	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	108	—	—	108
Accretion of redeemable convertible preferred stock to redemption value	—	1,265	—	6,683	—	—	(115)	—	(7,833)	(7,948)
Net loss	—	—	—	—	—	—	—	—	(10,895)	(10,895)
Balance at June 30, 2018	22,501,174	$ 32,205	60,719,500	$ 88,450	7,286,569	$ 7	$ —	$ —	$ (126,906)	$ (126,549)
Balance at January 1, 2019	22,501,174	$ 33,112	63,032,500	$ 91,038	7,301,248	$ 7	$ —	$ —	$ (137,867)	$ (137,860)
Vesting of common stock previously subject to repurchase	—	—	—	—	7,409	—	3	—	—	3
Exercise of stock options	—	—	—	—	36,874	—	8	—	—	8
Sale of Series B redeemable convertible preferred stock, net of stock issue costs of $117	—	—	10,554,514	12,126	—	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	—	—	(3)	—	(3)
Stock-based compensation expense	—	—	—	—	—	—	119	—	—	119
Accretion of redeemable convertible preferred stock to redemption value	—	893	—	3,894	—	—	(130)	—	(4,657)	(4,787)
Net loss	—	—	—	—	—	—	—	—	(11,227)	(11,227)
Balance at June 30, 2019	22,501,174	$ 34,005	73,587,014	$ 107,058	7,345,531	$ 7	$ —	$ (3)	$ (153,751)	$ (153,747)

See accompanying notes to unaudited interim consolidated financial statements.

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

	Six months ended June 30,	
	2018	2019
Cash flows from operating activities:		
Net loss	$ (10,895)	$ (11,227)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	309	135
Noncash loss on extinguishment of debt	513	—
Noncash interest expense	333	244
Amortization of intangible assets	633	152
Inventory excess and obsolescence charge	1,411	916
Change in fair value of warrants	(174)	38
Stock-based compensation expense	108	119
Changes in operating assets and liabilities:		
Accounts receivable	(475)	(599)
Inventory	(2,587)	(1,169)
Prepaid expenses and other assets	100	(156)
Accounts payable	324	(1,312)
Accrued expenses and other liabilities	(447)	(123)
Net cash used in operating activities	(10,847)	(12,982)
Cash flows from investing activities:		
Payment for intangible asset	—	(500)
Purchase of property and equipment	(31)	(89)
Net cash used in investing activities	(31)	(589)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt and preferred stock warrants	8,000	—
Repayment of long-term debt	(5,000)	—
Borrowings under revolving credit facility	2,741	—
Repayments of revolving credit facility	(1,487)	—
Proceeds from issuance of Series B redeemable preferred stocks, net	1,358	12,158
Payment of deferred financing costs	(830)	—
Proceeds from exercise of stock options	5	8
Net cash provided by financing activities	4,787	12,166
Net decrease in cash and cash equivalents	(6,091)	(1,405)
Cash and cash equivalents, beginning of period	11,346	17,278
Cash and cash equivalents, end of period	$ 5,255	$ 15,873
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 395	$ 1,582
Cash paid on loss on extinguishment of debt	$ 102	$ —
Supplemental disclosures of noncash investing and financing activities:		
Fair value of warrants issued in connection with equity and debt financing	$ 187	$ —
Accretion of redeemable preferred stock to redemption value	$ 7,948	$ 4,787
Intangible assets in accrued expenses and other liabilities	$ 4,000	$ 2,000
Offering costs in accrued expenses	$ —	$ 32
Issuance of common stock for early exercised stock options	$ 2	$ 3

See accompanying notes to unaudited interim consolidated financial statements.

TELA BIO, INC.

Notes to Unaudited Interim 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 focused on the commercialization and sale of OviTex, which utilizes surgical reconstruction medical device technology licensed from a strategic partner and on the research and development of additional medical devices with this strategic partner and on other internally developed technologies. In April 2019, the Company received 510(k) clearance from the United States Food and Drug Administration (FDA) for OviTex PRS — Restella Reconstructive Bioscaffold, or Restella, which addresses unmet needs in plastic reconstruction surgery. The Company's principal corporate office and research facility is located in Malvern, Pennsylvania.

(2) Risks and Liquidity

The Company's operations to date have focused on organization and staffing, business planning, raising capital, developing and acquiring technology and assets, and commercializing products. The Company has incurred recurring losses and negative cash flows from operations since inception and has an accumulated deficit of $153.8 million as of June 30, 2019. The Company anticipates incurring additional losses until such time, if ever, it can generate sufficient revenue from its products to cover its expenses and has limited resources available to fund current commercialization and research and development activities. As such, additional financings will be needed by the Company to fund its operations and to develop its products. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The accompanying unaudited interim consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Management is currently evaluating different strategies to obtain the required funding of future operations. These strategies may include, but are not limited to, additional funding from current investors, funding from new investors including strategic corporate investors, an initial public offering of the Company's common stock, and/or borrowings of additional debt, among others. There can be no assurance these future funding efforts will be successful.

Management believes that the Company's cash and cash equivalents as of June 30, 2019, along with the $1.7 million in net proceeds received from the sale of Series B in July 2019 (note 9), availability of borrowing under the credit facility, and anticipated cash receipts from sales of products are sufficient to fund operations into the second quarter of 2020.

The operations of the Company are subject to certain risks and uncertainties including, among others, uncertainty of product development; 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

The Company's complete summary of significant accounting policies can be found in "Note 3, Summary of Significant Accounting Policies" in the audited consolidated financial statements included elsewhere in this prospectus. Any reference in these notes to applicable guidance is meant to refer to generally accepted accounting principles in the United States (GAAP) as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) promulgated by the Financial Accounting Standards Board (FASB).

TELA BIO, INC.

Notes to Unaudited Interim Consolidated Financial Statements (Continued)

(3) Summary of Significant Accounting Policies (Continued)

Interim Financial Statements

The accompanying unaudited interim consolidated financial statements have been prepared from the books and records of the Company in accordance with GAAP for interim financial information and Rule 10-01 of Regulation S-X promulgated by the U.S. Securities and Exchange Commission (SEC), which permits reduced disclosures for interim periods. All adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the accompanying consolidated balance sheets and statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows have been made. Although these interim consolidated financial statements do not include all of the information and footnotes required for complete annual consolidated financial statements, management believes the disclosures are adequate to make the information presented not misleading. Unaudited interim results of operations and cash flows are not necessarily indicative of the results that may be expected for the full year. Unaudited interim consolidated financial statements and footnotes should be read in conjunction with the audited consolidated financial statements and footnotes included elsewhere in this prospectus, wherein a more complete discussion of significant accounting policies and certain other information can be found.

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 the fair value of redeemable convertible preferred stock, preferred stock warrant liability and 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.

Unaudited Pro Forma Financial Information

Immediately prior to the closing of an initial public offering, all of the Company's outstanding redeemable convertible preferred stock will automatically convert into common stock. The unaudited pro forma balance sheet as of June 30, 2019 assumes (1) the issuance of 1,463,959 shares of Series B redeemable convertible preferred stock that were sold in July 2019 for net proceeds of $1.7 million (2) the automatic conversion of all outstanding shares of redeemable convertible preferred stock including accrued dividends payable into shares of common stock based on an assumed initial public offering price of $, and (3) the reclassification of $1.7 million preferred stock warrant liability into additional paid-in capital upon the conversion of all outstanding warrants to purchase shares of Series B redeemable convertible preferred stock into warrants to purchase shares of common stock. In the consolidated statements of operations and comprehensive loss, unaudited pro forma basic and diluted net loss per share of common stock outstanding has been prepared to give effect to the automatic conversion of all outstanding shares of redeemable convertible preferred stock including dividend payable as if this proposed initial public offering had occurred on the later of the beginning of the reporting period or the issuance date of the redeemable convertible preferred stock.

Deferred Offering Costs

The Company capitalizes certain legal, accounting, and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs will be recorded as a reduction of additional paid-in capital generated as a result of the offering. Should the equity financing no longer be considered probable

TELA BIO, INC.

Notes to Unaudited Interim Consolidated Financial Statements (Continued)

(3) Summary of Significant Accounting Policies (Continued)

of being consummated, all deferred offering costs would be charged to operating expenses in the consolidated statement of operations. Deferred offering costs were $0.1 million at June 30, 2019.

Revenue Recognition

The Company accounts for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, which was adopted on January 1, 2019, using the modified retrospective method. The adoption of this guidance had no cumulative adjustment to the Company's consolidated financial statements as of the adoption date. Under ASC Topic 606, 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 consigned inventory maintained at hospitals or with sales representatives. 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 that 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. The Company uses an observable price to determine the selling price of the single performance obligation.

Payment terms with customers do not exceed one year and, therefore, the Company does not account for a financing component in its arrangements. 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.

Prior to the adoption of ASC Topic 606, revenue was recognized when persuasive evidence of an arrangement existed, the price was fixed or determinable, delivery had occurred, and there was a reasonable assurance of collection of the sales proceeds. Revenue for products sold to a customer was recognized when the product was shipped to the customer, at which time title passed to the customer. In the case of consigned inventory, revenue was recognized when the product was utilized in a surgical procedure.

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, prepaid expenses 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 the OrbiMed Credit Facility (note 5), it is impractical to determine the fair value of the

TELA BIO, INC.

Notes to Unaudited Interim Consolidated Financial Statements (Continued)

(3) Summary of Significant Accounting Policies (Continued)

debt. Items measured at fair value on a recurring basis include the Company's preferred stock warrants. The warrants are carried at their estimated fair value. The Company follows the provisions of FASB 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).

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, 2018 and June 30, 2019 (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)
December 31, 2018:			
Assets:			
Cash equivalents – money market fund	$ 16,002	$ —	$ —
Liability:			
Warrant liability	$ —	$ —	$ 1,640
June 30, 2019:			
Assets:			
Cash equivalents – money market fund	$ 4,444	$ —	$ —
Liability:			
Warrant liability	$ —	$ —	$ 1,678

A rollforward of the warrant liability (Level 3 measurement) is as follows:

January 1, 2019	$ 1,640
Change in fair value of warrants	38
June 30, 2019	$ 1,678

TELA BIO, INC.

Notes to Unaudited Interim Consolidated Financial Statements (Continued)

(3) Summary of Significant Accounting Policies (Continued)

The fair value of the warrants at June 30, 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	57.7%	57.2%	57.4%
Risk-free interest rate	2.00%	1.87%	1.87%
Remaining contractual term in years	8.8	7.6	7.8

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 entitles the holders of such shares to participate in distributions but contractually does not require the holders of such shares to participate in losses of the Company. Accordingly, 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.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares outstanding as of June 30, 2018 and 2019, as they would be antidilutive.

	Six months ended June 30,	
	2018	2019
Series A redeemable convertible preferred stock	22,501,174	22,501,174
Series B redeemable convertible preferred stock	60,719,500	73,587,014
Stock options (including shares subject to repurchase)	11,677,068	13,100,999
Series B redeemable convertible preferred stock warrants	2,186,693	2,186,693
Total	97,084,435	111,375,880

TELA BIO, INC.

Notes to Unaudited Interim Consolidated Financial Statements (Continued)

(3) Summary of Significant Accounting Policies (Continued)

The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the six months ended June 30, 2019 give effect to the conversion upon the initial public offering of all outstanding shares of redeemable convertible preferred stock as of June 30, 2019, into shares of common stock as if the conversion had occurred on the later of the beginning of the reporting period or the issuance date of the redeemable convertible preferred stock. The unaudited pro forma net loss per share also gives effect to the shares of common stock of which the proceeds would be necessary to pay the dividend amount of to the holders of redeemable convertible preferred stock at the initial public offering price of $ per share.

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Six months ended June 30, 2019
Numerator:	
Net loss attributable to common stockholders	$
Pro forma adjustments:	
Accretion of redeemable convertible preferred stock	
Change in fair value of preferred stock warrant liability	
Pro forma net loss per common share, basic and diluted	$
Denominator:	
Weighted average shares of common stock outstanding, basic and diluted	
Pro forma adjustments	
Conversion of redeemable convertible preferred stock and related payment of dividends	
Pro forma weighted average common shares outstanding, basic and diluted	
Pro forma net loss per share, basic and diluted	

TELA BIO, INC.

Notes to Unaudited Interim Consolidated Financial Statements (Continued)

(4) Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2018	June 30, 2019
Compensation and related benefits	$ 1,760	$ 1,672
Interest	42	42
Professional fees	552	391
Accrued milestone payments	2,500	2,000
Research and development expenses	133	142
Other	166	286
	$ 5,153	$ 4,533

(5) Long-term Debt

Long-term debt consisted of the following at December 31, 2018 and June 30, 2019 (in thousands):

	December 31, 2018	June 30, 2019
OrbiMed Term Loan (related party)	$ 30,000	$ 30,000
End of Term Charge	3,000	3,000
Unamortized issuance costs	(3,267)	(3,023)
Long-term debt	$ 29,733	$ 29,977

OrbiMed Term Loan (Related Party)

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 Term Loans 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 and used a portion of the proceeds to repay the MidCap Credit Facility (described below) and will use the remaining proceeds to fund operations and capital expenditures. The Company will be eligible to borrow Tranche 2 until December 31, 2019, provided the Company's consolidated revenue on a trailing six-month basis equals or exceeds $7.5 million. 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 event, (xi) regulatory matters, (xii) and key contracts. In addition, the Company must maintain a minimum cash balance of $2.0 million. In the event of default under the OrbiMed Credit Facility, the Company would be required to pay interest on principal and all other due and unpaid obligations at the current rate in effect plus 3%.

TELA BIO, INC.

Notes to Unaudited Interim Consolidated Financial Statements (Continued)

(5) Long-term Debt (Continued)

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%. At June 30, 2019, the interest rate was 10.25%. 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). The Company is also required to pay 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 $3.3 million of third-party and lender fees, which were recorded as along with the End of Term Charge and debt issuance costs, and are being recognized as interest expense over the term of the loan along with using the effective-interest method. Interest expense associated with the OrbiMed Credit Facility recorded during the six months ended June 30, 2019 was $1.8 million, $0.2 million related to the amortization of debt issuance costs.

(6) Redeemable Convertible Preferred Stock and Stockholders' Deficit

Preferred Stock

During the six months ended June 30, 2019, the Company entered into various stock purchase agreements with new and existing investors pursuant to which the Company sold an aggregate 10,554,514 shares of the Company's Series B redeemable convertible preferred stock (Series B) at $1.16 per share for aggregate gross proceeds of $12.2 million. Transaction fees of $0.1 million were recorded as a reduction of the carrying value of the Series B.

Warrants

The Company had the following warrants outstanding to purchase Series B at June 30, 2019:

	Outstanding	Exercise price	Expiration dates
Preferred stock warrants issued to MidCap	206,897	1.16	2028
Preferred stock warrants issued to note payable holders	387,932	1.16	2027
Preferred stock warrants issued to convertible promissory note holders	1,591,864	1.16	2027
	2,186,693		

The Company accounts for its warrants to purchase shares of redeemable convertible preferred stock issued as liabilities as they are exercisable for a redeemable instrument. The Company will continue to adjust the liability for changes in fair value of these warrants until the earlier of (1) exercise of warrants, (2) expiration of warrants, (3) a change of control of the Company, or (4) the consummation of the Company's initial public offering, at which time the liability will be reclassified to stockholders' deficit.

TELA BIO, INC.

Notes to Unaudited Interim Consolidated Financial Statements (Continued)

(7) Stock-Based Compensation

In 2012, the Company adopted the 2012 Stock Incentive Plan (the Plan), which was later amended and restated, pursuant to which 1,318,203 shares were available for future issuances as of June 30, 2019. The Plan provides for the grant of incentive stock options, nonqualified stock options, restricted stock awards, 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 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 on a straight-line basis 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):

	Six months ended June 30,	
	2018	2019
Sales and marketing	$ 30	$ 30
General and administrative	58	72
Research and development	20	17
Total stock-based compensation	$ 108	$ 119

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	12,079,157	$ 0.24	
Granted	1,400,500	0.24	
Exercised	(36,874)	0.24	
Early exercised	(11,681)	0.24	
Canceled/forfeited	(356,922)	0.24	
Outstanding at June 30, 2019	13,074,180	0.24	7.43
Vested and expected to vest at June 30, 2019	13,074,180	$ 0.24	7.43
Exercisable at June 30, 2019	7,649,251	$ 0.23	6.50

The 2012 Plan provides the holders of stock options an election to early exercise prior to vesting. The Company has the right, but not the obligation, to repurchase early exercised options without transferring any

TELA BIO, INC.

Notes to Unaudited Interim Consolidated Financial Statements (Continued)

(7) Stock-Based Compensation (Continued)

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 June 30, 2019, $6,000 of proceeds from early exercised options are recognized as a current liability in accrued expenses in the accompanying balance sheet.

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

	Number of shares
Unvested balance at January 1, 2019	22,547
Early exercised	11,681
Vested	(7,409)
Unvested balance at June 30, 2019	26,819

The weighted average grant-date fair value per share of options granted was $0.16 during the six months ended June 30, 2019. The aggregate intrinsic value of options exercised was nominal for the six months ended June 30, 2019. As of June 30, 2019, the total unrecognized compensation expense related to unvested employee and nonemployee stock option awards was $0.3 million, which is expected to be recognized in expense over a weighted-average period of approximately 2.83 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 requires 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 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.

TELA BIO, INC.

Notes to Unaudited Interim Consolidated Financial Statements (Continued)

(7) Stock-Based Compensation (Continued)

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

	Six months ended June 30, 2019
Expected dividend yield	—
Expected volatility	56.1%
Risk-free interest rate	2.40%
Expected term	6.25 Years

(8) 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 5.

(9) Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through August 16, 2019, the date at which the interim consolidated financial statements were available to be issued, and there are no other items requiring disclosure except for the following:

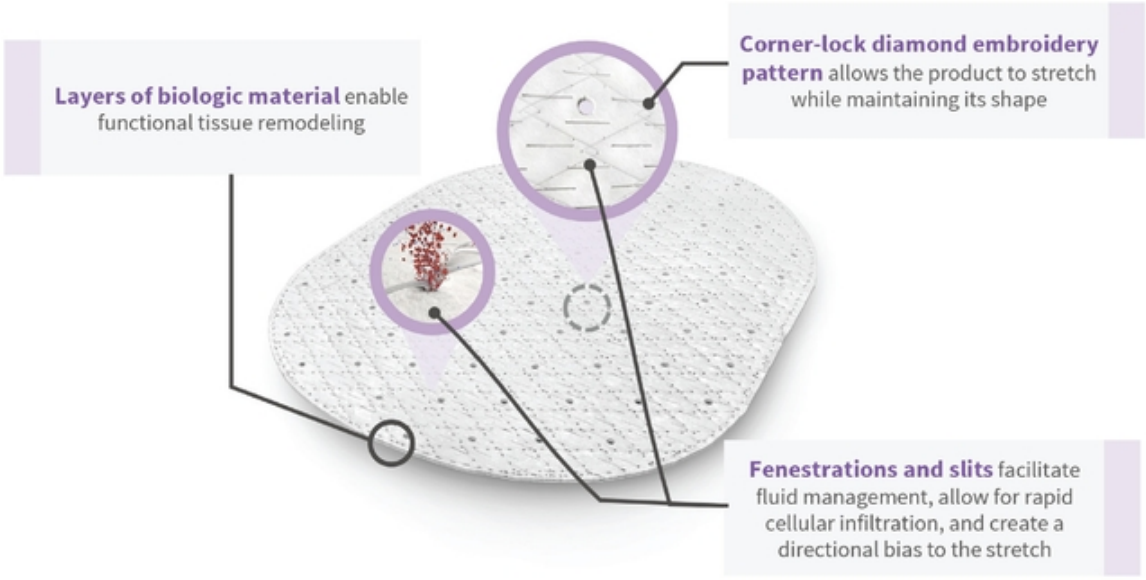
In July 2019, the Company sold 1,463,959 shares of Series B to new and existing investors at $1.16 per share for net proceeds of $1.7 million at the same terms as all other Series B shareholders, which are described elsewhere in this prospectus.

TELA BIO® INC
SURGICAL RECONSTRUCTION COMPANY

SCIENCE. VALUE. INNOVATION.

Restella® – designed for use in plastic and reconstructive surgery

An innovative bioscaffold designed to improve outcomes by facilitating fluid management and controlling the degree and direction of stretch



Full market launch planned for 1H 2020

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Shares

TELA Bio, Inc.

Common Stock

PRELIMINARY PROSPECTUS

Joint Book-Running Managers

Jefferies

Piper Jaffray

Lead Manager

Canaccord Genuity

Co-Manager

JMP Securities

, 2019

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, paid or payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and The Nasdaq Global Market listing fee.

Item	Amount
SEC registration fee	$ *
FINRA filing fee	*
Nasdaq Global Market listing fee	*
Printing expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* To be provided by amendment.

Item 14. Indemnification of Directors and Officers.

The registrant is governed by the DGCL. Section 145 of the DGCL provides that a corporation may indemnify any person, including an officer or director, who was or is, or is threatened to be made, a party to any threatened, pending or completed legal action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was or is an officer, director, employee or agent of such corporation or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided such officer, director, employee or agent acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, the corporation's best interest and, for criminal proceedings, had no reasonable cause to believe that such person's conduct was unlawful. A Delaware corporation may indemnify any person, including an officer or director, who was or is, or is threatened to be made, a party to any threatened, pending or contemplated action or suit by or in the right of such corporation, under the same conditions, except that such indemnification is limited to expenses (including attorneys' fees) actually and reasonably incurred by such person, and except that no indemnification is permitted without judicial approval if such person is adjudged to be liable to such corporation. Where an officer or director of a corporation is successful, on the merits or otherwise, in the defense of any action, suit or proceeding referred to above, or any claim, issue or matter therein, the corporation must indemnify that person against the expenses (including attorneys' fees) which such officer or director actually and reasonably incurred in connection therewith.

The registrant's second amended and restated bylaws will authorize the indemnification of its officers and directors, consistent with Section 145 of the DGCL.

Reference is made to Section 102(b)(7) of the DGCL, which enables a corporation in its original certificate of incorporation or an amendment thereto to eliminate or limit the personal liability of a director for violations of the director's fiduciary duty, except (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the DGCL, which provides for liability of directors for unlawful payments of dividends of unlawful stock purchase or redemptions or (iv) for any transaction from which a director derived an improper personal benefit.

We have entered or intend to enter into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act of 1933, or the Securities Act, against certain liabilities.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding all unregistered securities sold by us since January 1, 2016. Also included is the consideration received by us for such shares and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

1. *Issuance of Capital Stock, Convertible Notes and Warrants*.

A. On January 18, 2017, we issued a total of $7.4 million in aggregate principal amount of convertible promissory notes to holders of our preferred stock in connection with loans from the investors to the Company. The convertible promissory notes accrued interest at a rate of 12% per year and matured on October 20, 2017. On October 20, 2017, the convertible promissory notes and accrued interest thereon (in the aggregate amount of $8.1 million) converted into 6,951,175 shares of our Series B Preferred Stock at an effective per share purchase price of $1.16.

B. On January 18, 2017, in connection with the issuance of the convertible promissory notes described in (1)A above, we issued warrants to the investors to purchase 1,591,864 shares of our Series B Preferred Stock at an exercise price of $1.16 per share. An aggregate of $1.4 million of the loans advanced by the investors was allocated to the purchase price for the warrants. Immediately prior to the completion of this offering, these warrants will become exercisable for up to shares of our common stock, at an exercise price of $ per share. The holders of these warrants are not obligated to exercise the warrants in connection with this offering.

C. On March 31, 2017, in connection with a $15.0 million term loan facility we entered into with Hercules Capital, Inc., we issued warrants to Hercules Technology II, L.P. to purchase 387,932 shares of our Series B Preferred Stock at an exercise price of $1.16 per share. An aggregate of $0.3 million of the term loan was allocated to the purchase price for the warrants. Immediately prior to the completion of this offering, these warrants will become exercisable for up to shares of our common stock, at an exercise price of $ per share. The holders of these warrants are not obligated to exercise the warrants in connection with this offering.

D. On April 26, 2018, in connection with the closing of an $8.0 million term loan under our $14.0 million debt financing transaction with MidCap Financial, we issued warrants to MidCap Financial Trust to purchase 206,897 shares of our Series B Preferred Stock at an exercise price of $1.16 per share. An aggregate of $0.2 million of the term loan was allocated to the purchase price for the warrants. Immediately prior to the completion of this offering, these warrants will become exercisable for up to shares of our common stock, at an exercise price of $ per share. The holders of these warrants are not obligated to exercise the warrants in connection with this offering.

E. On October 23, 2017, we issued an aggregate of 12,931,034 shares of our Series B Preferred Stock to Pacira Pharmaceuticals, Inc. at a price per share of $1.16, for aggregate consideration of $15.0 million. These shares will automatically convert into shares of our common stock immediately prior to the completion of this offering.

F. On March 23, 2018, we issued an aggregate of 431,034 shares of our Series B Preferred Stock to ProMedica Health System, Inc. at a price per share of $1.16, for aggregate consideration of $0.5 million. These shares will automatically convert into shares of our common stock immediately prior to the completion of this offering.

G. On April 13, 2018, we issued an aggregate of 431,034 shares of our Series B Preferred Stock to Checkmate Strategic Capital 1, LLC at a price per share of $1.16, for aggregate consideration of $0.5 million. These shares will automatically convert into shares of our common stock immediately prior to the completion of this offering.

H. On April 27, 2018, we issued an aggregate of 432,000 shares of our Series B Preferred Stock to George DeNoto III, MD at a price per share of $1.16, for aggregate consideration of $0.5 million. These shares will automatically convert into shares of our common stock immediately prior to the completion of this offering.

I. On November 20, 2018, we issued an aggregate of 1,781,967 shares of our Series B Preferred Stock to investors at a price per share of $1.16, for aggregate consideration of $2.1 million. These shares will automatically convert into shares of our common stock immediately prior to the completion of this offering.

J. On December 31, 2018, we issued an aggregate of 531,034 shares of our Series B Preferred Stock to investors at a price per share of $1.16, for aggregate consideration of $0.6 million. These shares will automatically convert into shares of our common stock immediately prior to the completion of this offering.

K. On January 31, 2019, we issued an aggregate of 431,034 shares of our Series B Preferred Stock to Promedica Health Systems, Inc. at a price per share of $1.16, for aggregate consideration of $0.5 million.These shares will automatically convert into shares of our common stock immediately prior to the completion of this offering.

L. On June 28, 2019, we issued an aggregate of 10,123,480 shares of our Series B Preferred Stock to holders of our preferred stock at a price per share of $1.16, for aggregate consideration of $11.7 million. These shares will automatically convert into shares of our common stock immediately prior to the completion of this offering.

M. On July 31, 2019, we issued an aggregate of 1,463,959 shares of our Series B Preferred Stock to holders of our preferred stock at a price per share of $1.16, for aggregate consideration of $1.7 million. These shares will automatically convert into shares of our common stock immediately prior to the completion of this offering.

N. On August 30, 2019, we issued an aggregate of 509,483 shares of our Series B Preferred Stock to investors at a price per share of $1.16, for aggregate consideration of $0.6 million. These shares will automatically convert into shares of our common stock immediately prior to the completion of this offering.

2. *Equity Awards*.

A. Since January 1, 2016, we have granted stock options to employees, officers, directors and consultants, covering an aggregate of 10,016,897 shares of our common stock, having an exercise price of $0.24 per share, in connection with services provided to us by such parties.

B. Since January 1, 2016, we have issued an aggregate of 128,054 shares of our common stock to employees, officers, directors and consultants upon their exercise of stock options, for aggregate cash consideration of approximately $29,504.00.

Unless otherwise stated, the issuances of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. Individuals who purchased securities as described above represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the share certificates issued in such transactions.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering.

Item 16. Exhibits and Financial Statement Schedules.

a. Exhibits. See Exhibit Index attached to this registration statement, which is incorporated by reference herein.

b. Financial statement schedule. Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

1. For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant. pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

2. For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Exhibit Index

Exhibit Number	Exhibit Description
1.1†	Form of Underwriting Agreement
3.1#	Third Amended and Restated Certificate of Incorporation, as currently in effect
3.2†	Form of Fourth Amended and Restated Certificate of Incorporation, to be effective immediately prior to the completion of this offering
3.3#	Amended and Restated Bylaws, as currently in effect
3.4†	Form of Second Amended and Restated Bylaws, to be effective immediately prior to the completion of this offering
4.1†	Specimen Common Stock Certificate of Registrant
4.2#	Amended and Restated Investors' Rights Agreement
4.3#	First Amendment and Joinder to Amended and Restated Investor Rights Agreement
4.4#	Amended and Restated Stockholders Agreement
4.5#	First Amendment and Joinder to Amended and Restated Stockholders Agreement
4.6#	Form of Preferred Stock Purchase Warrant issued by the Registrant to certain investors
4.7#	Warrant Agreement to Purchase Shares of Preferred Stock in favor of Hercules Capital, Inc., dated March 31, 2017
4.8#	Warrant to Purchase Stock in favor of MidCap Funding XXVIII Trust, dated April 26, 2018
5.1†	Opinion of Pepper Hamilton LLP
10.1†+	Form of Indemnification Agreement by and between the Registrant and its individual directors and officers
10.2+#	TELA Bio, Inc. 2012 Stock Incentive Plan
10.3+#	Amendment to the TELA Bio, Inc. 2012 Stock Incentive Plan
10.4+#	Second Amendment to the TELA Bio, Inc. 2012 Stock Incentive Plan
10.5+#	Third Amendment to the TELA Bio, Inc. 2012 Stock Incentive Plan
10.6+#	Fourth Amendment to the TELA Bio, Inc. 2012 Stock Incentive Plan
10.7+#	Fifth Amendment to the TELA Bio, Inc. 2012 Stock Incentive Plan

Exhibit Number	Exhibit Description
10.8+#	Form of Incentive Stock Option Agreement pursuant to 2012 Stock Incentive Plan
10.9+#	Form of Nonstatutory Stock Option Agreement pursuant to 2012 Stock Incentive Plan
10.10†+	TELA Bio, Inc. 2019 Stock Incentive Plan
10.11†+	Form of Incentive Stock Option Agreement pursuant to 2019 Stock Incentive Plan
10.12†+	Form of Nonstatutory Stock Option Agreement pursuant to 2019 Stock Incentive Plan
10.13+#	Employment Agreement, dated December 3, 2012, by and between Registrant and Antony Koblish
10.14+#	Amendment to Employment Agreement, dated April 11, 2013, by and between Registrant and Antony Koblish
10.15+#	Amended and Restated Employment Agreement, dated January 29, 2013, by and between Registrant and Maarten Persenaire, M.D.
10.16+#	Amendment to Amended and Restated Employment Agreement, dated April 11, 2013, by and between Registrant and Maarten Persenaire, M.D.
10.17+#	Employment Agreement, dated December 16, 2016, by and between Registrant and Skott Greenhalgh
10.18#	Credit Agreement, dated November 16, 2018, by and between Registrant and OrbiMed Royalty Opportunities II, LP
10.19*†	Second Amended and Restated License, Product Development and Supply Umbrella Agreement, dated July 16, 2015, by and between the Registrant and Aroa Biosurgery Ltd.
10.20*†	Amendment to Second Amended and Restated License, Product Development and Supply Umbrella Agreement, dated November 26, 2015, by and between the Registrant and Aroa Biosurgery Ltd.
10.21*†	Addendum to Second Amended and Restated License, Product Development and Supply Umbrella Agreement, dated January 3, 2019, by and between the Registrant and Aroa Biosurgery Ltd.
10.22#	Lease between Registrant and Liberty Property Limited Partnership, dated January 31, 2013
10.23#	First Amendment to Lease between Registrant and Liberty Property Limited Partnership, dated June 19, 2014
10.24#	Second Amendment to Lease between Registrant and WPT Land 2 LP (as successor in interest to Liberty Property Limited Partnership), dated January 17, 2018
10.25+#	Stock Restriction Agreement, dated December 3, 2012, by and between the Registrant and Antony Koblish
10.26+#	Stock Restriction Agreement, dated December 3, 2012, by and between the Registrant and Maarten Persenaire
21.1#	Subsidiaries of the Registrant
23.1†	Consent of KPMG LLP, an Independent Registered Public Accounting Firm
23.2†	Consent of Pepper Hamilton LLP (included in Exhibit 5.1)
24.1†	Power of Attorney (included on the signature page to this registration statement)

Previously filed.
† To be filed by amendment.
+ Indicates management contract or compensatory plan.
* Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the Borough of Malvern, Commonwealth of Pennsylvania, on the day of , 2019.

TELA BIO, INC.

By: _____

POWER OF ATTORNEY

Each of the undersigned directors and officers of TELA Bio, Inc. hereby constitutes and appoints each of Antony Koblish and Nora Brennan as his true and lawful attorneys-in-fact and agents with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to execute any and all amendments (including post-effective amendments) to this registration statement, to sign any registration statement related to this registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, or the Securities Act, and to cause the same to be filed with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and desirable to be done in and about the premises as fully and to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all acts and things that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
_____ Antony Koblish	President and Chief Executive Officer (Principal Executive Officer)	, 2019
_____ Nora Brennan	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	, 2019
_____ Kurt Azarbarzin	Chairman, Board of Directors	, 2019
_____ Vince Burgess	Director	, 2019

Signature	Title	Date
_____ Ronald Ellis	Director	, 2019
_____ Ashley Friedman	Director	, 2019
_____ Adele Oliva	Director	, 2019
_____ Matt Zuga	Director	, 2019