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

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2022

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission File Number 001-41364

TENON MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**45-5574718**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

104 Cooper Court
Los Gatos, CA 95032
(Address of principal executive offices) (Zip Code)

(408) 649-5760
(Registrant's telephone number, including area code)

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

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Common stock, par value $0.001 per share	TNON	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
None

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2022 (the last business day of the registrant's most recently completed second quarter) was approximately $17,508,525, which is based on a closing price per share of $2.26 on such date.

As of March 10, 2023, the registrant had a total of 11,251,299 shares of its common stock, $0.001 par value per share, outstanding.

Tenon Medical, Inc.
Annual Report on Form 10-K
For the Fiscal Year ended December 31, 2022

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this report that are not statements of historical fact, including statements about our beliefs and expectations, are forward-looking statements, and should be evaluated as such. Forward-looking statements include information concerning possible or assumed future results of operations, including descriptions of our business plan and strategies. These statements often include words such as "anticipate," "expect," "suggest," "plan," "believe," "intend," "project," "forecast," "estimates," "targets," "projections," "should," "could," "would," "may," "might," "will," and other similar expressions. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. You should read these factors and the other cautionary statements made in this report and in the documents we incorporate by reference into this report as being applicable to all related forward-looking statements wherever they appear in this report or the documents we incorporate by reference into this report. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements.

We base these forward-looking statements or projections on our current expectations, plans, and assumptions, which we have made in light of our experience in the industry, as well as our perceptions of historical trends, current conditions, expected future developments, and other factors we believe, are appropriate under the circumstances and at this time. As you read and consider this report, you should understand that these statements are not guarantees of performance or results. The forward-looking statements and projections contained herein are subject to and involve risks, uncertainties, and assumptions, and therefore you should not place undue reliance on these forward-looking statements or projections. Although we believe that these forward-looking statements and projections are based on reasonable assumptions at the time they are made, you should be aware that many factors could affect our actual financial results, and therefore actual results might differ materially from those expressed in the forward-looking statements and projections. Factors that might materially affect such forward-looking statements and projections include:

- Our ability to effectively operate our business segments;
- Our ability to manage our research, development, expansion, growth, and operating expenses;
- Changes or delays in government regulation relating to the healthcare and Life Sciences industries;
- Our ability to respond and adapt to changes in technology and customer behavior;
- Our ability to compete, directly and indirectly, and succeed in the highly competitive and evolving medical devices industry;
- Our ability to evaluate and measure our business, prospects and performance metrics;
- Our ability to protect our intellectual property and to develop, maintain and enhance a strong brand; and
- Other factors (including the risks contained in the section of this report entitled "*Risk Factors*") relating to our industry, our operations, and results of operations.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. The forward-looking statements are based on our beliefs, assumptions, and expectations of future performance, taking into account the information currently available to us. These statements are only predictions based upon our current expectations and projections about future events. There are important factors that could cause our actual results, level of activity, performance, or achievements to differ materially from the results, level of activity, performance, or achievements expressed or implied by the forward-looking statements. Other sections of this report may include additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We cannot guarantee future results, levels of activity, performance, or achievements. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

Use of Certain Defined Terms

- Except where the context otherwise requires and for the purposes of this report only:
- all references to the "Company," "Tenon," the "registrant" (whether capitalized or not), "we," "our," or "us" in this report mean Tenon Medical, Inc.;
- "year" or "fiscal year" means the year ending December 31st;
- all dollar or $ references, when used in this report, refer to United States dollars;
- "Exchange Act" refers the Securities Exchange Act of 1934, as amended;
- "SEC" refers to the Securities and Exchange Commission; and
- "Securities Act" refers to the Securities Act of 1933, as amended

Risk Factors Summary

Our business is subject to numerous risks and uncertainties, any one of which could materially adversely affect our results of operations, financial condition or business. These risks include, but are not limited to, those listed below. This list is not complete, and should be read together with Item 1A, "Risk Factors" and should not be relied upon as an exhaustive summary of the material risks we face.

- We have incurred losses in the past, our financial statements have been prepared on a going concern basis and we may be unable to achieve or sustain profitability in the future;
- Epidemic diseases including COVID 19, or the perception of their effects could have a material adverse effect on our business, financial condition, results of operations, or cash flows;
- If hospitals, clinicians, and other healthcare providers are unable to obtain and maintain coverage and reimbursement from third-party payors for procedures performed using our products, adoption of our products may be delayed, and it is unlikely that they will gain further acceptance;
- We may not be able to convince physicians that The CATAMARAN System is an attractive alternative to our competitors' products and that our procedure is an attractive alternative to existing surgical and non-surgical treatments of the SI-Joint;
- Clinicians and payors may not find our clinical evidence to be compelling, which could limit our sales, and ongoing and future research may prove our products to be less safe and effective than initially anticipated;
- Pricing pressure from our competitors, changes in third-party coverage and reimbursement, healthcare provider consolidation, payor consolidation and the proliferation of "physician-owned distributorships" may impact our ability to sell our product at prices necessary to support our current business strategies;
- Practice trends or other factors, including the COVID-19 pandemic, may cause procedures to shift from the hospital environment to ambulatory surgical centers, or ASCs, where pressure on the prices of our products is generally more acute;
- We operate in a very competitive business environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not grow;
- We currently manufacture (through third parties) and sell products used in a single procedure, which could negatively affect our operations and financial condition;
- If we are unable to hire and train sales managers, clinical specialists, and expand our network of independent sales representatives, we may not be able to generate anticipated sales;
- We are dependent on a limited number of contract manufacturers, some of them single-source and some of them in single locations, for our product, and the loss of any of these contract manufacturers, or their inability to provide us with an adequate supply of products in a timely and cost-effective manner, could materially adversely affect our business;
- We and our contract manufacturers are subject to extensive governmental regulation both in the United States and abroad, and failure to comply with applicable requirements could cause our business to suffer;
- We and our independent sales representatives must comply with U.S. federal and state fraud and abuse laws, including those relating to physician kickbacks and false claims for reimbursement;
- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed;
- We may incur product liability losses, and insurance coverage may be inadequate or unavailable to cover these losses;

- We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks;
- The medical device industry is characterized by patent litigation and we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages, and/or prevent us from developing or marketing our existing or future products;
- Our business could suffer if we lose the services of key members of our senior management, key advisors or personnel;
- Various factors outside our direct control may adversely affect manufacturing and distribution of our product;
- We may seek to grow our business through acquisitions of or investments in new or complementary businesses, products or technologies, and the failure to manage acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us;
- Our ability to protect our intellectual property and proprietary technology is uncertain;
- The size and future growth in the market for the SI-Joint fixation market have not been established based on market reports and our estimates are based on our own review and analysis of public information and may be smaller than we estimate, possibly materially. In addition, our estimates of cost savings to the economy and healthcare system as a result of The CATAMARAN System procedure are based on our internal estimates and market research and could also be smaller than we estimate, possibly materially. If our estimates and projections overestimate the size of this market or cost savings, our sales growth may be adversely affected;
- We have a limited operating history and may face difficulties encountered by early-stage companies in new and rapidly evolving markets;
- Our failure to adequately protect personal information in compliance with evolving legal requirements could harm our business; and
- Geopolitical conditions, including trade disputes and direct or indirect acts of war or terrorism, could have an adverse effect on our operations and financial results.

PART I

Item 1. Business

Introduction

Tenon Medical, Inc. (the "Company"), was incorporated in the State of Delaware on June 19, 2012 and was headquartered in San Ramon, California until June 2021 when it relocated to Los Gatos, California. The Company is a medical device company that offers a novel, less invasive approach to the sacroiliac joint using a single, robust, titanium implant for treatment of the most common types of sacroiliac joint (the "SI-Joint") disorders that cause lower back pain. The system features the CATAMARAN™ Fixation Device which passes through both the axial and sagittal planes of the ilium and sacrum, stabilizing and transfixing the SI joint along its longitudinal axis. The angle and trajectory of the Catamaran surgical approach is also designed to provide a pathway away from critical neural and vascular structures and into the strongest cortical bone. The Company received U.S. Food and Drug Administration ("FDA") clearance in 2018 for The CATAMARAN™ SI-Joint Fusion System ("The CATAMARAN System"). The Company commercially launched The CATAMARAN System nationally in October 2022 at the North American Spine Society meeting held in Chicago. The Company's primary commercial focus will be the US market.

The Opportunity

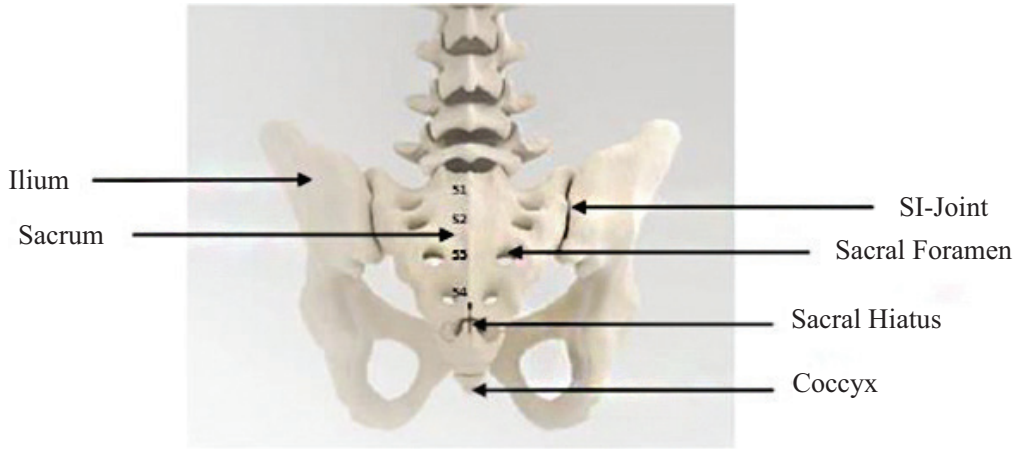
We estimate that over 30 million American adults have chronic lower back pain. Published clinical studies have shown that 15% to 30% of all chronic lower back pain is associated with the SI-Joint. For patients whose chronic lower back pain stems from the Sacroiliac Joint ("SI-Joint"), our experience in both clinical trials and commercial settings indicates the system to be introduced by Tenon could be beneficial for patients who are properly diagnosed and screened for surgery by trained healthcare providers.

In 2019, approximately 475,000 patients in the United States were estimated to have received an aesthetic injection to temporarily alleviate pain emanating from the SI-Joint and/or to diagnose SI-Joint pain. Additionally, several non-surgical technologies have been introduced in the past 10 years to address patients who do not respond to injection therapy, including systemic oral medications and opioids.

To date, the penetration of a surgical solution for this market has been relatively low (5-7%). We believe this is due to complex surgical approaches and suboptimal implant design of existing options. The penetration of this market with an optimized surgical solution is Tenon's focus.

We believe the SI-Joint is the last major joint to be successfully addressed by the orthopedic implant industry. Studies have shown that disability resulting from disease of the SI-Joint is comparable to the disability associated with a number of other serious orthopedic conditions, such as knee and hip arthritis and degenerative disc disease, each of which has surgical solutions where an implant is used, and a multi-billion-dollar market exists.

The SI-Joint



The SI-Joint is a strong weight bearing synovial joint situated between the lumbar spine and the pelvis and is aligned along the longitudinal load bearing axis of the human spine when in an upright posture. It functions as a force transfer conduit where it transfers axial loads bi-directionally from the spine to the pelvis and lower extremities and allows forces to be transmitted from the extremities to the spine. It also provides load sharing between the hip and spine to contribute towards attenuation of impact shock and stress from activities of daily living.

The SI-Joint is a relatively immobile joint that connects the sacrum (the spinal segment that is attached to the base of the lumbar spine at the L5 vertebra) and the ilium of the pelvis. Each SI-Joint is approximately 2mm wide and irregularly shaped.

Motion of the SI-Joint features vertical shear and rotation. Although the rotational forces about the SI-Joint are relatively low, repetitive motions created by daily activities such as walking, jogging, twisting at the hips, and jumping can increase the stresses on the SI-Joint. If the SI-Joint is compromised through injury or degeneration, the load bearing and motion restraints from the surrounding anatomical structures of the SI-Joint will be compromised resulting in abnormal stress transfers across the joint to these structures, thereby further augmenting the degenerative cascade of the SI-Joint. Eventual pain and cessation of an individual's normal activities due to a painful and unstable SI-Joint have led to an increase in the recent development of SI-Joint stabilization devices.

Non-Surgical Treatment of Sacroiliac Joint Disease

Several non-surgical treatments exist for suspected sacroiliac joint pain. These conservative steps often provide desired relief for the patient. Non-surgical treatments include:

- **Drug Therapy**: including opiates and non-steroidal anti-inflammatory medications.
- **Physical Therapy**: which can involve exercises as well as massage.
- **Intra-Articular Injections of Steroid Medications**: which are typically performed by physicians who specialize in pain treatment or anesthesia.
- **Radiofrequency Ablation**: or the cauterizing of the lateral branches of the sacral nerve roots.

When conservative steps fail to deliver sustained pain relief and return to quality of life, specific diagnostic protocols are utilized to explore if a surgical option should be considered.

Diagnosis

Historically, diagnosing pain from the SI-Joint was not routinely a focus of orthopedic or neurosurgery training during medical school or residency programs. Due to its invasiveness, post-operative pain, and muscle disruption along with a difficult procedure overall, the open SI-Joint fusion procedure was rarely taught in these settings.

The emergence of various SI-Joint surgical technologies has generated a renewed discussion of SI-Joint issues. Of particular focus is the diagnostic protocol utilized to properly select patients for SI-Joint surgery. Patients with low back pain typically start with primary care physicians who often refer to pain specialists. Here, the patient will undergo traditional physical therapy combined with oral medications (anti-inflammatory, narcotic, etc.). If the patient fails to respond to these steps the pain specialist may move to therapeutic injections of the SI-Joint. These injections may serve to lessen inflammation to the point that the patient is satisfied. However, the impact from these injections is often transient. In this case the patient is often referred to a clinician to determine if the patient may be a candidate for surgical intervention. A series of provocative tests in clinic, combined with a specific injection protocol to isolate the SI-Joint as the pain generator is then utilized to confirm the need for surgical intervention. Published literature has shown this technique to be a very effective step to determine the best treatment to alleviate pain.

Limitations of Existing Treatment Options

Surgical fixation and fusion of the SI-Joint with an open surgical technique was first reported in 1908, with further reports in the 1920s. The open procedure uses plates and screws, requires a 6 to 12-inch incision and is extremely invasive. Due to the high invasiveness and associated morbidity, the use of this procedure is limited to cases involving significant trauma, tumor, etc.

Less invasive surgical options along with implant design began to emerge over the past 15 years. These options feature a variety of approaches and implant designs and have been met with varying degrees of adoption. Lack of a standard and accepted diagnostic approach, complexity of approach, high morbidity of approach, abnormally high complication rates and inability to radiographically confirm fusion have all been cited as reasons for low adoption of these technologies.

The Market

Based on market research and internal estimates, Tenon believes the potential market for surgical intervention of the SI-Joint to be 279,000 procedures annually in the U.S. alone, for a potential annual market of more than $2.2 billion. These estimates are driven by coding data for SI-Joint injections to treat pain and informed assumptions relative to surgical intervention candidacy.

Based on public information, we believe that the largest clinical device supplier in this market does approximately 10-11,000 SI-Joint fixations a year representing the largest market share. The other competitive devices that are offered are all products generally part of much larger companies with a variety of orthopedic devices and as such do not specifically call out the number of specific SI-Joint procedures performed with their products. It is our belief that all other competitive devices represent approximately another 5,000 potential SI-Joint procedures.

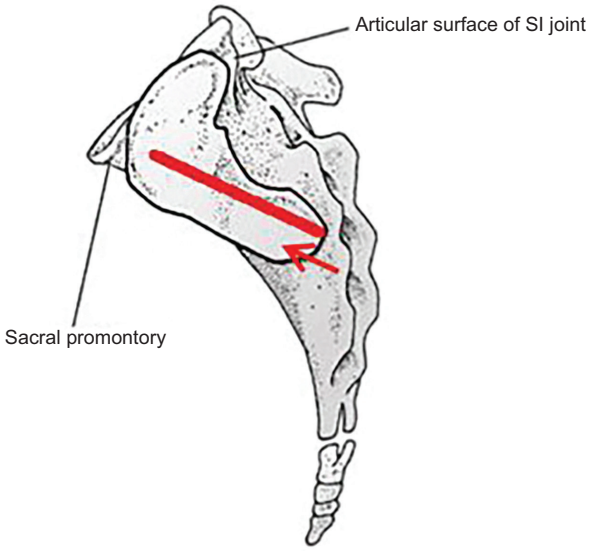
Based on this analysis we believe the market is vastly underserved and only penetrated 5-7%, leaving tremendous upside for a next generation device that meets the needs of this market.

Competitive Landscape

We believe Tenon is the first company to develop and manufacture a novel Inferior Posterior approach featuring a dual pontoon fixation technology cleared by the FDA expressly for SI-Joint fusion. The approach, referred to as Inferior Posterior Sacroiliac Fusion is focused on these critical aspects of the surgical procedure:

1. Designed for Safety: the approach trajectory and angle are away from the neural foramen.
2. Focus on Efficiency: the approach is designed to be direct to the SI-Joint, which allows for visualization of the joint and is designed to pass through minimal muscle structures, which may result in a faster and more efficient surgical procedure and reduced post-op pain for the patient.
3. Targeted Anatomy: the approach places the implant in the aspect of the SI-Joint with the densest bone, designed to provide maximum fixation and resistance to vertical shear. This is designed to provide a secure press fit of the implant, reducing the incidence of revision surgery due to implant loosening, which we believe is the reason for many competitive device failures as reported to the FDA Medical Device Reporting (MDR).

Note the trajectory used in the Inferior Posterior approach:



Over the past several years, other companies have recognized the opportunity and have entered the minimally invasive SI-Joint fixation market. However, these products are either screw/triangular rod-based or allograft products, which we believe have disadvantages when compared to The CATAMARAN System.

In the United States, we believe that our primary competitors will be SI-Bone, Inc., Globus Medical, Inc., Medtronic plc and RTI Surgical, Inc. We also compete against non-hardware products, such as allograft bone implants. These allograft products are comprised of human cells or tissues and are regulated by the FDA differently from implantable medical devices made of metallic or other non-tissue-based materials. The following chart is a comparison of specifications and features among the various available clinical devices:

Current Clinical Device Comparison – SI-Joint

Product Image	Company Name	Product Name	Approach	# of Implants	Direct visualization of SIJ	Radiographic Confirmation of Fusion	Minimal Radiation exposure	Insertion Trajectory Away from the Neural Foramen	Minimal Muscle Disruption	Bone Grafting
	Tenon Medical	CATAMARAN PiSIF™		1	✓	✓	✓	✓	✓	✓
			Lateral							
	SI-Bone	iFuse	Lateral	3	✗	✗	✗	✗	✗	✓
	RTI Surgical	Simmetry	Lateral	2	✗	✗	✗	✗	✗	✗
	Globus	SI-LOK	Lateral or Posterior	3	✗	✗	✗	✗	✗	✓
			Posterior							
	Medtronic	Ratio	Posterior	2	✗	✗	✗	✗	✗	✓
	Globus	SI-LOK	Lateral or Posterior	3	✗	✗	✗	✗	✗	✓

We believe from our study of the market that many physicians who have been trained to use one of the existing clinical devices have not adopted the procedure for a variety of reasons. Complexity of approach, high morbidity of approach, abnormally high complication rates and inability to radiographically confirm fusion have all been cited as reasons for low adoption of these technologies

The following are the primary factors on which companies compete in our industry:

- product and clinical procedure effectiveness;
- ease of surgical technique and use of associated instruments;
- safety;
- published clinical outcomes and evidence;
- sales force knowledge and service levels;
- product support and service, and customer service;
- comprehensive training, including disease, anatomy, diagnosis, and treatment;
- product innovation and the speed of innovation;
- intellectual property;
- accountability and responsiveness to customers' demands;

- pricing and reimbursement;
- scientific (biomechanics) data; and
- attracting and retaining key personnel.

Tenon believes that refined approaches and improved implant design will open the door to enhanced adoption and further penetration of this important market.

The CATAMARAN™ SI-Joint Fusion System Solution

Until October 2022 Tenon sold The CATAMARAN™ SI-Joint Fusion System ("The CATAMARAN System") to a limited number of clinician advisors to refine the product for a full commercial launch. In October 2022 Tenon initiated a full commercial launch at the NASS meeting in Chicago. The CATAMARAN System includes instruments and implants designed to prepare and fixate the SI-Joint for fusion. We believe The CATAMARAN System will address a large market opportunity with a superior product and is distinct from other competitive offerings in the following ways:

- Transfixes the SI joint
- Inferior Posterior Sacroiliac Fusion Approach (PiSIF™)
- Reduced Approach Morbidity
- Direct And Visualized Approach to the SI-Joint
- Single Implant Technique
- Insertion Trajectory Away from the Neural Foramen
- Insertion Trajectory Away from Major Vascular Structures
- Autologous Bone Grafting in the Ilium, Sacrum and Bridge
- Radiographic Confirmation of Bridging Bone Fusion of the SI-Joint

The fixation device and its key features are shown below:

Key Features

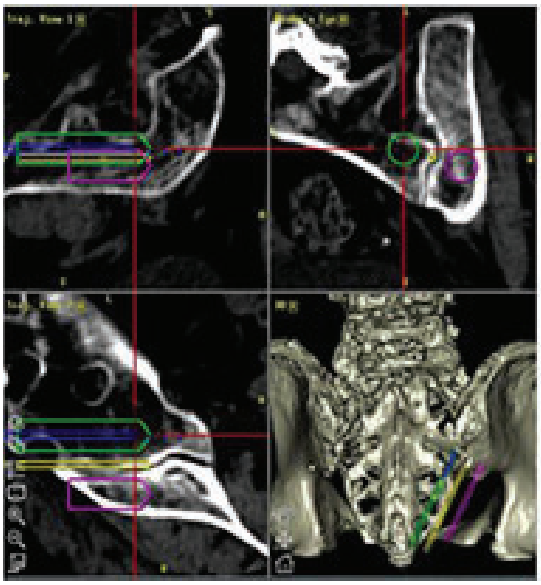
"Pontoon" in the ilium
"Pontoon" in the sacrum
"Pontoons and Bridge" filled with autologous bone from drilling process
Leading edge osteotome creates defect and facilitates ease of insertion

The CATAMARAN System is a singular implant designed with several proprietary components which allow for it to be explicitly formatted to transfix the SI-Joint with a single approach and implant. This contrasts with several competitive implant systems that require multiple approach pathways and implants to achieve fixation. In addition, the Inferior Posterior approach is designed to be direct to the joint and through limited anatomical structures which may minimize the morbidity of the approach. The implant features a patented dual pontoon open cell design which enables the clinician to pack the pontoons with the patient's own autologous bone designed to promote bone fusion across the joint. The CATAMARAN System is designed specially to resist vertical shear and rotation of the joint in which it was implanted, helping stabilize the joint in preparation for eventual fusion.

The instruments we have developed are proprietary to The CATAMARAN System and specifically designed to facilitate an Inferior Posterior approach that is unique to the system.

Tenon also has developed a proprietary 2D placement protocol as well as a protocol for 3D navigation utilizing the latest techniques in spine surgery. These Tenon advancements are intended to further enhance the safety of the procedure and encourage more physicians to adopt the procedure.

The CATAMARAN System, as mentioned previously, is placed in the densest aspect of the SI-Joint as confirmed by the pre-op planning images below:



Surgical Plan Key:

Yellow: Guidewire
Purple: Lateral Pontoon (Ilium)
Green: Medial Pontoon (Sacrum)

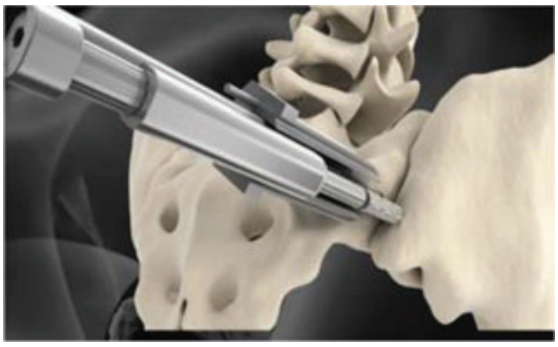
Notes:

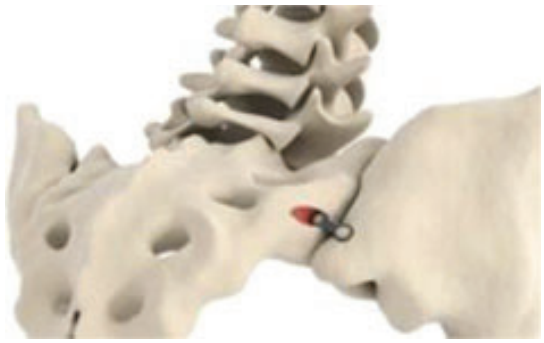
Upper Right Quadrant: The green and purple pontoons represent the placement in the dense bone inferior — contrasted with the dorsal gap superiorly where competitive systems are most often placed.

Lower Right Quadrant: The yellow and purple outlines represent The CATAMARAN System pontoons, illustrating the angle of insertion is away from the sacral neuro foramen providing for a much safter trajectory for device implantation.

The Procedure

We believe The CATAMARAN System and its differentiated characteristics allow for an efficient and effective procedure designed to deliver short-term stabilization and long-term fusion that can be confirmed radiographically. Shown below is an illustration demonstrating the unique placement of The CATAMARAN System inserted Inferior Posterior and coming directly down to and transfixing the joint



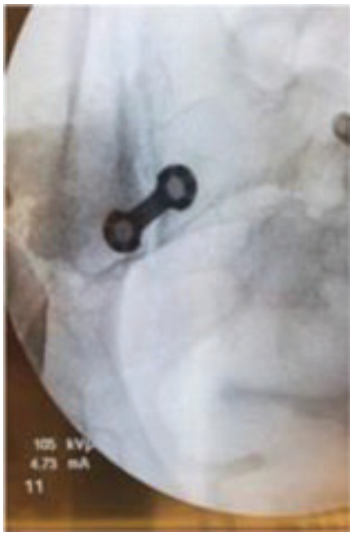


The CATAMARAN System procedure is typically performed under general anesthesia using a specially designed instrument set we provide to prepare for the Inferior Posterior access to the SI-Joint. Specially designed imaging and navigation protocols are designed to ensure the clinician has the proper Entry Point, Trajectory, Angle and Depth (ETAD™) so that the pontoons of The CATAMARAN System are placed for maximum fixation. The CATAMARAN System incorporates two pontoons and is designed so that when the system is impacted into the bone one pontoon is on the Illum side and the other is in the Sacrum side with the bridge spanning the joint, preventing shear and rotation of the joint. The device also features an open cell design where the patient's own (autologous) bone is packed into the pontoons and the bridge to facilitate fusion across the joint. The leading edge of the bridge is designed to

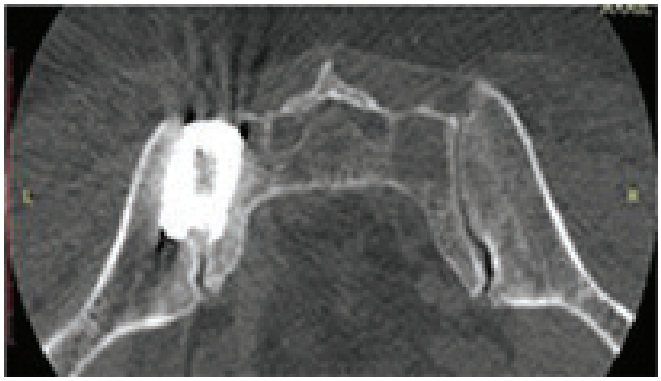
act as an osteotome, providing a self-created deficit upon insertion. These features are designed to create an ideal environment for bone ingrowth and fusion. Below is a fluoroscopic image of an implanted CATAMARAN Fixation Device spanning the SI-Joint.

Tenon believes the surgical approach and implant design it has developed, along with the 2D and 3D protocols for proper implantation will be received well by the clinician community who have been looking for a next generation device. Our initial clinical results indicate that The CATAMARAN System is promoting fusion across the joint as evidenced by post-op CT scans (the recognized gold standard widely accepted by the Clinical community).

Post-Op fluoroscopic image of implant spanning the SI-Joint



6-Month CT-Scan showing clear bridging bone fusion



A preliminary 18 case series (Michael Joseph Chaparro, MD, F.A.A.N.S., F.A.C.S.) has documented that The CATAMARAN System does in fact promote fusion across the SI-Joint, which many of our competitors have not been able to demonstrate. While products from some of our competitors use screws and triangular wedges to treat the SI-Joint, most do not effectively resist the vertical shear and twisting within the joint. This 18 patient series was presented at the North American Spine Society Annual Meeting in Chicago, IL in October 2022.

An independent biomechanical study (Lisa Ferrara, Ph.D. OrthoKinetic Technologies, LLC now part of Element) demonstrated that a single CATAMARAN SIJ Fixation Device was superior to predicate device in the areas of Fixation Strength, Shear Stiffness, Dynamic Endurance and Pullout Strength. We hold issued patents on The CATAMARAN System and its unique features including the dual pontoons and the open cell structure for bone graft packing. We also hold an issued patent for the method of placing The CATAMARAN System into the SI-Joint where one pontoon is in the ilium and the other in the sacrum.

The CATAMARAN System's unique design has already demonstrated radiographically confirmed fusion in initial patients. We believe that this beneficial advantage along with a simpler, safer, and less painful procedure will make this the procedure of choice for most physicians. Tenon has initiated post market, IRB controlled clinical trials to demonstrate this technology delivers on these advantages.

Coverage and Reimbursement

When a Tenon procedure utilizing The CATAMARAN System is performed, the healthcare facility, either a hospital (inpatient or outpatient clinic), and the clinician submit claims for reimbursement to the patient's insurer. Generally, the facility obtains a lump sum payment, or facility fee, for SI-Joint fusions. Our products are purchased by the facility, along with other supplies used in the procedure. The facility must also pay for its own fixed costs of operation, including certain operating room personnel involved in the procedure, ICD and other medical services care. If these costs exceed the facility reimbursement, the facility's managers may discourage or restrict clinicians from performing the procedure in the facility or using certain technologies, such as The CATAMARAN System, to perform the procedure.

The Medicare 2022 national average hospital inpatient payment for SI-Joint procedures ranges from approximately $25,000 to approximately $59,000 depending on the procedural approach and the presence of Complication and Comorbidity/Major Complication and Comorbidity.

The Medicare 2022 national average hospital outpatient clinic payment is $21,897. We believe that insurer payments to facilities are generally adequate for these facilities to offer The CATAMARAN System procedure.

Physicians are reimbursed separately for their professional time and effort to perform a surgical procedure. Depending on the surgical approach, the incision size, type and extent of imaging guidance, indication for procedure, and the insurer, The CATAMARAN System procedure may be reported by the physician using any one of the applicable following CPT® codes 27279, 27280, 27299. The Medicare 2022 national average payment for CPT® 27279 is $807 and $1,352 for 27280. CPT® 27299 has no national valuation. Clinicians, however, can present a crosswalk to another procedure believed to be fairly equivalent and/or comparison to a code for which there is an existing valuation. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for the procedures performed with our products, if any payment is made at all. Similar to Medicaid, many private payors' coverage and payment may differ from one payer to another.

We believe that some clinicians view the current Medicare reimbursement amount as insufficient for current SI-Joint procedures, given the work effort involved with the procedure, including the time to diagnose the patient and obtain prior authorization from the patient's health insurer when necessary. Many private payors require extensive documentation of a multi-step diagnosis before authorizing SI-Joint fusion for a patient. We believe that some private payors apply their own coverage policies and criteria inconsistently, and clinicians may experience difficulties in securing approval and coverage for sacroiliac fusion procedures. Additionally, many private payors limit coverage for open SI-Joint fusion to trauma, tumors or extensive spine fusion procedures involving multiple levels.

We believe the unique design of The CATAMARAN System and the fact The CATAMARAN System may be placed both via an open procedure based on the clinician's determination of trauma induced SI-Joint pain or as a minimally invasive approach provides a unique and differentiated approach for the clinician to determine the reimbursement code that best fits the clinical problem. We believe this is a significant advantage over competitive devices by providing the clinician the clinical flexibility of offering the best clinical solution and approach for patients.

Sales and Marketing

We will market and sell The CATAMARAN System primarily through independent distributors and sales representatives specializing in orthopedics and spine sales. Our target customer base includes approximately 12,000 physicians who perform spine and/or pelvic surgical procedures.

We will provide general sales and marketing training to our independent sales representative along with comprehensive, hands-on cadaveric and dry-lab training sessions focusing on the clinical benefits of The CATAMARAN System and the importance of using the 2D and 3D protocols we have developed. We believe many clinicians have already been trained using one of the alternative products but have not been satisfied with the approach and technology. This provides Tenon with an opportunity to demonstrate to an already-trained-clinician the unique attributes of The CATAMARAN System.

Our business objective is to introduce the Next Generation Implant for SI-Joint Fixation. The past 10 years has seen an acceleration in recognition and discussion of the SI-Joint as a cause of pain that can be treated. However, adoption has been hindered by complexity of the procedure as evidenced by the significant number of reported Medical Device Records (MDR's). The need for multiple implants and resulting post-op pain has also contributed to low adoption numbers. Our strategy is to provide a safer, faster, and better surgical experience and a significant pain reduction benefit for the patient. Our goals are simple but impactful and as such we plan on the following:

- Educate and inform physicians and other healthcare providers, payors, and patients about the growing body of evidence supporting what we believe is the safety, durable clinical effectiveness, economic benefit, and reduction in opioid use associated with SI-Joint fixation and The CATAMARAN System procedure.

- Utilize the most effective means of training via video and in-person labs demonstrating the ease of use with 2D and 3D navigation. Since many physicians have already been trained but have not incorporated SI-Joint fixation into their practices we will work with these physicians to reengage and train them on the Next Generation of an SI-Joint implant which incorporates a safer and simpler approach.
- Utilize the best approaches of direct-to-consumer outreach to educate patients that there is a safe solution to help them improve their quality of life. Additionally, to reach the broadest physician and patient audience on case study results from around the United States we plan to implement an active social media campaign incorporating Facebook, Instagram, YouTube, etc.
- Invest in our independent sales representative network to ensure that all Tenon representatives have the latest in marketing and education tools to reduce the time from training to adoption.
- Remain true to our next generation product development strategy by continually bringing out new advancements in and around the SI-Joint and pelvic region.
- Continue to grow our existing intellectual property portfolio.
- Execute post-market clinical research to confirm the benefits of the distinct approach and implant.

Regulatory Status

Tenon has received FDA 510(k) clearance to market and sell the CATAMARAN System for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. The company plans to expand initial sales in late Q-4 2021 with a full domestic product launch executed in October 2022 at the North American Spine Society (NASS) meeting.

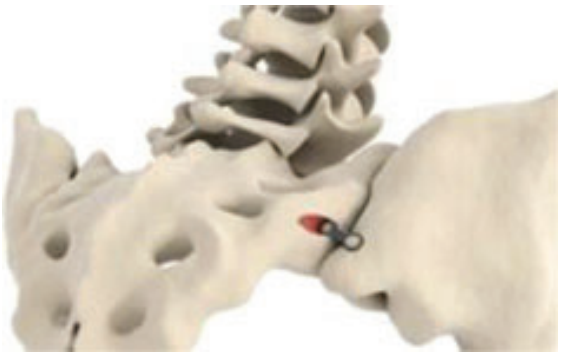
Research & Development

Our initial development of The CATAMARAN System has incorporated several differentiating features which we believe will make an important contribution for many patients suffering from SI-Joint pain. To our knowledge no other competitive product incorporates these Next Generation features:

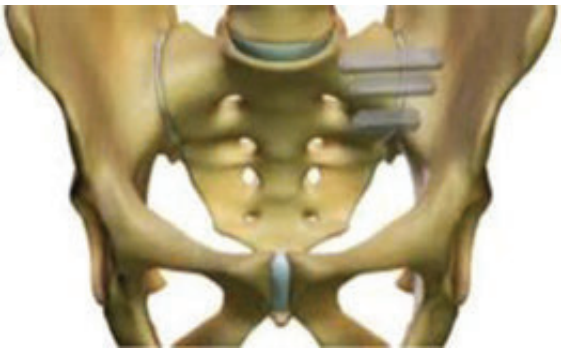
- Dual Pontoon implant that transfixes the targeted joint;
- Open cell design designed for utilizing the patient's own autologous bone for promotion of fusion;
- Bridge design between the dual pontoons for enhanced strength;
- Leading edge of the implant designed to function as an osteotome providing a self-creating defect feature not available with competitive systems;
- Single implant designed with varying pontoon sizes to ensure a robust fixation based on anatomy; and
- Additional smaller Catamaran designed for smaller anatomy and/or revision surgery.

The Tenon development plan is to expand The CATAMARAN System offering by introducing a series of progressively longer pontoons so that the clinician has a full complement of sized implants to choose from depending on the patient's anatomy. These product enhancements will enable the clinician to optimize the size of each implant to ensure full fixation based on anatomy. Tenon believes, based on literature searches of prior SI-Joint fixation technologies, that adverse event incidence where the implant has loosened or been misplaced thereby requiring a revision surgery could reach 20%. Tenon believes that its ability to make The CATAMARAN System a specifically sized fixation device will benefit many patients requiring a revision surgery.

The CATAMARAN System shown below has been cleared by the FDA for commercialization. This patented titanium implant incorporates The CATAMARAN SI-Joint Fixation Device pontoon design and the open cell configuration which we believe, when filled with the patient's autologous bone, promotes fusion. The two images below show a comparison of a competitive implant requiring three implants and The CATAMARAN System unique pontoon design showing the need of only one implant to cover the same amount of the SI-Joint.



The CATAMARAN™ SIJ Fusion System Single Implant



SI Bone iFuse® Three Implants

Our mission will be to continue developing enhancements to The CATAMARAN System to meet our customers' changing needs and to improve the surgery's effectiveness. This includes revision surgery options as well as options as an adjunct to long fusion constructs in the lumbar spine.

Coinciding with our commercial launch, Tenon will initiate various post marketing clinical studies in accordance with FDA cleared indications for use. Since we have already received FDA 510(k) clearance to market The CATAMARAN System, our clinical study activities will be focused on capturing post-market safety and efficacy data. Tenon has received IRB approval for two post-market trials, including a 50 patient, 10 center mult-center trial and a prospective CT trial to demonstrate fusion in patient who have already been treated with The CATAMARAN System. Clinical study endpoints may include but are not limited to; length of surgical procedure, blood loss, post-op pain, length of stay, duration of non-weight-bearing post-op, radiographic confirmation of fusion and surgical complication rates. Statistical analysis plans may be designed to demonstrate non-inferiority to historical control, as reported in published literature, which may be used for submission to peer reviewed articles/posters/presentations and the like.

Intellectual Property

Developing and maintaining a strong intellectual property position is an important element of our business. We maintain the intellectual property through a combination of patent protection, trademarks, and trade secrets. We have sought, and will continue to seek, patent protection for our technology, for improvements to our technology, as well as for any of our other technologies where we believe such protection will be advantageous.

As of March 10, 2023, we own four (4) issued U.S. utility patents, sixteen (16) pending U.S. utility patent applications, four (4) issued foreign utility patents in Australia, Canada, Japan and Israel, and two (2) pending foreign utility patent applications in the European Community, Brazil and Japan. We also have thirteen (13) registered trademarks (seven (7) U.S. and six (6) foreign) and twelve (12) pending trademark applications in the U.S.

Our utility patents and patent applications are directed to several different aspects of our sacroiliac (SI) joint stabilization technology and related patent platform. By way of example, our granted patents and pending patent applications cover various structural features of our unique CATAMARAN™ SI-Joint prosthesis and means for employing same to stabilize a dysfunctional SI-Joint.

The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term for a utility patent is generally 20 years from the earliest claimed filing date of a nonprovisional patent application in the applicable country. Our issued U.S. and foreign utility patents are anticipated to naturally expire around 2031, and our U.S. pending utility patent applications, if issued into patents, are similarly anticipated to naturally expire around 2031, excluding any additional patent term

adjustment(s) or extension(s), and assuming payment of all applicable maintenance or annuity fees. Once a patent expires, patent protection ends and an invention enters the public domain allowing anyone to commercially exploit the invention without infringing the patent.

We cannot guarantee that patents will be issued from any of our pending applications or that issued patents will be of sufficient scope or strength to provide meaningful protection for our technology. Notwithstanding the scope of the patent protection available to us, a competitor could develop methods or devices that are not covered by our patents or circumvent these patents. Furthermore, although, at present, we are unaware of any patent applications that may result in one or more issued patents that our existing products or technologies may be alleged to infringe, since U.S. and foreign applications can take many months to publish, there may be applications unknown to us that may result in one or more issued patents that our existing products or technologies may be alleged to infringe.

As of March 10, 2023, we also have priority rights in and to several significant trademarks that support our products and brand, including seven (7) registered U.S. trademarks, twelve (12) U.S. trademark applications and six (6) foreign trademark applications in the European Community (excluding the United Kingdom), Australia and Japan.

Regulation

Domestic Regulation of Our Products and Business. Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to the federal Food, Drug and Cosmetic Act (the "FDCA"), as implemented and enforced by the FDA. The FDA governs the following activities that we perform or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses:

- product design, development, and manufacture;
- product safety, testing, labeling, and storage;
- record keeping procedures;
- product marketing, sales, distribution and export; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions, and repair or recall of products.

There are numerous FDA regulatory requirements governing the clearance or approval and marketing of our products. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- investigational device exemptions to conduct premarket clinical trials, which include extensive monitoring, recordkeeping, and reporting requirements;
- QSR, which requires manufacturers, including contract manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;

approval of product modifications that affect the safety or effectiveness of one of our approved devices;

- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;

- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

The FDA has broad post-market and regulatory enforcement powers. We and our contract manufacturers are subject to announced and unannounced inspections by the FDA to determine our compliance with the QSR and other regulations and these inspections may include the manufacturing facilities of our suppliers. Tenon has a robust Supplier Qualification and Audit process as part of our quality system that ensures contract manufacturers, and their suppliers meet all requirements.

An FDA pre-approval inspection is not required for The CATAMARAN System due to its lower device classification, class II versus the higher class III. As is the case for most medical device firms, Tenon is subject to routine and "for cause" FDA inspections. Routine inspections are mandated by law every 2 years for class II and class III device manufacturers and make up the majority of FDA's inspections. If a serious public health risk is identified during a routine inspection, the inspection may convert to a "for cause" inspection. In the current environment, FDA has limited compliance resources and has not been able to perform routine inspections in accordance with the 2-year mandate. Therefore, FDA uses a risk-based approach when deciding which firms should be selected for a routine inspection. Using the Establishment Registration and Device Listing databases, FDA identifies who manufactures and/or distributes which devices. The firms are then prioritized by risk, class III > class II > class I. Firms that have recently introduced a new device to the market also are given higher priority, as well as those that have had significant prior violations and complaints. At present, Tenon has not been selected for an FDA inspection. Tenon uses best practices to secure and maintain regulatory compliance by engaging with suppliers and contract manufacturing firms that are ISO 13485 (or equivalent) compliant and by periodically performing internal, external, and third-party inspections and audits of the facilities and systems to assess compliance.

FDA Premarket Clearance and Approval Requirements. Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either premarket notification, or 510(k), clearance or approval of a PMA from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risks are placed in either Class I or II, which typically requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low-risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life- supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring a PMA. 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" process, 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. All of our currently marketed products are Class II devices, subject to 510(k) clearance.

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, PMA approval. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer using available FDA guidance. Many minor modifications today are accomplished by a "letter to file" in which the manufacture documents the rationale for the change and why a new 510(k) is not required. However, the FDA may review such letters to file to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

Clinical Trials. Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance. Such trials for implanted devices such as the CATAMARAN™ SIJ Fixation Device generally require an investigational device exemption application, or IDE, approved in advance by the FDA for a specified number of subjects and study sites, unless the product is deemed a nonsignificant risk device eligible for more abbreviated IDE requirements. Clinical trials are subject to extensive monitoring, recordkeeping, and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board, or IRB, for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the subjects' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA, or the institutional review board, or IRB, could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and effectiveness of the device or may otherwise not be sufficient to obtain FDA clearance or approval to market the product in the United States.

Pervasive and Continuing Regulation. After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- Product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including contract manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved, or off-label use or indication;
- clearance of product modifications that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our approved devices;
- post-approval restrictions or condition, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of some of our subcontractors. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties;
- unanticipated expenditures to address or defend such actions
- customer notifications for repair, replacement, refunds;
- Recall, detention, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying our requests for 510(k) clearance or PMA approval of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted:
- refusal to grant export approval for our products; or
- criminal prosecution.

The FDA has not yet inspected our contract manufacturer's manufacturing facilities.

Promotional Materials "Off-Label" Promotion. Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state, or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of the products would be impaired.

In addition, under the federal Lanham Act and similar state laws, competitors, and others can initiate litigation relating to advertising claims.

Healthcare Fraud and Abuse

Federal and state governmental agencies and equivalent foreign authorities subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. These laws constrain the sales, marketing and other promotional activities of medical device manufacturers by limiting the kinds of financial arrangements we may have with hospitals, physicians and other potential purchases of our products. Federal healthcare fraud and abuse laws apply to our business when a customer submits a claim for an item or service that is reimbursed under Medicare, Medicaid, or other federally funded healthcare programs. Descriptions of some of the laws and regulations that may affect our ability to operate follows.

The federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of, or a specific intent to violate, the law. The Anti-Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; however, those exceptions and safe harbors are drawn narrowly, and there is no exception or safe harbor for many common business activities. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the totality of the facts and circumstances. A number of states also have anti-kickback laws that establish similar prohibitions that may apply to items or services reimbursed by government programs, as well as by any third-party payors, including commercial payors.

The civil False Claims Act prohibits, among other things, knowingly presenting or causing the presentation of a false or fraudulent claim for payment of federal funds, or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Actions under the False Claims Act may be brought by the government or as a *qui tam* action by a private individual in the name of the government. *Qui tam* actions are filed

under seal and impose a mandatory duty on the U.S. Department of Justice to investigate such allegations. Most private citizen actions are declined by the Department of Justice or dismissed by federal courts. However, the investigation costs for a company can be significant and material even if the allegations are without merit. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting a false or fictitious or fraudulent claim to the federal government.

False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of $11,181 to $22,363 per claim (adjusted annually for inflation). Because of the potential for large monetary exposure, healthcare companies often resolve allegations without admissions of liability for significant and sometimes material amounts to avoid the uncertainty of treble damages and per claim penalties that may awarded in litigation proceedings. Moreover, to avoid the risk of exclusion from federal healthcare programs as a result of a False Claims Act settlement, companies may enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance.

In addition, HIPAA created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

The federal Physician Payment Sunshine Act, implemented by CMS as the Open Payments program, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to payments or other "transfers of value" made to physicians and teaching hospitals, and requires applicable manufacturers to report annually to CMS ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" to such physician owners.

Certain states also mandate implementation of corporate compliance programs, impose restrictions on device manufacturer marketing practices, and/or require tracking and reporting of gifts, compensation, and other remuneration to healthcare professionals and entities.

The Foreign Corrupt Practices Act and similar anti-bribery laws in other countries, such as the UK Bribery Act, generally prohibit companies and their intermediaries from making improper payments to government officials and/or other persons for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws.

Violations of these federal and state fraud abuse laws can subject us to administrative, civil, and criminal penalties, including imprisonment, substantial fines, penalties, damages, and exclusion from participation in federal healthcare programs, including Medicare and Medicaid.

Data Privacy and Security Laws

HIPAA requires the notification of patients, and other compliance actions, in the event of a breach of unsecured PHI. If notification to patients of a breach is required, such notification must be provided without unreasonable delay and in no event later than 60 calendar days after discovery of the breach. In addition, if the PHI of 500 or more individuals is improperly used or disclosed, we could be required to report the improper use or disclosure to the U.S. Department of Health and Human Services, or HHS, which would post the violation on its website, and to the media. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $55,910 per violation, not to exceed $1.68 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment.

In addition, even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and

the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

We are subject to the supervision of local data protection authorities in those jurisdictions where we are established or otherwise subject to applicable law. We depend on a number of third parties in relation to our provision of our services, a number of which process personal data on our behalf. With each such provider we enter into contractual arrangements to ensure that they only process personal data according to our instructions, and that they have sufficient technical and organizational security measures in place. Where we transfer personal data outside the EEA, we do so in compliance with the relevant data export requirements. We take our data protection obligations seriously, as any improper disclosure, particularly with regard to our customers' sensitive personal data, could negatively impact our business and/or our reputation.

Manufacturing and Supply

We do not manufacture any products or component parts and currently use five contract manufacturers to produce all of our instruments, implants and sterilization cases. The majority of our instruments have a secondary manufacturing supplier, and we continually work with additional manufacturers to establish secondary manufacturing suppliers. Our contract manufacturers source and purchase all raw materials used in the manufacture of The CATAMARAN System which includes mainly stainless steel and aluminum for our instruments and sterilization cases and titanium for our implants.

We do not currently have manufacturing agreements with any of our contract manufacturers and orders are controlled through purchase orders. The Company does not believe its relationship with any one contract manufacturer is material to its business.

We believe the manufacturing operations of our contract manufacturers, and those of the suppliers of our manufacturers, comply with regulations mandated by the FDA, as well as Medical Devices Directive regulations in the EEA. Manufacturing facilities that produce medical devices or component parts intended for distribution world-wide are subject to regulation and periodic planned and unannounced inspection by the FDA and other domestic and international regulatory agencies.

In the United States, the product we sell is required to be manufactured in compliance with the QSR, which covers the methods used in, and the facilities used for, the design, testing, control, manufacturing, labelling, quality assurance, packaging, storage, and shipping.

We are required to demonstrate continuing compliance with applicable regulatory requirements and will be subject to FDA inspections. Further, we and certain of our contract manufacturers are required to comply with all applicable regulations and current good manufacturing practices. As set forth above, these FDA regulations cover, among other things, the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of our products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections. If we or our manufacturers fail to adhere to current good manufacturing practice requirements, this could delay production of our products and lead to fines, difficulties in obtaining regulatory approvals, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

Product Liability and Insurance

The manufacture and sale of our products subjects us to the risk of financial exposure to product liability claims. Our products are used in situations in which there is a risk of serious injury or death. We carry insurance policies which we believe to be customary for similar companies in our industry. We cannot assure you that these policies will be sufficient to cover all or substantially all losses that we experience.

We endeavor to maintain executive and organization liability insurance in a form and with aggregate coverage limits that we believe are adequate for our business purposes.

Employees

As of March 10, 2023, we have a total of 22 employees, all of whom are full-time, and 5 senior consulting advisors of various specialty including product development, general administrative and accounting. None of our employees is subject to a collective bargaining agreement, and we consider our relationship with our employees to be good.

Corporate Information

We were incorporated on June 6, 2012, in Delaware. Our principal executive offices are located at 104 Cooper Court, Los Gatos, CA 95032 and our telephone number is (408) 649-5760. Our website address is *www.tenonmed.com*. The information on, or that can be accessed through, our website is not part of this report. We have included our website address as an inactive textual reference only.

Item 1A. Risk Factors

Investing in our common stock is highly speculative and involves a significant degree of risk. Before you invest in our securities, you should give careful consideration to the following risk factors, in addition to the other information included in this Annual Report on Form 10-K, including our financial statements and related notes, before deciding whether to invest in our securities. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Operations

We have incurred losses in the past, our financial statements have been prepared on a going concern basis and we may be unable to achieve or sustain profitability in the future.

To date, we have financed our operations primarily through the issuance of public and private equity and convertible notes. We have devoted substantially all of our resources to research and development, creating the infrastructure for a publicly traded medical device company, preparing for our national commercial launch, and clinical and regulatory matters for our products. There can be no assurances that we will be able to generate sufficient revenue from our existing products or from any future product candidates to transition to profitability and generate consistent positive cash flows. We expect that our operating expenses will continue to increase as we continue to build our commercial infrastructure, develop, enhance, and commercialize our existing and new products and incur additional operating and reporting 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. Furthermore, 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 profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives.

Our recurring losses from operations and negative cash flows raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the fiscal year ended, December 31, 2022, describing the existence of substantial doubt about our ability to continue as a going concern. Our expected future capital requirements may depend on many factors including expanding our clinician base, increasing the rate at which we train clinicians, the number of additional clinical papers initiated, and the timing and extent of spending on the development of our technology to increase our product offerings. We may need additional funding to fund our operations but additional funds may not be available to us on acceptable terms on a timely basis, if at all. We may seek funds through borrowings or through additional rounds of financing, including private or public equity or debt offerings. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. 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, and engage in certain merger, consolidation or asset sale transactions. Any future debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we are unable to raise additional capital or generate sufficient cash from operations to adequately fund our operations, we will need to curtail planned activities to reduce costs, which will likely harm our ability to execute on our business plan and continue operations.

Epidemic diseases including COVID-19, or the perception of their effects could have a material adverse effect on our business, financial condition, results of operations, or cash flows.

Outbreaks of infectious diseases, such as COVID-19, could divert medical resources and priorities towards the treatment of that disease. An outbreak of an infectious disease, or continued escalation of the outbreak of COVID-19 could also negatively affect hospital admission rates and the decision by patients to undergo elective surgery, which could decrease demand for procedures using The CATAMARAN System and cause other disruptions to our business. Business disruptions could include disruptions or restrictions on our ability to travel or to distribute our products, government orders suspending the performance of elective surgical procedures such as The CATAMARAN System, inability of our customers to meet their financial commitments due to strain on the healthcare system, as well as temporary closures of our facilities or the facilities of our suppliers and their contract manufacturers, and a reduction in the business hours of hospitals and ambulatory surgery centers. Any disruption of our contract manufacturers or our customers would likely impact our sales and operating results. In addition, a significant outbreak of an infectious disease in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our products. Any of these events could negatively impact the number of procedures using The CATAMARAN System that are performed and have a material adverse effect on our business, financial condition, results of operations, or cash flows.

COVID-19 may have an adverse impact on the timing and success of the commercialization of The CATAMARAN System and our future operations as a result of preventive and precautionary measures that we may find necessary to take. There are numerous uncertainties associated with this COVID-19 outbreak, including the number of individuals who will become infected, the level of resistance to taking vaccines by significant portions of the population in the United States, the extent of the protective and preventative measures that have been put in place by both governmental entities and other businesses and those that may be put in place in the future, the effect that general availability of vaccines, testing for COVID-19 and antibodies will enable relaxation of protective measures for a subset of the population, and numerous other uncertainties. We intend to continue to execute on our product development and strategic plans during the COVID-19 outbreak. However, the aforementioned uncertainties may result in delays or modifications to our product development and strategic plans.

In addition, the COVID-19 pandemic has adversely affected, and may continue to adversely affect, the economies and financial markets of many countries, which may result in a period of regional, national, and global economic slowdown or regional, national, or global recessions that could curtail or delay spending by hospitals and affect demand for our products as well as increased risk of customer defaults or delays in payments. These market disruptions could impair our ability to raise capital, should our business experience a prolonged period of reduced revenue requiring additional capital to sustain the business. COVID-19 and the current financial, economic, and capital markets environment, and future developments in these and other areas present material uncertainty and risk with respect to our performance, financial condition, results of operations, and cash flows. Due to the uncertain scope and duration of the pandemic and uncertain timing of global recovery and economic normalization, we are unable to estimate the long-term impacts on our operations and financial results.

The existence and further duration of the COVID-19 pandemic may also further exacerbate certain of the risks described below.

Practice trends or other factors, including the COVID-19 pandemic, may cause procedures to shift from the hospital environment to ambulatory surgical centers ("ASCs"), where pressure on the prices of our products is generally more acute.

To protect health care professionals involved in surgical care and their patients, we anticipate that more outpatient eligible procedures will be performed in ASCs during the COVID-19 pandemic, and as its acuity declines and the healthcare system returns to a more normalized state. Since patients do not stay overnight in ASCs and COVID-19 patients would not otherwise be treated in ASCs, it is likely that the ASC will be viewed as a safer site of service for patients and health care providers, where the risk of transmission of the novel coronavirus can be more effectively controlled. Because ASC facility fee reimbursement is typically less than facility fee reimbursement for hospitals, we typically experience more pressure on the pricing of our products by ASCs than by hospitals, and the average price for which we sell our products to ASCs is less than the average prices we charge to hospitals. An accelerated shift of procedures using our products to ASCs as a result of the COVID-19 pandemic could adversely impact the average selling prices of our products and our revenues could suffer as a result.

If hospitals, clinicians, and other healthcare providers are unable to obtain coverage and reimbursement from third-party payors for procedures performed using our products, adoption of our products may be delayed, and it is unlikely that they will gain further acceptance.

Growing sales of our product depends on the availability of adequate coverage and reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans, and managed care programs. Hospitals, clinicians, and other healthcare providers that purchase or use medical devices generally rely on third-party payors to pay for all or part of the costs and fees associated with the procedures performed with these devices.

Adequate coverage and reimbursement for procedures performed with our products is central to the acceptance of our current and future products. We may be unable to sell our products on a profitable basis if third-party payors deny coverage, continue to deny coverage or reduce their current levels of payment, or if our costs for the product increase faster than increases in reimbursement levels.

Many private payors refer to coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services, or CMS, which administers the Medicare program, as guidelines for setting their coverage and reimbursement policies. By June 30, 2016, all Medicare Administrative Contractors were regularly reimbursing for minimally invasive and/or open SI-Joint fusion. Private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for procedures performed with our products. Private commercial payors have been slower to adopt positive coverage policies for minimally invasive and/or open SI-Joint fusion, and many private payors still have policies that treat the procedure as experimental or investigational and do not regularly reimburse for the procedure. Future action by CMS or third-party payors may further reduce the availability of payments to physicians, outpatient surgery centers, and/or hospitals for procedures using our products.

The healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs. Payors are imposing lower payment rates and negotiating reduced contract rates with service providers and being increasingly selective about the technologies and procedures they choose to cover. There can be no guarantee that we will be able to provide the scientific and clinical data necessary to overcome these policies. Payors may adopt policies in the future restricting access to medical technologies like ours and/or the procedures performed using such technologies. Therefore, we cannot be certain that the procedures performed with each of our products will be reimbursed. There can be no guarantee that, should we introduce additional products in the future, payors will cover those products or the procedures in which they are used.

If the reimbursement provided by third-party payors to hospitals, clinicians, and other healthcare providers for procedures performed using our products is insufficient, adoption and use of our products and the prices paid for our implants may decline.

When a Tenon procedure utilizing The CATAMARAN System is performed, both the clinician and the healthcare facility, a hospital (inpatient or outpatient clinic), submit claims for reimbursement to the patient's insurer. Generally, the facility obtains a lump sum payment, or facility fee, for SI-Joint fusions. Our products are purchased by the facility, along with other supplies used in the procedure. The facility must also pay for its own fixed costs of operation, including certain operating room personnel involved in the procedure, and other medical services care. If these costs exceed the facility reimbursement, the facility's managers may discourage or restrict clinicians from performing the procedure in the facility or using certain technologies, such as The CATAMARAN System, to perform the procedure.

The Medicare 2022 national average hospital inpatient payment ranges from approximately $25,000 to approximately $59,000 depending on the procedural approach and the presence of Complication and Comorbidity (CC)/Major Complication and Comorbidity (MCC).

The Medicare 2022 national average hospital outpatient clinic payment is $21,897. We believe that insurer payments to facilities are generally adequate for these facilities to offer The CATAMARAN System. However, there can be no guarantee that these facility payments will not decline in the future. The number of procedures performed, and the prices paid for our implants may in the future decline if payments to facilities for SI-Joint fusions decline.

Clinicians are reimbursed separately for their professional time and effort to perform a surgical procedure. Depending on the surgical approach, the incision size, type and extent of imaging guidance, indication for procedure, and the insurer, The CATAMARAN System procedure may be reported by the clinician using any one of the applicable

following CPT® codes 27279, 27280, 27299. The Medicare 2022 national average payment for CPT® 27279 is $807 and $1,325 for 27280. CPT® 27299 has no national valuation. Clinicians, however, can present a crosswalk to another procedure believed to be fairly equivalent and/or comparison to a code for which there is an existing valuation.

For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for the procedures performed with our products, if any payment is made at all. Similar to Medicaid, many private payors' coverage and payment may differ from one payer to another as well.

We believe that some clinicians view the current Medicare reimbursement amount as insufficient for the procedure, given the work effort involved with the procedure, including the time to diagnose the patient and obtain prior authorization from the patient's health insurer when necessary. Many private payors require extensive documentation of a multi-step diagnosis before authorizing SI-Joint fusion for a patient. We believe that some private payors apply their own coverage policies and criteria inconsistently, and clinicians may experience difficulties in securing approval and coverage for sacroiliac fusion procedures. Additionally, many private payors limit coverage for open SI-Joint fusion to trauma, tumors or extensive spine fusion procedures involving multiple levels. The perception by physicians that the reimbursement for SI-Joint fusion is insufficient to compensate them for the work required, including diagnosis, documentation, obtaining payor approval for the procedure, and burden on their office staff, may negatively affect the number of procedures performed and may therefore impede the growth of our revenues or cause them to decline.

We may not be able to convince physicians that The CATAMARAN System is an attractive alternative to our competitors' products and that our procedure is an attractive alternative to existing surgical and non-surgical treatments of the SI-Joint.

Clinicians play the primary role in determining the course of treatment in consultation with their patients and, ultimately, the product that will be used to treat a patient. In order for us to sell The CATAMARAN System successfully, we must convince clinicians through education and training that treatment with The CATAMARAN System is beneficial, safe, and cost-effective for patients as compared to our competitors' products. If we are not successful in convincing clinicians of the merits of The CATAMARAN System, they may not use our product, and we will be unable to increase our sales and achieve or grow profitability.

Historically, most spine clinicians did not include SI-Joint pain in their diagnostic work-up because they did not have an adequate surgical procedure to perform for patients diagnosed with the condition. As a result, some patients with lower back pain resulting from SI-Joint dysfunction are misdiagnosed. We believe that educating clinicians and other healthcare professionals about the clinical merits and patient benefits of The CATAMARAN System is an important element of our growth. If we fail to effectively educate clinicians and other medical professionals, they may not include a SI-Joint evaluation as part of their diagnosis and, as a result, those patients may continue to receive unnecessary or only non-surgical treatment.

Clinicians may also hesitate to change their medical treatment practices for other reasons, including the following:

- lack of experience with minimally invasive procedures;
- perceived liability risks generally associated with the use of new products and procedures;
- costs associated with the purchase of new products; and
- time commitment that may be required for training.

Furthermore, we believe clinicians may not widely adopt The CATAMARAN System unless they determine, based on experience, clinical data, and published peer-reviewed publications, that surgical intervention provides benefits or is an attractive alternative to non-surgical treatments of SI-Joint dysfunction. In addition, we believe support of our products relies heavily on long-term data showing the benefits of using our product. If we are unable to provide that data, clinicians may not use our product. In such circumstances, we may not achieve expected sales and may be unable to achieve profitability.

Clinicians and payors may not find our clinical evidence to be compelling, which could limit our sales, and on-going and future research may prove our product to be less safe and effective than initially anticipated.

All of the component parts of The CATAMARAN System have either received premarket clearance under Section 510(k) of the U.S. federal Food, Drug, and Cosmetic Act, or FDCA, or are exempt from premarket review. The 510(k) clearance process of the U.S. Food and Drug Administration, or FDA, requires us to document that our product is "substantially equivalent" to another 510(k) -cleared product. The 510(k) process is shorter and typically requires the submission of less supporting documentation than other FDA approval processes, such as a premarket approval, or PMA, and does not usually require pre-clinical or clinical studies. Additionally, to date, we have not been required to complete clinical studies in connection with the sale of our product. For these reasons, clinicians may be slow to adopt our product, third-party payors may be slow to provide coverage, and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our product does not improve patient outcomes. Such results would slow the adoption of our product by clinicians, significantly reduce our ability to achieve expected sales, and could prevent us from achieving profitability. Moreover, if future results and experience indicate that our product causes unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls, suspension, or withdrawal of FDA clearance.

Pricing pressure from our competitors, changes in third-party coverage and reimbursement, healthcare provider consolidation, payor consolidation and the proliferation of "physician-owned distributorships" may impact our ability to sell our product at prices necessary to support our current business strategies.

If competitive forces drive down the prices we are able to charge for our product, our profit margins will shrink, which will adversely affect our ability to invest in and grow our business. The SI-Joint fusion market has attracted numerous new companies and technologies. As a result of this increased competition, we believe there will be continued and increased pricing pressure, resulting in lower gross margins, with respect to our product.

Even to the extent our product and procedures using our product are currently covered and reimbursed by third-party private and public payors, adverse changes in coverage and reimbursement policies that affect our product, discounts, and number of implants used may also drive our prices down and harm our ability to market and sell our product.

We are unable to predict what changes will be made to the reimbursement methodologies used by third-party payors. We cannot be certain that under current and future payment systems, in which healthcare providers may be reimbursed a set amount based on the type of procedure performed, such as those utilized by Medicare and in many privately managed care systems, the cost of our product will be justified and incorporated into the overall cost of the procedure. In addition, to the extent there is a shift from inpatient setting to outpatient settings, we may experience pricing pressure and a reduction in the number of The CATAMARAN System procedures performed.

Consolidation in the healthcare industry, including both third-party payors and healthcare providers, could lead to demands for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, results of operations, or financial condition. Because healthcare costs have risen significantly over the past several years, numerous initiatives and reforms initiated by legislators, regulators, and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to aggregate purchasing power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks, and large single accounts continue to use their market power to consolidate purchasing decisions for hospitals. We expect that market demand, government regulation, third-party coverage, and reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the price of our product, and adversely impact our business, results of operations, or financial condition. As we continue to expand into international markets, we will face similar risks relating to adverse changes in coverage and reimbursement procedures and policies in those markets.

We operate in a very competitive business environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not grow.

The CATAMARAN System is subject to intense competition. Many of our competitors are major medical device companies that have substantially greater financial, technical, and marketing resources than we do, and they may succeed in developing products that would render our product obsolete or non-competitive. In addition, many of these competitors have significantly longer operating histories and more established reputations than we do. Our field is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement from third-party payors, and are safer, less invasive, and more effective than alternatives available for similar purposes as demonstrated in peer-reviewed clinical publications. Because of the size of the potential market, we anticipate that other companies will dedicate significant resources to developing competing products.

In the United States, we believe that our primary competitors are currently SI-bone, Inc., Globus Medical, Inc., Medtronic plc, XTant Medical Holdings, Inc., and RTI Surgical, Inc. At any time, these or other industry participants may develop alternative treatments, products or procedures for the treatment of the SI-Joint that compete directly or indirectly with our product. If alternative treatments are, or are perceived to be, superior to our product, sales of our product and our results of operations could be negatively affected. Some of our larger competitors are either publicly traded or divisions or subsidiaries of publicly traded companies. These competitors may enjoy several competitive advantages over us, including:

- greater financial, human, and other resources for product research and development, sales and marketing, and legal matters;
- significantly greater name recognition;
- established relationships with clinicians, hospitals, and other healthcare providers;
- large and established sales and marketing and distribution networks;
- greater experience in obtaining and maintaining domestic and international regulatory clearances or approvals, or CE Certificates of Conformity for products and product enhancements;
- more expansive portfolios of intellectual property rights; and
- greater ability to cross-sell their products or to incentivize hospitals or clinicians to use their products.

New participants have increasingly entered the medical device industry. Many of these new competitors specialize in a specific product or focus on a particular market segment, making it more difficult for us to increase our overall market position. The frequent introduction by competitors of products that are or claim to be superior to our product or that are alternatives to our existing or planned products may make it difficult to differentiate the benefits of our product over competing products. In addition, the entry of multiple new products and competitors may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our product and pricing in the market generally.

As a result, without the timely introduction of new products and enhancements, our product may become obsolete over time. If we are unable to develop innovative new products, maintain competitive pricing, and offer products that clinicians and other physicians perceive to be as reliable as those of our competitors, our sales or margins could decrease, thereby harming our business.

We currently manufacture (through third parties) and sell products used in a single procedure, which could negatively affect our operations and financial condition.

Presently we do not sell any products other than The CATAMARAN System and related tools and instruments. Therefore, we are solely dependent on widespread market adoption of The CATAMARAN System and we will continue to be dependent on the success of this single product for the foreseeable future. There can be no assurance that The CATAMARAN System will gain a substantial degree of market acceptance among clinicians, patients or healthcare providers. Our failure to successfully increase sales of The CATAMARAN System or any other event impeding our ability to sell The CATAMARAN System, would result in a material adverse effect on our results of operations, financial condition and continuing operations.

We have a limited operating history and may face difficulties encountered by early-stage companies in new and rapidly evolving markets.

Even though we were formed in 2012 we have just built the infrastructure necessary to commercially launch The CATAMARAN System. Accordingly, we have a limited operating history upon which to base an evaluation of our business and prospects. In assessing our prospects, you must consider the risks and difficulties frequently encountered by early-stage companies in new and rapidly evolving markets, particularly companies engaged in the development and sales of medical devices. These risks include our inability to:

- obtain coverage by third-party, private, and government payors;
- establish and increase awareness of our brand and strengthen customer loyalty;
- attract and retain qualified personnel;
- find and develop relationships with contract manufacturers that can manufacture the necessary volume of product;
- manage our independent sales representatives to achieve our sales growth objectives;
- commercialize new products and enhance our existing product;
- manage rapidly changing and expanding operations;
- implement and successfully execute our business and marketing strategy;
- respond effectively to competitive pressures and developments.

We can also be negatively affected by general economic conditions. Because of our limited operating history, we may not have insight into trends that could emerge and negatively affect our business. As a result of these or other risks, our business strategy might not be successful.

Our sales volumes and our operating results may fluctuate over the course of the year.

Since we had our first sales in April 2021 and our official national launch commenced in October 2022, we have limited history with respect to how rapidly adoption of The CATAMARAN System will occur. Sales growth could be slower than we have projected. Our sales and results of operations will be affected by numerous factors, including, among other things:

- payor coverage and reimbursement;
- maintaining our training schedule with clinicians;
- the number of procedures performed in the quarter and our ability to drive increased sales of our product;
- our ability to identify and sign-up independent sales representatives and their performance;
- pricing pressure applicable to our product, including adverse third-party coverage and reimbursement outcomes;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- our ability to find and develop relationships with contract manufacturers and their ability to timely provide us with an adequate supply of products;
- the evolving product offerings of our competitors;
- the demand for, and pricing of, our product and the products of our competitors;
- factors that may affect the sale of our product, including seasonality and budgets of our customers;
- ability of clinicians to do our procedure given possible COVID restrictions;
- interruption in the manufacturing or distribution of our product;

- the effect of competing technological, industry and market developments;
- our ability to expand the geographic reach of our sales and marketing efforts;
- the costs of maintaining adequate insurance coverage, including product liability insurance;
- the availability and cost of components and materials needed by our contract manufacturers;
- the number of selling days in the quarter; and
- impairment and other special charges.

Some of the products we may seek to develop and introduce in the future will require FDA clearance or approval before commercialization in the United States. As a result, it will be difficult for us to forecast demand for these products with any degree of certainty. In addition, we will be increasing our operating expenses as we expand our commercial capabilities. Accordingly, we may experience significant, unanticipated quarterly losses. If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. Quarterly comparisons of our financial results may not always be meaningful and should not be relied upon as an indication of our future performance.

If we do not successfully implement our business strategy, our business and results of operations will be adversely affected.

Our business strategy was based on assumptions about the market that might prove wrong. We believe that various demographics and industry-specific trends will help drive growth in the market and our business, but these demographics and trends have been and will continue to be uncertain. Actual demand for our product could differ materially from projected demand if our assumptions regarding these factors prove to be incorrect or do not materialize, or if alternative treatments to those offered by our product gains widespread acceptance. Also, our strategy of focusing exclusively on the SI-Joint market may limit our ability to grow. In addition, in order to increase our sales, we will need to identify and contract with independent sales representatives in existing and new regions as well, and in the future, commercialize new products. Moreover, we may decide to alter or discontinue aspects of our business strategy and may adopt different strategies due to business or competitive factors not currently foreseen, such as new medical technologies that would make our product obsolete. Any failure to implement our business strategy may adversely affect our business, results of operations, and financial condition.

Our business could suffer if we lose the services of key members of our senior management, key advisors or personnel.

We are dependent upon the continued services of key members of our senior management and a number of key advisors and personnel. The loss of members of our senior management team, key advisors or personnel, or our inability to attract or retain other qualified personnel or advisors, could have a material adverse effect on our business, results of operations, and financial condition. We do not maintain "key person" insurance for any of our executives or employees. In addition, several of the members of our executive management team are not subject to non-competition agreements that restrict their ability to compete with us. Accordingly, the adverse effect resulting from the loss of certain executives could be compounded by our inability to prevent them from competing with us.

Various factors outside our direct control may adversely affect manufacturing and distribution of our product.

The manufacture and distribution of our product is challenging. Changes that our contract manufacturers may make outside the purview of our direct control can have an impact on our processes, quality of our product, and the successful delivery of products to our customers. Mistakes and mishandling are not uncommon and can affect supply and delivery. Some of these risks include:

- failure to manufacture in compliance with the required regulatory standards;
- transportation risk;
- the cost and availability of components and supplies required by our contract manufacturers to manufacture our products;

- delays in analytical results or failure of analytical techniques that we will depend on for quality control and release of products;
- natural disasters, labor disputes, financial distress, raw material availability, issues with facilities and equipment, or other forms of disruption to business operations affecting our manufacturers or their suppliers; and
- latent defects that may become apparent after products have been released and that may result in a recall of such products.

If any of these risks were to materialize, our ability to provide our product to customers on a timely basis would be adversely impacted.

We are dependent on a limited number of contract manufacturers, some of them single-source and some of them in single locations, for our product, and the loss of any of these contract manufacturers, or their inability to provide us with an adequate supply of products in a timely and cost-effective manner, could materially adversely affect our business.

We rely on contract manufacturers to supply our product. For us to be successful, our contract manufacturers must be able to provide us with product in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable prices, and on a timely basis. We have a limited history with our current contract manufacturers and do not have long-term supply contracts with them. We are in the process of identifying and evaluating new contract manufacturers for our product. The inability to find the required contract manufacturers or the time required to switch contract manufacturers could adversely affect sales.

In addition, our anticipated growth could strain the ability of our contract manufacturers to deliver an increasingly large supply of product. Contract manufacturers often experience difficulties in scaling up production, including financial issues, or problems with production yields and quality control and assurance.

We use a small number of contract manufacturers for our instruments. Our dependence on such a limited number of contract manufacturers exposes us to risks, including, among other things:

- contract manufacturers may fail to comply with regulatory requirements or make errors in manufacturing that could negatively affect the safety or effectiveness of our product or cause delays in shipments of our product;
- some of our contract manufacturers have long lead times of 12 to 16 weeks and we may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, we or our contract manufacturers may have excess or inadequate inventory of materials and components;
- our contract manufacturers may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;
- our contract manufacturers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our product;
- we may experience delays in delivery by our contract manufacturers due to changes in demand from us or their other customers;
- fluctuations in demand for products that our contract manufacturers manufacture for others may affect their ability or willingness to deliver our product to us in a timely manner;
- our contract manufacturers may wish to discontinue supplying products or services to us for risk management reasons;
- we may not be able to find new or alternative contract manufacturers in a timely manner if our current contract manufacturers stop producing products; and
- our contract manufacturers may encounter financial hardships unrelated to our demand, which could inhibit their ability to fulfil our orders and meet our requirements.

If any one or more of these risks materialize, it could significantly increase our costs and impact our ability to meet demand for our product. If we are unable to satisfy commercial demand for our product in a timely manner, our ability to generate revenue would be impaired, market acceptance of our product could be adversely affected, and customers may instead purchase or use our competitors' products. Additionally, we could be forced to seek alternative sources of supply.

Because of the nature of our internal quality control requirements, regulatory requirements, and the custom and proprietary nature of our product, we may not be able to quickly engage additional or replacement contract manufacturers for our product and accessories. We may also be required to assess any potential new contract manufacturer's compliance with all applicable regulations and guidelines, which could further impede our ability to obtain our product in a timely manner. As a result, we could incur increased product costs, experience delays in deliveries of our product, suffer damage to our reputation, and experience an adverse effect on our business and financial results. Failure of any of our contract manufacturers to meet our product demand level would limit our ability to meet our sales commitments to our customers and could have a material adverse effect on our business.

We may also have difficulty obtaining similar product from other contract manufacturers that are acceptable to the FDA and the failure of our contract manufacturers to comply with strictly enforced regulatory requirements could expose us to delays in obtaining clearances or approvals, regulatory action including warning letters, product recalls, termination of distribution, product seizures, civil, administrative, or criminal penalties. We could incur delays while we locate and engage qualified alternative contract manufacturers, and we may be unable to engage alternative contract manufacturers on favorable terms or at all. Any such disruption or increased expenses could harm our commercialization efforts and adversely affect our ability to generate sales.

In addition, we expect that most of our contract manufacturers will operate at a facility in a single location and substantially all their inventory of component supplies and finished goods will be held at these locations. We, and our contract manufacturers, will take precautions to safeguard facilities, including acquiring insurance, adopting health and safety protocols, and utilizing off-site storage of computer data. However, vandalism, terrorism, or a natural or other disaster, such as an earthquake, fire, or flood, could damage or destroy equipment or component supplies or finished product, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our or our contract manufacturers' facilities could harm our business, financial condition, and operating results.

As our sales grow, our contract manufacturers may encounter problems or delays in the manufacturing of our product or fail to meet certain regulatory requirements which could result in an adverse effect on our business and financial results.

To become profitable, our contract manufactures must manufacture our product in adequate quantities in compliance with regulatory requirements and at an acceptable cost. Increasing their capacity to manufacture and inspect our product may require them to improve internal efficiencies or require us to re-design or change the specifications of our product. Our contract manufacturers may encounter several difficulties in increasing this capacity, including:

- managing production yields;
- maintaining quality control and assurance;
- providing component and service availability;
- maintaining adequate control policies and procedures;
- hiring and retaining qualified personnel; and
- complying with state, federal, and foreign regulations.

If we are unable to satisfy commercial demand for The CATAMARAN System due to our contract manufacturer's inability to manufacture and inspect our product, our ability to generate revenue would be impaired, market acceptance of our product could be adversely affected and customers may instead purchase or use our competitors' products.

The size and future growth in the market for the SI-Joint fixation market have not been established based on market reports and our estimates are based on our own review and analysis of public information and may be smaller than we estimate, possibly materially. In addition, our estimates of cost savings to the economy and healthcare system as a result of The CATAMARAN System procedure are based on our internal estimates and market research and could also be smaller than we estimate, possibly materially. If our estimates and projections overestimate the size of this market or cost savings, our sales growth may be adversely affected.

We are not aware of an independent third-party study that reliably reports the potential market size for the SI-Joint fixation market. Therefore, our estimates of the size and future growth in the market for The CATAMARAN System product, including cost savings to the economy overall, including patients and employers, and to the healthcare system and the number of people currently suffering from lower back pain who may benefit from and be amenable to our procedure, is based on a number of internal and third-party studies, surveys, reports, and estimates. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for our product and procedures and health cost savings, these estimates may not be correct and the conditions supporting our estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. For example, we have consulted with our clinical advisors and utilized public information as the basis for our market projections. Additionally, the surveys we have conducted are based on a small number of respondents and are not statistically significant and may have other limitations. The actual incidence of lower back pain, and the actual demand for our product or competitive products, could differ materially from our projections if our assumptions and estimates are incorrect. As a result, our estimates of the size and future growth in the market for our product may prove to be incorrect. In addition, actual health cost savings to the healthcare system as a result of The CATAMARAN System procedure may materially differ from those presented in this report. If the actual number of people with lower back pain who would benefit from The CATAMARAN System and the size and future growth in the market and related costs savings to the healthcare system is smaller than we have estimated, it may impair our projected sales growth and have an adverse impact on our business.

In the future our product 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 The CATAMARAN System or that would render The CATAMARAN System obsolete or non-competitive. Additionally, new surgical procedures, medications and other therapies could be developed that replace or reduce the importance of our product. Accordingly, our success will depend in part on our ability to respond quickly to medical and changes through the development and introduction of new products. 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.

If we experience significant disruptions in our information technology systems, our business, results of operations, and financial condition could be adversely affected.

The efficient operation of our business depends on our information technology systems. We will rely on our information technology systems to effectively manage:

- sales and marketing, accounting, and financial functions;
- inventory management;
- engineering and product development tasks; and
- our research and development data.

Our information technology systems are vulnerable to damage or interruption from:

- earthquakes, fires, floods, and other natural disasters;
- terrorist attacks and attacks by computer viruses or hackers;
- power losses; and
- computer systems, or Internet, telecommunications, or data network failures.

The failure of our information technology systems to perform as we anticipate or our failure to effectively implement new systems could disrupt our entire operation and could result in decreased sales, increased overhead costs, excess inventory and product shortages, and legal liability issues, all of which could have a material adverse effect on our reputation, business, results of operations, and financial condition.

We may seek to grow our business through acquisitions of or investments in new or complementary businesses, products or technologies, and the failure to manage acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us.

From time to time, we expect to consider opportunities to acquire or make investments in other technologies, products, and businesses that may enhance our capabilities, complement our current product, or expand the breadth of our markets or customer base. Potential and completed acquisitions and strategic investments involve numerous risks, including:

- problems assimilating the purchased technologies, products, or business operations;
- issues maintaining uniform standards, procedures, controls, and policies;
- unanticipated costs and liabilities associated with acquisitions;
- diversion of management's attention from our core business;
- adverse effects on existing business relationships with suppliers and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We have no current commitments with respect to any acquisition or investment. We do not know if we will be able to identify acquisitions, we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired business, product, or technology into our business or retain any key personnel, suppliers, or distributors. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete, and integrate suitable target businesses and to obtain any necessary financing. These efforts could be expensive and time consuming and may disrupt our ongoing business and prevent management from focusing on our operations. If we are unable to successfully integrate any acquired businesses, products, or technologies effectively, our business, results of operations, and financial condition will be materially adversely affected.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships with third-parties that may not result in the development of commercially viable products or the generation of significant future revenue.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships, or other arrangements to develop products and to pursue new markets. We have not entered into any collaboration arrangements to date. Proposing, negotiating, and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances, or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology, or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. These collaborations may not result in the development of products that achieve commercial success or result in significant revenue and could be terminated prior to developing any products.

Additionally, we may not be able to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance

milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any future collaborators, they may act in their self- interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products.

Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty, or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we will collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. We have also outsourced significant elements of our information technology infrastructure; as a result, we manage independent vendor relationships with third parties who are responsible for maintaining significant elements of our information technology systems and infrastructure and who may or could have access to our confidential information. The size and complexity of our information technology systems, and those of our third-party vendors, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors. These systems are also vulnerable to attacks by malicious third parties and may be susceptible to intentional or accidental physical damage to the infrastructure maintained by us or by third parties. Maintaining the secrecy of confidential, proprietary and/or trade secret information is important to our competitive business position. While we have taken steps to protect such information and have invested in systems and infrastructures to do so, there can be no guarantee that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination or misuse of critical or sensitive information. A breach our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology or information, and/or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations and/or cash flow.

Geopolitical conditions, including trade disputes and direct or indirect acts of war or terrorism, could have an adverse effect on our operations and financial results.

Recently, Russia initiated significant military action against Ukraine. In response, the U.S. and certain other countries imposed significant sanctions and export controls against Russia, Belarus and certain individuals and entities connected to Russian or Belarusian political, business, and financial organizations, and the U.S. and certain other countries could impose further sanctions, trade restrictions, and other retaliatory actions should the conflict continue or worsen. It is not possible to predict the broader consequences of the conflict, including related geopolitical tensions, and the measures and retaliatory actions taken by the U.S. and other countries in respect thereof as well as any counter measures or retaliatory actions by Russia or Belarus in response, including, for example, potential cyberattacks or the disruption of energy exports, is likely to cause regional instability, geopolitical shifts, and could materially adversely

affect regional economies and the global economy. The situation remains uncertain, and while it is difficult to predict the impact of any of the foregoing, the conflict and actions taken in response to the conflict could increase our costs, disrupt our supply chain, reduce our sales and earnings, impair our ability to raise additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.

The failure of Silicon Valley Bank could cause us to lose our deposits in excess of the federally insured bank deposit limitation.

On March 10, 2023, the Federal Deposit Insurance Corporation (the "FDIC") took control of Silicon Valley Bank ("SVB") and created the National Bank of Santa Clara to hold the deposits of SVB after SVB was unable to continue their operations. SVB's deposits are insured by the FDIC in amount up to $250,000 for any depositor and any deposit in excess of this insured amount could be lost. As of March 10, 2023, we had approximately $585,000 on deposit with SVB, of which approximately $335,000 will not be insured by the FDIC (the "Uninsured Amount"). We expect to have access to the insured portion of our SVB deposit in the coming days, but do not know when, if ever, we will have access to the Uninsured Amount. The loss of all or a significant portion of the Uninsured Amount would not have an adverse effect on our ability to pay our operational expenses or make other payments, but may require the Company to move our accounts to another bank which could cause a temporary delay in making payments to our vendors and employees and cause other operational inconveniences.

Risks Related to Our Legal and Regulatory Environment

We and our contract manufacturers are subject to extensive governmental regulation both in the United States and abroad, and failure to comply with applicable requirements could cause our business to suffer.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. The FDA and other U.S. and foreign governmental agencies 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;
- marketing, sales, and distribution;
- premarket clearance and approval;
- conformity assessment procedures;
- record keeping procedures;
- advertising and promotion;
- compliance with good manufacturing practices requirements;
- 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 tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, difficulties achieving new product clearances, higher than anticipated costs or lower than anticipated sales.

Before we can market or sell a new regulated product or make a significant modification to an existing product in the United States, with very limited exception, we must obtain either clearance under Section 510(k) of the FDCA for Class II devices or approval of a premarket approval application from the FDA for a Class III device. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology, and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device 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. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). Both the 510(k) and PMA processes can be expensive and lengthy and require the payment of significant fees, unless exempt. The FDA's 510(k) clearance process usually takes from three to 12 months but may 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 submitted to the FDA until an approval is obtained. The process of obtaining domestic and international regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all.

In the United States, all of the components to The CATAMARAN System have either received premarket clearance under Section 510(k) of the FDCA or are exempt from premarket review. 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, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy, and uncertain PMA process. Although we do not currently market any devices under PMA, the FDA may demand that we obtain a PMA prior to marketing certain of our future products. In addition, if the FDA disagrees with our determination that a product, we currently market is subject to an exemption from premarket review, the FDA may require us to submit a 510(k) or PMA in order to continue marketing the product. Further, even with respect to those future products where a PMA is not required, we cannot assure you that we will be able to obtain the 510(k) clearances with respect to those products.

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 our product is safe and effective for their intended users;
- the data from our pre-clinical 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 clearance or approval of our product under development or impact our ability to modify our currently approved or cleared product on a timely basis.

Any delay in, or failure to receive or maintain, clearance or approval for our product under development could prevent us from generating revenue from these products or achieving profitability.

In addition, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-market surveillance on our product. These studies can be very expensive and time consuming to conduct. Failure to comply with those studies in a timely manner could result in the revocation of the 510(k) clearance for a product that is subject to such surveillance and the recall or withdrawal of the product, which could prevent us from generating sales from that product in the United States.

Additionally, as part of the conformity assessment process, medical device manufacturers must carry out a clinical evaluation of their medical devices to verify that they comply with the relevant Essential Requirements covering safety and performance. A clinical evaluation includes an assessment of whether a medical device's performance is in accordance with its intended use and that the known and foreseeable risks linked to the use of the device under normal conditions are minimized and acceptable when weighed against the benefits of its intended purpose. The clinical evaluation conducted by the manufacturer must also address any clinical claims, the adequacy of the device

labeling and information (particularly claims, contraindications, precautions/ warnings) and the suitability of related Instructions for Use. This assessment must be based on clinical data, which can be obtained from (i) clinical studies conducted on the devices being assessed; (ii) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated; or (iii) both clinical studies and scientific literature.

The FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some clinicians from using our product and adversely affect our reputation and the perceived safety and effectiveness of our product.

Failure to comply with applicable regulations could jeopardize our ability to sell our product 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;
- facility closures;
- refusal of the FDA other regulators to grant future clearances or approvals; or
- in the most serious cases, criminal penalties.

Adverse action by an applicable regulatory agency the FDA could result in inability to produce our product in a cost-effective and timely manner, or at all, decreased sales, higher prices, lower margins, additional unplanned costs or actions, damage to our reputation, and could have material adverse effect on our reputation, business, results of operations, and financial condition.

We and our independent sales representatives must comply with U.S. federal and state fraud and abuse laws, including those relating to physician kickbacks and false claims for reimbursement.

Healthcare providers, distributors, physicians, and third-party payors play a primary role in the distribution, recommendation, ordering, and purchasing of any implant or other medical device for which we have or obtain marketing clearance or approval. Through our arrangements with customers and third-party payors, we are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, or independent sales representatives may engage in fraudulent or other illegal activity. Misconduct by these parties could include, among other infractions or violations, intentional, reckless and/or negligent conduct or unauthorized activity that violates FDA regulations, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, laws that require the true, complete, and accurate reporting of financial information or data, other commercial or regulatory laws or requirements, and equivalent foreign rules. We plan to implement a compliance program, code of conduct, and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we plan to take to detect and prevent this activity 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, and government authorities may conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance despite our good faith efforts to comply.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback and false claims laws. Our relationships with clinicians, other healthcare professionals, and hospitals are subject to scrutiny under these laws.

Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under federal healthcare programs, such as the Medicare and Medicaid programs;

- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds; knowingly making, using, or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease, or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. There are also criminal penalties for making or presenting a false or fictitious or fraudulent claim to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program including private third-party payors, or knowingly and willfully falsifying, concealing, or covering up a material fact or making a materially false, fictitious, or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services;

- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services information related to payments or other "transfers of value" made to physicians and teaching hospitals, and requires applicable manufacturers to report annually to CMS ownership and investment interests held by physicians and their immediate family members and payments or other "transfers of value" to such physician owners; and

- analogous state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state beneficiary inducement laws, and state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

If we or our employees are found to have violated any of the above laws we may be subjected to administrative, civil and criminal penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties and damages, and damage to our reputation. Additional information about these laws is provided in "*Business — Regulation*."

We have entered into consulting agreements with clinicians who are also customers. We anticipate entering into additional agreements with clinicians who use our product as we continue to commercialize our product. The primary mission of these clinician advisors is research and development and clinician education. Medical device technology development requires thoughtful clinician input from experienced healthcare professionals. Medical device clinician education requires experienced faculty for didactic and anatomic lab activities in a peer-to-peer setting. We believe these engagements will allow us to successfully meet the expectations of the physician community. In addition, a small number of clinicians (which are or may become customers) own less than 1.0% of our stock, or were granted stock options which they either purchased in an arm's length transaction on terms identical to those offered to others or received from us as fair market value consideration for consulting services performed. While all of these transactions were structured with the intention of complying with all applicable laws, including the federal Anti-Kickback Statute, state anti-kickback laws and other applicable laws, to the extent applicable, it is possible that regulatory agencies may

view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to significant penalties. We would be materially and adversely affected if regulatory agencies interpret our financial relationships with clinicians who order our product to be in violation of applicable laws and we were unable to comply with such laws, which could subject us to, among other things, monetary penalties for non-compliance, the cost of which could be substantial.

In certain cases, federal and state authorities pursue actions for false claims on the basis that manufacturers and distributors are promoting unapproved, or "off-label" uses of their products. Pursuant to FDA regulations, we can only market our product for cleared or approved uses. Although clinicians are permitted to use medical devices for indications other than those cleared or approved by the FDA, we are prohibited from promoting products for "off-label" uses. We market our product and provide promotional materials and training programs to clinicians regarding the use of our product. If it is determined that our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, criminal penalty, and damage to our reputation. Federal and state authorities also pursue actions for false claims based upon improper billing and coding advice or recommendations, as well as decisions related to the medical necessity of procedures, including the site-of-service where procedures are performed. Actions under the federal False Claims Act may also be brought by whistleblowers under its *qui tam* provisions.

To enforce compliance with the federal laws, the U.S. Department of Justice has increased its 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. Dealing with investigations can be time and resource consuming and can divert management's attention from the business. Additionally, if a healthcare company settles an investigation with the Department of Justice or other law enforcement agencies, it may need to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

The scope and enforcement of these laws is uncertain and subject to rapid change. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that we may run afoul of one or more of the requirements or that federal or state regulatory authorities might challenge our current or future activities under these laws. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

Our failure to adequately protect personal information in compliance with evolving legal requirements could harm our business.

In the ordinary course of our business, we plan to collect and store sensitive data, including legally protected personally identifiable information. We may collect this kind of information during the course of future clinical trials and for possible post-marketing safety vigilance, helping enable clinicians and their patients to pursue claims for reimbursement for procedures using The CATAMARAN System and servicing potential warranty claims.

There are a number of state, federal, and international laws protecting the privacy and security of health information and personal data. These data protection and privacy-related laws and regulations are evolving and may result in ever-increasing regulatory and public scrutiny of companies' data practices and escalating levels of enforcement and sanctions. As part of the American Recovery and Reinvestment Act 2009, or ARRA, Congress amended the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA. HIPAA imposes certain requirements regarding the privacy, security, use, and disclosure of an individual's protected health information, or PHI, by certain health care providers, health care clearinghouses, and health insurance plans, collectively referred to as "covered entities," and their "business associates," or subcontractors who provide services to covered entities that involve the creation, use, maintenance, or disclosure of PHI. ARRA included significant increases in the penalties for improper use or disclosure of an individual's PHI under HIPAA and extended enforcement authority to state attorneys general. The amendments also created notification requirements applicable to covered entities and business associates in certain cases when PHI in their control has been inappropriately accessed or disclosed. In the case of a

breach of unsecured PHI, covered entities may be required to provide notification to individuals affected by the breach, federal regulators, and, in some cases, local and national media. In addition to HIPAA, most states have laws requiring notification of affected individuals and state regulators in the event of a breach of "personal information," which is a broader class of information than the PHI protected by HIPAA. Certain states also have data privacy requirements applicable to individually identifiable health information. Privacy laws in different states may contain different requirements, and such laws may not be pre-empted by HIPAA, which could complicate our efforts to comply.

In addition, even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Medical data is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

Our failure to comply with applicable laws and regulations, or to protect such data, could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by end-customers, and other affected individuals, and the imposition of integrity obligations and agency oversight, damage to our reputation, and loss of goodwill, any of which could harm on our operations, financial performance, and business. Evolving and changing definitions of personal data and personal information, within the United States, and elsewhere, may limit or inhibit our ability to operate or expand our business, including limiting strategic partnerships that may involve the sharing of data. Moreover, if the relevant laws and regulations change, or are interpreted and applied in a manner that is inconsistent with our data practices or the operation of our product, or if we expand into new regions and are required to comply with new requirements, we may need to expend resources in order to change our business operations, data practices, or the manner in which our product operates. Even the perception of privacy concerns, whether or not valid, may harm our reputation and inhibit adoption of our product.

Even if our product is approved by regulatory authorities if our contract manufacturers fail to comply with ongoing FDA, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain regulatory clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data, and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic bodies. In particular, we and our contract manufacturers are required to comply with FDA's Quality System Regulations ("QSR") for the manufacture of our product and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of any product for which we obtain regulatory clearance or approval.

The failure by us or one of our contract manufacturers to comply with applicable statutes and regulations, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent, and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, refunds;
- recall, detention, or seizure of our product;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval and conformity assessments of new products or modified products;
- limitations on the intended uses for which the product may be marketed;

- operating restrictions;
- withdrawing 510(k) clearances or PMA approvals that have already been granted; or
- criminal prosecution.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our product, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our product. Later discovery of previously unknown problems with our product, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace, or refund the cost of any medical device we manufacture or distribute, fines, suspension, variation, or withdrawal of regulatory approvals product seizures, injunctions, or the imposition of civil, administrative, or criminal penalties which would adversely affect our business, operating results, and prospects.

If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false or fraudulent claims for payment of government funds.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our product on a timely basis and in the required quantities, if at all.

The FDA has not yet inspected our facility, but we expect an inspection in the future.

Our employees, independent contractors, consultants, contract manufacturers, and our independent sales representatives may engage in misconduct or other improper activities, relating to regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, contract manufacturers, and our independent sales representatives may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We plan to implement a compliance program, code of conduct and associated policies and procedures, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity 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. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, including, without limitation, damages, fines, disgorgement of profits, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

We may be subject to enforcement action, including fines, penalties or injunctions, if we are determined to be engaging in the off-label promotion of our product.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of off-label use. Physicians may use our product off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. In the United States,

the full indication for The CATAMARAN System is: "The Tenon Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation System) is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis." Contraindications are patients with the following conditions: skeletally immature spines; deformities; severe osteoporosis; morbid obesity, tumor resection and active infection at treatment site.

We believe that the specific surgical procedures for which our product are marketed fall within the scope of the surgical applications that have been cleared by the FDA. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials, require us to stop promoting our product for those specific procedures until we obtain FDA clearance or approval for them, or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fines, and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false or fraudulent claims for payment of government fund. In that event, our reputation could be damaged, and adoption of the product would be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our product, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our product may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

We are required to report certain malfunctions, deaths, and serious injuries associated with our product, which can result in voluntary corrective actions or agency enforcement actions.

Further, under the FDA's medical device reporting regulations, we are required to report to the FDA any information that our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. If we fail to report these events to the FDA within the required timeframes, or at all, FDA could take enforcement action against us. Any such adverse event involving our product or repeated product malfunctions may result in a voluntary or involuntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit could divert managerial and financial resources, impair our ability to manufacture our product in a cost-effective and timely manner, and have an adverse effect on our reputation, results of operations, and financial condition.

Any adverse event involving our product in the United States could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or agency action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

A recall of our product, either voluntarily or at the direction of the FDA or the discovery of serious safety issues or malfunctions with our product, can result in voluntary corrective actions or agency enforcement actions, which could have a significant adverse impact on us.

The FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found.

In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is an unreasonable risk of substantial public harm. In addition, foreign governmental bodies have the authority to require the recall of our product in the event of material deficiencies or defects in design or manufacture. A government-mandated or voluntary recall by us or one of the independent sales representatives could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our product would divert managerial and financial resources and have an adverse effect on our reputation, results

of operations, and financial condition, which could impair our ability to produce our product in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our product in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

Modifications to our product may require new 510(k) clearances or premarket approvals may require us to cease marketing or recall the product until clearances

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, a PMA. The FDA requires every manufacturer make and document this determination in the first instance. A manufacturer may determine that a modification could not significantly affect safety or effectiveness and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. FDA may review any manufacturer's decision and may not agree with our decisions regarding whether new clearances or approvals are necessary. The FDA may also on its own initiative determine that a new clearance or approval is required.

We have modified our product and have determined based on our review of the applicable FDA guidance that a new 510(k) clearances or PMAs is not required. If the FDA disagrees with our determination and requires us to submit new 510(k) clearances or PMAs for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant enforcement action, regulatory fines, or penalties.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or effectiveness or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application. Where we determine that modifications to our product require a new 510(k) clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. FDA's ongoing review of the 510(k) programs may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a new 510(k) for a modification to a previously cleared product must be submitted or applying more onerous review criteria to such submissions.

Clinical trials necessary to support a 510(k) or reimbursement may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials could affect third party reimbursement as many of the payors want to see peer reviewed articles to maintain coverage and lack of changes in reimbursement could materially slow down our commercial efforts and affect our revenue projections.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

If our clinical trials are completed as planned, we cannot be certain that their results will support our product marketing claims or third party reimbursors will agree with our conclusions regarding them. The clinical trial process may fail to demonstrate efficacy and cost effectiveness of our product and may hinder the adoption of our product or ability to obtain payor coverage. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

We may incur product liability losses, and insurance coverage may be inadequate or unavailable to cover these losses.

Our business exposes us to potential product liability claims that are inherent in the testing, design, manufacture, and sale of medical devices for SI-Joint surgery procedures. SI-Joint surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis, and even death. In addition, if longer-term patient results

and experience indicates that our product or any component of such product cause tissue damage, motor impairment, or other adverse effects, we could be subject to significant liability. Clinicians may misuse or ineffectively use our product, which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, manufacturing flaws, design defects, or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients. Product liability lawsuits and claims, safety alerts, or product recalls, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation, our ability to attract and retain customers and our results of operations or financial condition.

Although we maintain third-party product liability insurance coverage, it is possible that claims against us may exceed the coverage limits of our insurance policies or cause us to record a self-insured loss. Even if any product liability loss is covered by an insurance policy, these policies typically have substantial retentions or deductibles that we are responsible for. Product liability claims in excess of applicable insurance coverage could have a material adverse effect on our business, results of operations, and financial condition.

In addition, any product liability claim brought against us, with or without merit, could result in an increase of our product liability insurance rates. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all.

We are subject to environmental laws and regulations that can impose significant costs and expose us to potential financial liabilities.

Our business and facility and those of our contract manufacturer are subject to foreign, federal, state, and local laws and regulations relating to the protection of human health and the environment, including those governing the use, manufacture, storage, handling, and disposal of, and exposure to, such materials and wastes. In addition, under some environmental laws and regulations, we could be held responsible for costs relating to any contamination at our past or present facilities and at third-party waste disposal sites even if such contamination was not caused by us. A failure to comply with current or future environmental laws and regulations could result in severe fines or penalties. Any such expenses or liability could have a significant negative impact on our business, results of operations, and financial condition.

U.S. tax legislation may materially affect our financial condition, results of operations and cash flows.

The Tax Cuts and Jobs Act (the "Tax Act") has significantly changed the U.S. federal income taxation of U.S. businesses, including by reducing the U.S. corporate income tax rate, limiting interest deductions, permitting immediate expensing of certain capital expenditures, modifying or repealing many business deductions and credits.

The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") modifies certain provisions of the Tax Act, including increasing the amount of interest expense that may be deducted.

The Tax Act as modified by the CARES Act is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and IRS, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. Our analysis and interpretation of this legislation is preliminary and ongoing and there may be material adverse effects resulting from the legislation that we have not yet identified. While some of the changes made by the tax legislation may adversely affect us, other changes may be beneficial. We continue to work with our tax advisors and auditors to determine the full impact that the recent tax legislation as a whole will have on us. We urge our investors to consult with their legal and tax advisors with respect to such legislation and its potential effect on an investment in our common stock.

Risks Related to Our Intellectual Property

Our ability to protect our intellectual property and proprietary technology is uncertain.

We rely primarily on patent, copyright, trademark and trade secret laws, as well as confidentiality and non- disclosure agreements and other methods, to protect our proprietary technologies and know-how. As of March 10, 2023, we

owned eight issued patents (four domestic and four foreign), eighteen pending patent applications (sixteen domestic and two foreign), thirteen registered trademarks (seven domestic and six foreign) and twelve pending domestic trademark applications.

We have applied for patent protection relating to certain existing and proposed products and processes. While we generally apply for patents in those countries where we intend to make, have made, use, or sell patented products, we may not accurately predict all the countries where patent protection will ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so later. Furthermore, we cannot assure you that any of our patent applications will be approved. The rights granted to us under our patents, including prospective rights sought in our pending patent applications, may not be meaningful or provide us with any commercial advantage. In addition, those rights could be opposed, contested, or circumvented by our competitors or be declared invalid or unenforceable in judicial or administrative proceedings. The failure of our patents to adequately protect our technology might make it easier for our competitors to offer the same or similar products or technologies. Competitors may be able to design around our patents or develop products that provide outcomes which are comparable to ours without infringing on our intellectual property rights. Due to differences between foreign and U.S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the United States. Even if patents are granted outside the United States, effective enforcement in those countries may not be available. Since most of our issued patents are for the United States only, we lack a corresponding scope of patent protection in other countries. In countries where we do not have significant patent protection, we may not be able to stop a competitor from marketing products in such countries that are the same as or similar to our product.

We plan to rely on our trademarks, trade names and brand names to distinguish our product from the products of our competitors and have registered or applied to register many of these trademarks. We cannot assure you that our trademark applications will be approved. Third parties may also oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

We also rely on trade secrets, know-how, and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality and intellectual property assignment agreements with parties that develop intellectual property for us and/or have access to it, such as our officers, employees, consultants, contract manufacturers and advisors. However, in the event of unauthorized use or disclosure or other breaches of such agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary information. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees, and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. If any of our trade secrets, know-how or other technologies not protected by a patent were to be disclosed to or independently developed by a competitor, our business, financial condition, and results of operations could be materially adversely affected.

In the future, we may enter into licensing agreements to maintain our competitive position. If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain, and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty, or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek damages or to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

If a competitor infringes upon one of our patents, trademarks, or other intellectual property rights, enforcing those patents, trademarks, and other rights may be difficult and time consuming. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management's attention from managing our business. Moreover, we may not have

sufficient resources to defend our patents or trademarks against challenges or to enforce our intellectual property rights. In addition, if third parties infringe any intellectual property that is not material to the products that we make, have made, use, or sell, it may be impractical for us to enforce this intellectual property against those third parties.

We may be subject to damages resulting from claims that we, our employees, or independent distributors along with their independent sales representatives have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors, in some cases until recently. Some independent distributors and their independent sales representatives sell, or in the past have sold, products of our competitors. We may be subject to claims that we, our employees or independent sales personnel have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Even if we are successful in defending against these claims, litigation could result in substantial costs, divert the attention of management from our core business and harm our reputation. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. There can be no assurance that this type of litigation will not continue, and any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations, and financial condition.

The medical device industry is characterized by patent litigation, and we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages, and/or prevent us from developing or marketing our existing or future products.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, 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 and sell our product. We have conducted a limited review of patents issued to third parties. The large number of patents, the rapid rate of new patent issuances, the complexities of the technology involved, and the uncertainty of litigation increase the risk of business assets and management's attention being diverted to patent litigation. 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 core business, and harm our reputation. Further, as the number of participants in the medical device industry grows, the possibility of intellectual property infringement claims against us increases. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages, including treble, or triple, damages if an infringement is found to be willful, and/or royalties and could be prevented from selling our product unless we obtain a license or are able to redesign our product 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 product in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our product or technologies, we may have to withdraw our existing product from the market or may be unable to commercialize one or more of our future products, all of which could have a material adverse effect on our business, results of operations, and financial condition. If passed into law, patent reform legislation currently pending in the U.S. Congress could significantly change the risks associated with bringing or defending a patent infringement lawsuit. For example, fee shifting legislation could require a non-prevailing party to pay the attorney fees of the prevailing party in some circumstances.

Patent terms are limited, and we may not be able to effectively protect our product and business.

Patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. In addition, upon issuance in the U.S., the patent term may be extended based on certain delays caused by the applicant(s) or the USPTO. Even if we obtain effective patent rights for all our current patent applications, we may not have sufficient patent terms or regulatory exclusivity to protect our product, and our business and results of operations would be adversely affected.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product.

As is the case with other medical devices companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the medical devices industry involves both technological and legal complexity. Therefore, obtaining and enforcing patents is costly, time-consuming, and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened 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 future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our product and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

In addition to patent protection, we also rely upon copyright and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants, contract manufacturers 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, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, 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 product 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 is unpredictable. Even though we use commonly accepted security measures, 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 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.

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 or potential 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, 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.

Risks Related to the Ownership of our Common Stock

The market for our common stock is new and may not develop to provide investors with adequate liquidity.

We only recently conducted our initial public offering in April of 2022. Therefore, the market for our common stock is new, and we cannot assure you that an active trading market for our common stock will develop, or if it does develop, it may not be maintained. You may not be able to sell your common stock quickly or at the market price if trading in our securities is not active.

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

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If too few securities or industry analysts provide coverage or if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, the price of our stock would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our stock could decrease, which might cause the price of our stock and trading volume to decline.

The price of our common stock may be volatile, and you may be unable to resell your shares at or above the offering price.

The trading price of our common stock may fluctuate substantially. The market price of our common stock may be higher or lower than the price investors paid in the offering, depending on many factors, some of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose all or part of your investment in our common stock. Factors that could cause fluctuations in the trading price of our common stock include the following:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- commercial success and market acceptance of our product;
- success of our competitors in developing or commercializing products;
- ability to commercialize or obtain regulatory approvals for our product, or delays in commercializing or obtaining regulatory approvals;
- strategic transactions undertaken by us;
- additions or departures of key personnel;
- product liability claims;
- prevailing economic conditions;
- disputes concerning our intellectual property or other proprietary rights;

- FDA or other U.S. or foreign regulatory actions affecting us or the healthcare industry;
- healthcare reform measures in the United States;
- sales of our common stock by our officers, directors or significant stockholders;
- future sales or issuances of equity or debt securities by us;
- business disruptions caused by earthquakes, fires or other natural disasters;
- the exercise and sale of any outstanding warrants or options;
- issuance of new or changed securities analysts' reports or recommendations regarding us; and
- Covid-19 restrictions on elective surgeries.

In addition, if the market for medical device or healthcare stocks or the stock market, in general, experience a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, results of operations, or financial condition. The trading price of our common stock might also decline in reaction to events that affect other companies in our industry even if these events do not directly affect us. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. If our stock price is volatile, we may become the target of securities litigation. Securities litigation could result in substantial costs and divert our management's attention and resources from our business. This could have a material adverse effect on our business, results of operations, and financial condition.

The price and volume of our common stock may rapidly fluctuate or may decline regardless of our operating performance, resulting in substantial losses for investors.

The trading price of our common stock may be subject to instances of extreme stock price run-ups followed by rapid price declines and stock price volatility unrelated to both our actual and expected operating performance and financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our stock. Further, the trading price of our common stock could be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume, actual or anticipated fluctuations in our results of operations; the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections; failure of securities analysts to initiate or maintain coverage of our Company, changes in financial estimates or ratings by any securities analysts who follow our Company or our failure to meet these estimates or the expectations of investors; announcements by us or our competitors of significant innovations, acquisitions, strategic partnerships, joint ventures, operating results or capital commitments; changes in operating performance and stock market valuations of other companies in our industry; price and volume fluctuations in the overall stock market, including as a result of trends in the economy as a whole; changes in our Board or management; sales of large blocks of our Common Stock, including sales by our executive officers, directors and significant stockholders; lawsuits threatened or filed against us; changes in laws or regulations applicable to our business; the expiration of lock-up agreements; changes in our capital structure, such as future issuances of debt or equity securities; short sales, hedging and other derivative transactions involving our capital stock; general economic and geopolitical conditions, including the current or anticipated impact of military conflict and related sanctions imposed on Russia by the United States and other countries due to Russia's recent invasion of Ukraine; and the other factors described in this section of the report captioned "*Risk Factors*."

Sales of substantial amounts of our common stock in the public markets, or the perception that sales might occur, could reduce the price of our common stock and may dilute our current stockholders voting power and their ownership interest in us.

Sales of a substantial number of shares of our common stock in the public or the perception that these sales could occur, could adversely affect the market price of our common stock, and may make it more difficult for holders of our common stock to sell their common stock at a time and price that you deem appropriate and affect our ability to raise capital through the sale of equity securities.

We may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investments or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

The market price of our securities may be volatile, and in the past companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns.

We may not be able to satisfy listing requirements of Nasdaq to maintain a listing of our common stock.

We must meet certain financial and liquidity criteria to maintain the listing of our common stock on Nasdaq. If we violate the maintenance requirements for continued listing of our common stock, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. In addition, the delisting of our common stock could significantly impair our ability to raise capital.

Our failure to maintain effective internal controls over financial reporting could have an adverse impact on us.

We are required to establish and maintain appropriate internal controls over financial reporting. Failure to establish those controls, or any failure of those controls once established, could adversely impact our public disclosures regarding our business, financial condition, or results of operations. In addition, management's assessment of internal controls over financial reporting may identify weaknesses and conditions that need to be addressed in our internal controls over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting, disclosure of management's assessment of our internal controls over financial reporting or disclosure of our public accounting firm's attestation to or report on management's assessment of our internal controls over financial reporting may have an adverse impact on the price of our common stock.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no system of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

At present, management has identified a material weakness due to lack of segregation of duties. The lack of segregation of duties existed as a result of the Company having no employees until June 2021. Management has taken initial steps to remedy this weakness by hiring a Chief Financial Officer, a director of SEC reporting and compliance and a senior accountant and engaging a cost accounting consultant and external financial consultants, and plans to continue to add additional resources, technology and headcount as warranted by the growth of the Company. While we believe these efforts will improve our internal controls and address the underlying causes of the material weakness, such material weakness will not be remediated until our remediation plan has been fully implemented and we have concluded that our controls are operating effectively for a sufficient period of time. We cannot be certain that the steps we are taking will be sufficient to remediate the control deficiencies that led to our material weakness in our internal control over financial reporting or prevent future material weaknesses or control deficiencies from occurring. While we are working to remediate the material weakness as timely and efficiently as possible, at this time we cannot provide an

estimate of costs expected to be incurred in connection with the implementation of this remediation plan, nor can we provide an estimate of the time it will take to complete this remediation plan. Even if management does establish effective remedial measures, we cannot guarantee that those internal controls and disclosure controls that we put in place will prevent all possible errors, mistakes, or all fraud.

Our financial controls and procedures may not be sufficient to ensure timely and reliable reporting of financial information, which, as a public company, could materially harm our stock price.

We will require significant financial resources to maintain our public reporting status. We cannot assure you we will be able to maintain adequate resources to ensure that we will not have any future material weakness in our system of internal controls. The effectiveness of our controls and procedures may in the future be limited by a variety of factors including:

- faulty human judgment and simple errors, omissions or mistakes;
- fraudulent action of an individual or collusion of two or more people;
- inappropriate management override of procedures; and
- the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial information.

Our internal control over financial reporting will be a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Despite these anticipated controls, because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives. Furthermore, smaller reporting companies like us face additional limitations. Smaller reporting companies employ fewer individuals and can find it difficult to employ resources for complicated transactions and effective risk management. Additionally, smaller reporting companies tend to utilize general accounting software packages that lack a rigorous set of software controls.

If we fail to have effective controls and procedures for financial reporting in place, we could be unable to provide timely and accurate financial information and be subject to investigation by the SEC and civil or criminal sanctions.

We must implement additional and expensive procedures and controls in order to grow our business and organization and to satisfy reporting requirements, which will increase our costs and require additional management resources.

As a public company, we are required to comply with the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") and the related rules and regulations of the SEC, including the requirements that we maintain disclosure controls and procedures and adequate internal control over financial reporting. Compliance with the Sarbanes-Oxley Act and other SEC and national exchange requirements will increase our costs and require additional management resources. We have begun the process of upgrading our procedures and controls and will need to begin implementing additional procedures and controls as we grow our business and organization and to satisfy new reporting requirements. If we are unable to complete the required assessment as to the adequacy of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act or if we fail to establish and maintain internal control over financial reporting, our ability to produce timely, accurate and reliable periodic financial statements could be impaired.

If we do not establish and maintain adequate internal control over financial reporting, investors could lose confidence in the accuracy of our periodic reports filed under the Exchange Act. Additionally, our ability to obtain additional financing could be impaired or a lack of investor confidence in the reliability and accuracy of our public reporting could cause our stock price to decline.

We are an "emerging growth company" under the JOBS Act of 2012 and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. 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 be more volatile.

In addition, Section 107 of the JOBS Act also 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 (the "Securities Act") for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to take advantage of the extended transition period for complying with new or revised accounting standards.

We will remain an "emerging growth company" until the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common stock pursuant to an effective registration statement under the Securities Act, although we will lose that status sooner if our revenues exceed $1.235 billion, if we issue more than $1 billion in non-convertible debt in a three year period, or we are deemed to be a large accelerated filer under applicable SEC rules.

Our status as an "emerging growth company" under the JOBS Act may make it more difficult to raise capital as and when we need it.

Because of the exemptions from various reporting requirements provided to us as an "emerging growth company" and because we will have an extended transition period for complying with new or revised financial accounting standards, we may be less attractive to investors, and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. We currently intend to retain any future earnings to support the development of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our board of directors after taking into account various factors, including, but not limited to, our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. In addition, our ability to pay dividends on our common stock may be limited by Delaware state law. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize a return on their investment. Investors seeking cash dividends should not purchase our common stock.

The elimination of personal liability against our directors and officers under Delaware law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenses.

Our amended and restated certificate of incorporation, as amended ("Certificate of Incorporation"), and our bylaws ("Bylaws") eliminate the personal liability of our directors and officers to us and our stockholders for damages for breach of fiduciary duty as a director or officer to the extent permissible under Delaware law. Further, our Certificate of Incorporation allows for us to and our Bylaws provide that we are obligated to indemnify each of our directors or officers to the fullest extent authorized by Delaware law and, subject to certain conditions, advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could expose us to substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to afford. Further, those provisions and resulting costs may discourage us or our stockholders from bringing a lawsuit against any of our current or former directors or officers for breaches of their fiduciary duties, even if such actions might otherwise benefit our stockholders.

Our Certificate of Incorporation will designate the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our Certificate of Incorporation specifies that, except for claims arising under federal securities laws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the Company, (b) any action asserting a claim of breach of a fiduciary duty owed by any director, officer, employee or agent of the Company to the Company or the Company's stockholders, (c) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our Certificate of Incorporation or Bylaws, or (d) any action asserting a claim governed by the internal affairs doctrine, in each case subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our Certificate of Incorporation as described above.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. As such, stockholders of the Company seeking to bring a claim regarding the internal affairs of the Company may be subject to increased costs associated with litigating in Delaware as opposed to their home state or other forum, precluded from bringing such a claim in a forum they otherwise consider to be more favorable, and discouraged from bringing such claims as a result of the foregoing or other factors related to forum selection. Alternatively, if a court were to find the choice of forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

We believe these provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees, and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. 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 Certificate of Incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties

We lease and maintain our primary offices at 104 Cooper Court, Los Gatos, CA 95032. We do not currently own any real estate.

Item 3. Legal Proceedings

On September 2, 2021, Khalid Mentak, a former director and Chief Executive Officer of the Company filed an arbitration claim with the American Arbitration Association ("AAA") against the Company, asserting damages in excess of $3,000,000, plus attorneys' fees and other costs, for alleged unpaid wages, defamation, and other claims. The services provided by Mr. Mentak were governed by a Consulting Agreement between the Company and Key Medical Technologies, Inc ("Key Medical"), a company which Mr. Mentak served as Chief Executive Officer.The AAA proceeding was also initiated pursuant to the arbitration provision in the Consulting Agreement. The parties selected an arbitrator and the Company filed a motion to dismiss the proceeding as currently pled because the proper parties should be Key Medical and the Company, and not Mr.Mentak as an individual. The arbitrator ruled that Mr. Mentak was the real-party-in-interest and denied the motion, without prejudice to any arguments on the merits of the underlying claims. On March 1, 2022, Mr. Mentak filed a more detailed Statement of Claims, which the Company responded to on March 16, 2022. The Company also filed a cross-complaint for declaratory relief seeking to establish its rights and obligations under the Consulting Agreement with respect to the claimant and Key Medical, which was formally named a defendant in the cross complaint. The claimant objected to the cross-complaint as unnecessary. On July 21, 2022, the Company entered into a Settlement Agreement and General Release of All Claims (the "Settlement Agreement") with Key Medical and Mr. Mentak to settle all claims and counterclaims. Pursuant to the Settlement Agreement, the Company has agreed to pay Key Medical the total sum of $1,200,000. The settlement amount was fully paid as of December 31, 2022.

From time to time, we may also be subject to legal proceedings and claims in the ordinary course of business. As our growth continues, we may become party to an increasing number of litigation matters and claims. We may in the future receive claims from third parties asserting, among other things, infringement of their intellectual property rights. Future litigation may be necessary to defend ourselves, our partners and our customers by determining the scope, enforceability and validity of third-party proprietary rights, or to establish our proprietary rights. The outcome of litigation and claims cannot be predicted with certainty, and the resolution of these matters could materially affect our future results of operations, cash flow or financial position.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is trading on the Nasdaq Capital Market under the symbol "TNON."

Holders

As of March 10, 2023, we have issued and outstanding 11,250,049 shares of common stock issued and outstanding held by 159 stockholders of record. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, this number is not representative of the total number of beneficial owners of our stock.

We also have outstanding:

- Warrants to purchase up to 96,000 shares of our common stock at an exercise price equal to $5.00 per share issued to our underwriters in our initial public offering; and
- Options and restricted stock units related to 2,217,374 shares of our common stock, 456,874 shares of which are vested.

Dividends

We have never declared or paid any cash dividend on our common stock. We intend to retain any future earnings to be used to provide working capital, to support our operations, and to finance the growth and development of our business, including potentially the acquisition of, or investment in, businesses, technologies or products that complement our existing business. We do not expect to pay cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

Set forth below is information as to all of our equity securities sold by us during our fiscal year ended December 31, 2022, which was not registered under the Securities Act of 1933, as amended.

(a) Issuance of Capital Stock.

None.

(b) Option Grants.

None.

(c) Warrants.

In April 2022, in connection with the Company's initial public offering, the Company granted the underwriters warrants to purchase a total of 96,000 shares of the Company's common stock. The warrants are immediately exercisable at an exercise price of $5.00 per share and expire on the fifth anniversary of the commencement of sales under the IPO.

The warrant described above were deemed exempt from registration in reliance on Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder in that the issuance of securities were made to an accredited investor and did not involve a public offering. The recipients of such securities represented its intention to acquire the securities for investment purposes only and not with a view to or for sale in connection with any distribution thereof.

(d) Issuance of Notes.

None.

Securities Authorized for Issuance under Equity Compensation Plans

On October 1, 2012, the Board of Directors of the Company adopted the 2012 Plan. The 2012 Plan terminated in April 2022. There are 727,394 options issued and outstanding under the 2012 Plan that have not been exercised. These options are administered under the 2022 Plan.

In January and February of 2022 our board of directors and our shareholders approved our 2022 Equity Incentive Plan (the "2022 Plan," together with the 2012 Plan, the "Plans"). The 2022 Plan governs equity awards to our employees, directors, officers, consultants and other eligible participants. Initially, the maximum number of shares of our common stock that may be subject to awards under the 2022 Plan are equal to (i) 1,600,000 plus (ii) the lesser of (a) 750,000 shares of our common stock and (b) the number of shares of our common stock subject to awards granted under the 2012 Plan that after the 2012 Plan is terminated are cancelled, expired or otherwise terminated without having been exercised in full, are tendered to or withheld by the Company for payment of an exercise price or for tax withholding obligations, or are forfeited to or repurchased by the Company due to failure to vest. The maximum number of shares that are subject to awards under the 2022 is subject to an annual increase equal to the lesser of (i) 1,100,000 shares of our common stock; (ii) a number of shares of our common stock equal to 4% of the prior year's maximum number or (iii) such number of shares of our common stock as determined by the 2022 Plan administrator.

The types of awards permitted under the Plans include nonqualified stock options, incentive stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, performance units and other awards. Each option shall be exercisable at such times and subject to such terms and conditions as the Board may specify.

The Board of Directors has the power to amend, suspend or terminate the Plans without stockholder approval or ratification at any time or from time to time. No change may be made that increases the total number of shares of our common stock reserved for issuance pursuant to incentive awards or reduces the minimum exercise price for options or exchange of options for other incentive awards, unless such change is authorized by our stockholders within one year.

Equity Compensation Plan Information

The table below sets forth information as of December 31, 2022.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	727,394	$ 5.32	10,122
Equity compensation plans not approved by security holders	—	$ —	—
Total	727,394	$ 5.32	10,122

Use of Proceeds from our Initial Public Offering of Common Stock

Not applicable.

Transfer Agent

The transfer agent for the common stock is Vstock Transfer LLC, 18 Lafayette Place, Woodmere, New York, telephone (212) 828-8436.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Selected Financial Data

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, this discussion and analysis contains forward-looking statements that reflect our plans, estimates and beliefs. You should not place undue reliance on these forward-looking statements, which involve risks and uncertainties. As a result of many factors, including but not limited to those set forth under "Risk Factors," our actual results may differ materially from those anticipated in these forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements."

Overview

Tenon Medical, Inc., a medical device company formed in 2012, has developed a proprietary, U.S. Food and Drug Administration ("FDA") approved surgical implant-system, which we call The Catamaran™ SI Joint Fusion System ("The Catamaran System"). The Catamaran System offers a novel, less invasive inferior-posterior approach to the sacroiliac joint ("SI Joint") using a single, robust titanium implant to treat SI Joint dysfunction that often causes severe lower back pain. The system features the Catamaran™ Fixation Device which passes through both the axial and sagittal planes of the ilium and sacrum, transfixing the SI Joint along its longitudinal axis. Published clinical studies have shown that 15% to 30% of all chronic lower back pain is associated with the SI Joint.

With an entry similar to the SI Joint injection, the surgical approach is direct to the joint. The angle and trajectory of the Inferior-Posterior approach is designed to point away from critical neural and vascular structures and into the strongest cortical bone. Joined by a patented osteotome bridge, the implant design consists of two hollow fenestrated pontoons with an open framework to facilitate bony in-growth through the SI Joint. One pontoon fixates into the ilium and the other into the sacrum. The osteotome is designed to disrupt the articular portion of the joint to help facilitate a fusion response.

Our initial clinical results indicate that The Catamaran System implant is promoting fusion across the joint as evidenced by CT scans which is the gold standard widely accepted by the clinical community. We had our national launch of The Catamaran System in October 2022 and are building a sales and marketing infrastructure to market our product and address the greatly underserved market opportunity that exists.

We believe that the implant design and procedure we have developed, along with the 2D and 3D protocols for proper implantation will be received well by the clinician community who have been looking for a next generation device.

We have incurred net losses since our inception in 2012. We had net losses of approximately $18.9 million and $7.1 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of approximately $39.5 million. To date, we have financed our operations primarily through private placements of equity securities, certain debt-related financing arrangements, and sales of our product. We have devoted substantially all of our resources to research and development, regulatory matters and sales and marketing of our product.

Reverse Stock Split

On April 6, 2022, we effected a 1:2 reverse stock split (the "Reverse Stock Split"). Any fractional shares that would have resulted from the Reverse Stock Split were rounded up to the nearest whole share. Our authorized common stock was not impacted by the Reverse Stock Split. Immediately after the Reverse Stock Split there were 989,954 shares of our common stock outstanding. Profit per share and share amounts for the consolidated financial statements as of and for the years ended December 31, 2022 and 2021 reflect the impact of the Reverse Stock Split. Further, we have retrospectively adjusted the 2021 financial statements for profit per share and share amounts as a result of the Reverse Stock Split.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our audited consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported results of operations during the reporting periods. Our estimates are based on our historical experience and on 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. Actual results could differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the accounting policies discussed below are those that are most critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates. For more detail on our critical accounting policies, see Note 2 to our consolidated financial statements.

Investments

We classify our investments in marketable debt securities as available-for-sale and record them at fair value in our consolidated balance sheets. Net unrealized gains and losses are recorded as a separate component of stockholders' equity. Realized gains and losses are recorded in the consolidated statements of operations and comprehensive loss. We determine realized gains or losses on the sale of marketable debt securities on a specific identification method, and record such gains and losses as a component of other income (expense), net.

Revenue Recognition

Our revenue is derived from the sale of our products to medical groups and hospitals in the United States. Revenue is recognized when control is transferred to the customer, in an amount that reflects the consideration we expect to be entitled to in exchange for the goods or services, using the following five step approach: (1) identify the contract with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when a performance obligation is satisfied.

We generate our revenue from the sale of products to hospitals or medical facilities where our products are delivered in advance of a procedure. The performance obligation is the delivery of the products along with the completion of the surgery and therefore, revenue is recognized upon delivery to the customers and completion of the surgery, net of rebates and price discounts. We account for rebates and price discounts as a reduction to revenue, calculated based on the terms agreed to with the customer. Historically, there have been no significant rebates or price discounts. Sales prices are specified prior to the transfer of control to the customer, via either the customer contract, agreed price list, purchase order, or written communication with the customer. Prior to October 2022, we had an agreement in place with a national distributor, which included standard terms that did not allow for payment contingent on resale of the product, obtaining financing, or other terms that could impact the distributor's payment obligation. We billed and collected directly with the end-user customers and recognized revenue based on the gross sales price. For direct sales to end-user customers, our standard payment terms are generally net 30 days.

We offer our standard warranty to all customers. We do not sell any warranties on a standalone basis. Our warranty provides that our products are free of material defects and conform to specifications, and includes an offer to replace or refund the purchase price of defective products. This assurance does not constitute a service and is not considered a separate performance obligation. We estimate warranty liabilities at the time of revenue recognition and record them as a charge to cost of goods sold.

Stock-Based Compensation

We account for all stock-based compensation awards using a fair-value method on the grant date and recognize the fair value of each award as an expense over the requisite service period.

We recognize compensation costs related to stock-based awards granted to employees, directors, and consultants including stock options, based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

The Black-Scholes option-pricing model requires the use of subjective assumptions to determine the fair value of stock-based awards. These assumptions include:

Expected Term — The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the expected term to be the midpoint between the vesting date and the contractual life of the stock-based awards.

Expected Volatility — Since we have only been publicly held since April 2022 and do not have any trading history for our common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle, or area of specialty.

Risk-Free Interest Rate — The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Expected Dividend — We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

We account for forfeitures as they occur.

Our board of directors intends all options granted to be exercisable at a price per share not less than the per share fair value of our common stock underlying those options on the date of grant.

Prior to our initial public offering, the estimated fair value of our common stock was determined at each valuation date by a third-party independent valuation firm in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. These valuations took into account numerous factors, including developments at our company and market conditions.

The May 21, 2021 valuation used a hybrid method which combines the Probability Weighted Expected Return Method ("PWERM") with the OPM. The PWERM considers a set of discrete potential liquidity scenarios for the Company, the value common stock would receive in each scenario, and the time required and risk inherent in achieving those values. The May 21, 2021 valuation examined the following scenarios for the Company: (i) an IPO; (ii) remaining private and raising capital; and (iii) dissolution. Within the IPO scenario, 100% weighting was placed on the Market Approach for determining the enterprise value. The Market Approach assumes that businesses operating in the same industry will share similar characteristics, and therefore a comparison of the business to similar businesses whose financial information is publicly available may provide a reasonable basis to estimate a subject business's value. The equity value in the IPO scenario was estimated considering guideline IPOs, the anticipated size of the Company's offering, and forecasted cash and debt. The estimated common stock value as of the IPO was present valued using a discount rate of 22.4% based on Company's WACC, less an adjustment of 2.0% to reflect the risk reduction of an IPO event.

The August 31, 2021 valuation used a hybrid method which combines the Probability Weighted Expected Return Method ("PWERM") with the OPM. The PWERM considers a set of discrete potential liquidity scenarios for the Company, the value common stock would receive in each scenario, and the time required and risk inherent in achieving those values. The August 31, 2021 valuation examined the following scenarios for the Company: (i) an IPO; (ii) remaining private and raising capital; and (iii) dissolution. Within the IPO scenario, 100% weighting was placed on the Market Approach for determining the enterprise value. The Market Approach assumes that businesses operating in the same industry will share similar characteristics, and therefore a comparison of the business to similar businesses whose financial information is publicly available may provide a reasonable basis to estimate a subject business's value.

The equity value in the IPO scenario was estimated considering guideline IPOs, the anticipated size of the Company's offering, and forecasted cash and debt. The estimated common stock value as of the IPO was present valued using a discount rate of 32.0% based on Company's WACC, less an adjustment of 5.0% to reflect the risk reduction of an IPO event.

The October 28, 2021 valuation used a hybrid method which combines the Probability Weighted Expected Return Method ("PWERM") with the OPM. The PWERM considers a set of discrete potential liquidity scenarios for the Company, the value common stock would receive in each scenario, and the time required and risk inherent in achieving those values. The October 28, 2021 valuation examined the following scenarios for the Company: (i) an IPO; (ii) remaining private and raising capital; and (iii) dissolution. Within the IPO scenario, 100% weighting was placed on the Market Approach for determining the enterprise value. The Market Approach assumes that businesses operating in the same industry will share similar characteristics, and therefore a comparison of the business to similar businesses whose financial information is publicly available may provide a reasonable basis to estimate a subject business's value. The equity value in the IPO scenario was estimated considering guideline IPOs, the anticipated size of the Company's offering, and forecasted cash and debt. The estimated common stock value as of the IPO was present valued using a discount rate of 27.2% based on Company's WACC, less an adjustment of 5.0% to reflect the risk reduction of an IPO event.

In determining the enterprise value within the remain private scenario, 100% weighting was applied to the DCF Method under the income approach, in the same manner as in the December 31, 2018, 2019, and 2020 valuations. The discount rate in this scenario was determined to be 22.4% based on Company's WACC. Adjustments were made to the enterprise value for the Company's cash and debt as of the valuation date to determine the equity value in this scenario. The OPM was used to allocate the equity value to our common stock. The equity volatility rate was determined to be 70.0% based on the volatility rate of certain comparable public companies. DLOMs of (i) 10.0% in the IPO scenario and (ii) 30.0% in the remaining private scenario were applied to the common stock.

Following the closing of the initial public offering, the fair value of our common stock was determined based on the closing price of our common stock on the Nasdaq Capital Market.

Common Stock Warrants

We account for warrants for shares of common stock as equity in accordance with the accounting guidance for derivatives. The accounting guidance provides a scope exception from classifying and measuring as a financial liability a contract that would otherwise meet the definition of a derivative if the contract is both (i) indexed to the entity's own stock and (ii) classified in the stockholders' deficit section of the consolidated balance sheet. We estimate the fair value of our warrants for shares of common stock by using the Black-Scholes option pricing model. Warrants classified as equity are recorded as additional paid-in capital on the consolidated balance sheet and no further adjustments to their valuation are made after the issuance of the warrants.

Income Taxes

We account for income taxes under the asset and liability method, whereby deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. We assess the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

We did not record a provision or benefit for income taxes during the twelve months ended December 31, 2022 or 2021. We continue to maintain a full valuation allowance against our net deferred tax assets.

We assess all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and we will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit may change as new information becomes available.

The Tax Reform Act of 1986 limits the use of net operating loss and tax credit carryforwards in certain situations where changes occur in the stock ownership of a company. We have not completed a study to determine whether any ownership changes per the provisions of Section 382 of the Tax Reform Act of 1986, as amended, as well as similar state provisions, have occurred.

Financial Operations Overview

Revenue

We derive substantially all our revenue from sales of The Catamaran System to a limited number of clinicians. Revenue from sales of The Catamaran System fluctuates based on volume of cases (procedures performed), discounts, and the number of implants used for a particular patient. Similar to other orthopedic companies, our revenue can also fluctuate from quarter to quarter due to a variety of factors, including reimbursement, changes in independent sales representatives and physician activities.

Cost of Goods Sold, Gross Profit, and Gross Margin

We utilize contract manufacturers for production of The Catamaran System implants and instrument sets. Cost of goods sold consists primarily of costs of the components of The Catamaran System implants and instruments, quality inspection, packaging, scrap and inventory obsolescence, as well as distribution-related expenses such as logistics and shipping costs. We anticipate that our cost of goods sold will increase in absolute dollars as case levels increase.

Our gross margins have been and will continue to be affected by a variety of factors, including the cost to have our product manufactured for us, pricing pressure from increasing competition, and the factors described above impacting our revenue.

Operating Expenses

Our operating expenses consist of sales and marketing, research and development, and general and administrative expenses. Personnel costs are the most significant component of operating expenses and consist of consulting expenses, salaries, sales commissions and other cash and stock-based compensation related expenses. We expect operating expenses to increase in absolute dollars as we continue to invest and grow our business.

Sales and Marketing Expenses

Sales and marketing expenses primarily consist of independent sales representative training and commissions in addition to salaries and stock-based compensation expense. Starting in May 2021, commissions to our national distributor have been based on a percentage of sales and we anticipate that these commissions will make up a significant portion of our sales and marketing expenses. We expect our sales and marketing expenses to increase in absolute dollars with the commercial launch of The Catamaran System resulting in higher commissions, increased The Catamaran System clinician and sales representative training, and the start of clinical studies to gain wider clinician adoption of The Catamaran System. Our sales and marketing expenses may fluctuate from period to period due to timing of sales and marketing activities related to the commercial launch of our product.

Research and Development Expenses

Our research and development expenses primarily consist of engineering, product development, regulatory expenses, and consulting services, outside prototyping services, outside research activities, materials, and other costs associated with development of our product. Research and development expenses also include related personnel and consultants' compensation and stock-based compensation expense. We expense research and development costs as they are incurred. We expect research and development expense to increase in absolute dollars as we improve The Catamaran System, develop new products, add research and development personnel, and undergo clinical activities that may be required for regulatory clearances of future products.

General and Administrative Expenses

General and administrative expenses primarily consist of salaries, consultants' compensation, stock-based compensation expense, and other costs for finance, accounting, legal, compliance, and administrative matters. We expect our general and administrative expenses to increase in absolute dollars as we add personnel and IT infrastructure to support the growth of our business. We also expect to incur additional general and administrative expenses as a result of operating as a public company, including but not limited to: expenses related to compliance with the rules and regulations of the SEC and those of The Nasdaq Capital Market LLC on which our securities will be traded; additional insurance expenses; investor relations activities; and other administrative and professional services. While we expect the general and administrative expenses to increase in absolute dollars, we anticipate that it will decrease as a percentage of revenue over time.

Gain (Loss) on Investments

Gain (loss) on investments consists of interest income and realized gains and losses from the sale of our investments in money market and corporate debt securities.

Interest Expense

Interest expense is related to borrowings and includes deemed interest derived from the beneficial conversion prices of notes payable.

Other Income (Expense), Net

Other income and expenses have not been significant to date.

Results of Operations (in thousands, except percentages)

	Years Ended December 31,	
Consolidated Statements of Operations Data in Dollars:	**2022**	**2021**
Revenue	$ 691	$ 160
Cost of goods sold	1,332	55
Gross (loss) profit	(641)	105
Operating expenses:		
Research and development	2,828	1,718
Sales and marketing	7,833	2,141
General and administrative	7,423	2,707
Total operating expenses	18,084	6,566
Loss from operations	(18,725)	(6,461)
Interest and other income (expense), net:		
Gain on investments	180	2
Interest expense	(354)	(621)
Other income (expense)	(18)	(1)
Net loss	(18,917)	(7,081)
Loss attributable to non-controlling interest	—	(33)
Net loss attributable to Tenon Medical, Inc.	$ (18,917)	$ (7,048)

Consolidated Statements of Operations Data as a Percent of Revenue:	Years Ended December 31, 2022	2021
Revenue	100%	100%
Cost of goods sold	193	34
Gross profit	(93)	66
Operating expenses:		
Research and development	409	1,074
Sales and marketing	1,134	1,338
General and administrative	1,074	1,692
Total operating expenses	2,617	4,104
Loss from operations	(2,710)	(4,038)
Interest and other income (expense), net:		
Gain on investments	26	1
Interest expense	(51)	(388)
Other expense	(3)	(1)
Net loss	(2,738)	(4,426)
Loss attributable to non-controlling interest	—	(21)
Net loss attributable to Tenon Medical, Inc.	(2,738)%	(4,405)%

Comparison of the years ended December 31, 2022 and 2021 (in thousands, except percentages)

Revenue, Cost of Goods Sold, Gross Profit, and Gross Margin

	Years Ended December 31, 2022	2021	$ Change	% Change
Revenue	$ 691	$ 160	$ 531	332%
Cost of goods sold	1,332	55	1,277	2,322%
Gross (loss) profit	$ (641)	$ 105	$ (746)	(710)%
Gross (loss) profit percentage	(93)%	66%		

Revenue. The increase in revenue for the year ended December 31, 2022 as compared to 2021 was primarily due to increases of 361% in the number of surgical procedures in which The Catamaran System was used, combined with lower revenue per procedure due to a national distribution agreement in effect for sales from July 2020 through April of 2021 that decreased the amount of revenue that the Company was able to recognize per surgical procedure.

Cost of Goods Sold, Gross Profit, and Gross Margin. The increase in cost of goods sold for the year ended December 31, 2022 as compared to 2021 was due to an increase in operations overhead spending as the Company progressed toward commercial launch of The Catamaran System, combined with a 361% year-over-year increase in the number of surgical procedures. Gross (loss) profit decreased due to the increases in overhead spending and the number of surgical procedures. Gross margin percentage decreased due to higher operations overhead spending, and partially offset by higher revenue per procedure from resulting from an amended and restated national distribution agreement.

Operating Expenses

	Years Ended December 31, 2022	2021	$ Change	% Change
Research and development	$ 2,828	$ 1,718	$ 1,110	65%
Sales and marketing	7,833	2,141	5,692	266%
General and administrative	7,423	2,707	4,716	174%
Total operating expenses	$ 18,084	$ 6,566	$ 11,518	

Research and Development Expenses. Research and development expenses for the year ended December 31, 2022 increased as compared to 2021 primarily due to increased stock-based compensation ($899) and payroll expenses ($344), partially offset by decreased professional fees ($212). The increase in payroll and stock-based compensation expenses in 2022 reflects the fact that we did not have any employees during the first three months of 2021. The decrease in consulting expenses in 2022 relates to a quality/regulatory consulting group hired in May 2021 to upgrade our quality system.

Sales and Marketing Expenses. Sales and marketing expenses for the year ended December 31, 2022 increased as compared to 2021 primarily due to payments to SpineSource in association with the termination of the Sales Agreement ($3,611), increased payroll expenses ($674), consulting fees ($509), sales commissions ($255), clinical and marketing collateral expenses ($189), and sales training expenses ($157). The increase in consulting fees in 2022 is primarily due to the common stock issued for services in the second quarter of 2022.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2022 increased as compared to 2021 primarily due to the legal settlement accrual ($574), increased stock-based compensation ($1,459), payroll expenses ($756), insurance expense ($1,052), consulting fees ($479), and legal fees ($208). The significant increase in general and administrative expenses in 2022 was a result of the Company's ongoing transition to an operating company with formalization and amendment of consulting and sales representative agreements, an audit of our 2021 consolidated financial statements and reviews of our quarterly results by our outside accounting firm and by legal representatives, and the creation of an infrastructure to support future growth through the hiring of employees and establishment of a facility lease.

Gain (Loss) on Investments, Interest Expense and Other Income (Expense), Net

	Years Ended December 31,			
	2022	2021	$ Change	% Change
Gain on investments	$ 180	$ 2	$ 178	8,900%
Interest expense	(354)	(621)	267	(43)%
Other expense, net	(18)	(1)	(17)	1,700%
Total operating expenses	$ (192)	$ (620)	$ 428	

Gain on Investments. Gain on investments for the year ended December 31, 2022 increased as compared to 2021 due to interest on our investments in money market and corporate debt securities. We did not have significant investments in corporate debt securities during the first nine months of 2021.

Interest Expense. Interest expense for the year ended December 31, 2022 decreased as compared to 2021 primarily due to the conversion of our convertible debt in association with our initial public offering in April 2022.

Other Expense, Net. Other income and expenses were not significant during the twelve months ended December 31, 2022 and 2021.

Liquidity and Capital Resources

As of December 31, 2022, we had cash and cash equivalents and short-term investments of $8.6 million. Since inception, we have financed our operations through private placements of preferred stock, debt financing arrangements, our initial public offering and the sale of our products. As of December 31, 2022, we had no outstanding debt.

As of December 31, 2022, we had an accumulated deficit of $39.5 million. During the years ended December 31, 2022 and 2021, we incurred net losses of $18.9 million and $7.1 million, respectively, and expect to incur additional losses in the future. We have not achieved positive cash flow from operations to date. On April 29, 2022, the Company closed an initial public offering of its common stock. Based upon our current operating plan, we believe that the net proceeds from this initial public offering, together with our existing cash and cash equivalents, will not be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months from the date these consolidated financial statements were available to be released. We plan to raise the necessary additional capital through one or a combination of public or private equity offerings, debt financings, and collaborations or licensing arrangements. We continue to face challenges and uncertainties and, as a result, our available capital resources may

be consumed more rapidly than currently expected due to (a) the uncertainty of future revenues from The Catamaran System; (b)changes we may make to the business that affect ongoing operating expenses; (c)changes we may make in our business strategy; (d)regulatory developments affecting our existing products; (e)changes we may make in our research and development spending plans; and (f)other items affecting our forecasted level of expenditures and use of cash resources.

As we attempt to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our sales and marketing efforts, research and development activities, or other operations. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, and collaborations or licensing arrangements. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we are unable to raise capital, we will need to delay, reduce, or terminate planned activities to reduce costs. Doing so will likely harm our ability to execute our business plans.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2022:

	Payments Due By Period (In thousands)				
	Total	Less than 1 year	1–3 years	4-5 years	More than 5 years
Operating leases	$ 1,048	$ 293	$ 611	$ 144	$ —
Purchase obligations	—	—	—	—	—
Total	$ 1,048	$ 293	$ 611	$ 144	$ —

Cash Flows (in thousands, except percentages)

The following table sets forth the primary sources and uses of cash for each of the periods presented below:

	Years Ended December 31,			
	2022	2021	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$ (12,025)	$ (4,292)	$ (7,733)	180%
Investing activities	(2,884)	(4,504)	1,620	(36)%
Financing activities	14,114	11,469	2,645	23%
Effect of foreign currency translation on cash flow	7	(2)	9	(450)%
Net (decrease) increase in cash and cash equivalents	$ (788)	$ 2,671	$ (3,459)	(130)%

The increase in net cash used in operating activities for the year ended December 31, 2022 as compared to 2021 was primarily attributable to our increased net loss of $11.8 million as we continued to fund operations, adjusted for increases in non-cash stock-based compensation expenses ($2,520) and common stock issued for services ($333), in addition to increases in inventory ($82) and accrued expenses ($1,862) and decreases in accounts payable ($372).

Cash used in investing activities for the year ended December 31, 2022 consisted primarily of the net purchase of short-term investments of approximately $2.0 million as we invested a portion of our IPO proceeds, in addition to purchases of property and equipment of $0.8 million as we acquired the components for our surgical tray sets. Cash used in investing activities for year ended December 31, 2021 consisted primarily of the purchase of short-term investments of $4.4 million and purchased of property and equipment of $0.1 million.

Cash provided by financing activities for the year ended December 31, 2022 consisted of the $14.1 million cash received from our initial public offering in April 2022, net of relevant expenses. Cash provided by financing activities for the year ended December 31, 2021 consisted primarily of the issuance of $12.1 million in convertible notes payable.

Off-Balance Sheet Arrangements

As of December 31, 2022 and 2021, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Tenon Medical, Inc.
Consolidated Financial Statements
December 31, 2022 and 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Tenon Medical, Inc. and Subsidiary

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Tenon Medical, Inc and Subsidiary (collectively the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, consolidated statements of convertible preferred stock and stockholders' equity (deficit), and consolidated statements of cash flows for each of the years then ended, and the related notes (collectively referred to as 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, 2022 and 2021, and the results of its operations and its cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Emphasis of Matter

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 suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans regarding 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.

/s/ Armanino LLP
San Jose, California
March 10, 2023

We have served as the Company's auditor since 2021.

Tenon Medical, Inc.
Consolidated Balance Sheets
(In thousands, except share data)

	December 31, 2022	December31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 2,129	$ 2,917
Short-term investments	6,441	4,404
Accounts receivable	228	76
Inventory	415	188
Prepaid expenses	134	87
Total current assets	9,347	7,672
Fixed assets, net	793	101
Deposits	51	41
Operating lease right-of-use asset	873	1,084
Deferred offering costs	25	374
TOTAL ASSETS	$ 11,089	$ 9,272
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 550	$ 478
Accrued expenses	717	1,074
Current portion of accrued commissions	1,035	14
Current portion of operating lease liability	228	202
Convertible notes payable and accrued interest, net of debt discount of $0 and $31 at December 31, 2022 and 2021, respectively	—	12,857
Convertible notes payable and accrued interest due to related parties, net of debt discount of $0 and $2 at December 31, 2022 and 2021, respectively	—	649
Total current liabilities	2,530	15,274
Accrued commissions, net of current portion	1,624	—
Operating lease liability, net of current portion	683	911
Total liabilities	4,837	16,185
Commitments and contingencies (Notes 6 and 10)		
Convertible preferred stock:		
Series A convertible preferred stock, $0.001 par value; 4,500,000 and 2,805,839 shares authorized at December 31, 2022 and 2021, respectively; 0 and 2,550,763 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	12,367
Series B convertible preferred stock, $0.001 par value; 491,222 shares authorized; 0 and 491,222 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	1,272
Stockholders' equity (deficit):		
Common stock, $0.001 par value; 130,000,000 and 10,487,904 shares authorized at December 31, 2022 and 2021, respectively; 11,236,801 and 989,954 shares issued and outstanding at December 31, 2022 and 2021, respectively	11	1
Additional paid-in capital	45,833	113
Accumulated deficit	(39,492)	(20,575)
Accumulated other comprehensive income (loss)	(100)	(91)
Total stockholders' equity (deficit)	6,252	(20,552)
TOTAL LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 11,089	$ 9,272

The accompanying notes are an integral part of these consolidated financial statements.

Tenon Medical, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share data)

	Years Ended December 31,	
	2022	**2021**
Revenue	$ 691	$ 160
Cost of sales	1,332	55
Gross (Loss) Profit	(641)	105
Operating Expenses		
Research and development	2,828	1,718
Sales and marketing	7,833	2,141
General and administrative	7,423	2,707
Total Operating Expenses	18,084	6,566
Loss from Operations	(18,725)	(6,461)
Other Income (Expense)		
Gain on investments	180	2
Interest expense	(354)	(621)
Other expense, net	(18)	(1)
Total Other Income (Expense), net	(192)	(620)
Net Loss	(18,917)	(7,081)
Loss attributable to non-controlling interest	—	(33)
Net Loss Attributable to Tenon Medical, Inc.	$ (18,917)	$ (7,048)
Net Loss Attributable to Tenon Medical, Inc. Per Share of Common Stock		
Basic and diluted	$ (2.36)	$ (7.81)
Weighted-Average Shares of Common Stock Outstanding		
Basic and diluted	8,008	903
Consolidated Statements of Comprehensive Loss:		
Net loss	$ (18,917)	$ (7,081)
Unrealized loss on investments	(16)	—
Foreign currency translation adjustment	7	1
Total Comprehensive Loss	(18,926)	(7,080)
Comprehensive loss attributable to non-controlling interest	—	(33)
Total comprehensive loss attributable to Tenon Medical, Inc.	$ (18,926)	$ (7,047)

The accompanying notes are an integral part of these consolidated financial statements.

Tenon Medical, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share data)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Non-Controlling	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Income	Interest	Total
Balance at January 1, 2021	—	$ —	491,222	$ 1,272	830,000	$ 1	$ 126	$ (4,486)	$ (57)	$ 1,707	$ (2,709)
Stock-based compensation expense	—	—	—	—	—	—	377	—	—	—	377
Common stock issued for services	—	—	—	—	159,954	—	1,228	—	—	—	1,228
Issuance of Series A preferred stock in exchange for Series A preferred stock of subsidiary	2,550,763	12,367	—	—	—	—	(9,596)	—	—	(2,771)	(12,367)
Reclass of non-controlling interest to additional paid-in capital	—	—	—	—	—	—	(1,063)	—	(34)	1,097	—
Reclass of negative additional paid-in capital to accumulated deficit	—	—	—	—	—	—	9,041	(9,041)	—	—	—
Net loss	—	—	—	—	—	—	—	(7,048)	—	(33)	(7,081)
Balance at December 31, 2021	2,550,763	$12,367	491,222	$ 1,272	989,954	$ 1	$ 113	$ (20,575	$ (91)	$ —	$ (20,552)
Stock-based compensation expense	—	—	—	—	—	—	2,897	—	—	—	2,897
Issuance of common stock and warrants, net of issuance costs	—	—	—	—	3,200,000	3	13,762	—	—	—	13,765
Common stock issued upon conversion of Series A preferred stock	(2,550,763)	(12,367)	—	—	2,447,728	2	12,365	—	—	—	12,367
Common stock issued upon conversion of Series B preferred stock	—	—	(491,222)	(1,272)	245,614	—	1,272	—	—	—	1,272
Common stock issued upon conversion of debt	—	—	—	—	3,955,415	4	13,864	—	—	—	13,868
Common stock issued for services	—	—	—	—	398,090	1	1,560	—	—	—	1,561
Other comprehensive income	—	—	—	—	—	—	—	—	(9)	—	(9)
Net loss	—	—	—	—	—	—	—	(18,917)	—	—	(18,917)
Balance at December 31, 2022	—	$ —	—	$ —	11,236,801	$ 11	$ 45,833	$ (39,492)	$ (100	$ —	$ 6,252

The accompanying notes are an integral part of these consolidated financial statements.

Tenon Medical, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Years Ended December 31,	
	2022	**2021**
Cash Flows from Operating Activities		
Net loss	$ (18,917)	$ (7,081)
Adjustments to reconcile net loss to net cash used in operating activities:		
Unrealized loss on investments	(16)	(2)
Non-cash interest expense	362	620
Stock-based compensation expense	2,897	377
Common stock issued for services	1,561	1,228
Depreciation	78	2
Loss on w rite-off of fixed assets	77	—
Amortization of operating right-of-use asset	211	112
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(152)	(61)
Inventory	(227)	(145)
Prepaid expenses and other assets	(57)	(130)
Accounts payable	72	444
Accrued expenses	2,288	426
Operating lease liability	(202)	(82)
Net cash used in operating activities	(12,025)	(4,292)
Cash Flows from Investing Activities		
Sales of short-term investments	8,079	—
Purchases of short-term investments	(10,116)	(4,402)
Purchases of property and equipment	(847)	(102)
Net cash used in investing activities	(2,884)	(4,504)
Cash Flows from Financing Activities		
Proceeds from issuance of common stock, net of issuance costs	14,139	—
Proceeds from issuance of convertible notes payable	—	12,072
Repayment of notes payable	—	(245)
Debt issuance costs	—	(71)
Deferred offering costs	(25)	(287)
Net cash provided by financing activities	14,114	11,469
Effect of foreign currency translation on cash flow	7	(2)
Net (Decrease) Increase in Cash and Cash Equivalents	(788)	2,671
Cash and Cash Equivalents at Beginning of Period	2,917	246
Cash and Cash Equivalents at End of Period	$ 2,129	$ 2,917
Cash at End of Period	$ 480	$ 616
Cash Equivalents at End of Period	$ 1649	$ 2301
Supplemental Disclosures of Cash Flow Information		
Cash paid during the year for:		
Interest	$ —	$ 1
Income taxes	$ —	$ 1
Non-cash investment and financing activities:		
Common stock issued upon conversion of preferred stock	$ 13,639	$ —
Common stock issued upon conversion of debt	$ 13,868	$ —
Right-of-use assets obtained in exchange for lease liability	$ —	$ 1,195
Conversion of trade payable to law firm to note payable	$ —	$ 556

The accompanying notes are an integral part of these consolidated financial statements.

1. Organization and Business

Nature of operations

Tenon Medical, Inc. (the "Company"), was incorporated in the State of Delaware on June 19, 2012 and was headquartered in San Ramon, California until June 2021 when it relocated to Los Gatos, California. The Company is a medical device company that has developed a novel, minimally invasive approach to the sacroiliac joint (the "SI Joint") using a single, robust, titanium implant for treatment of the most common types SI Joint disorders that cause lower back pain. The Company received U.S. Food and Drug Administration ("FDA") clearance in 2018 for its primary product, The Catamaran™ SI Joint Fusion System ("The Catamaran System") which is designed to transfix and stabilize the SI Joint. The Company is in the early stages of its commercial launch with its primary focus being on the US market.

Basis of consolidation

The consolidated financial statements of the Company include the accounts of the Company and its wholly-owned subsidiary, Tenon Technology AG ("TTAG"), a Swiss company. TTAG was a majority-owned subsidiary until October 28, 2021, at which date the Company acquired the remaining non-controlling interest of TTAG (see Note 8). All intercompany balances and transactions have been eliminated in consolidation. The financial statements of the subsidiary are prepared for the same reporting period as the parent, using consistent accounting policies in all material respects. The amount of consolidated net loss attributable to the Company and the non-controlling interest are both presented on the face of the Consolidated Statements of Operations and Comprehensive Loss.

2. Summary of Significant Accounting Principles

Basis of presentation

The accompanying consolidated financial statements have been prepared on the accrual basis in accordance with generally accepted accounting principles as promulgated in the United States of America ("U.S. GAAP"). Prior year amounts have been adjusted to conform to the current year presentation.

The financial statements of the subsidiary are prepared for the same reporting period as the parent, using consistent accounting policies in all material respects. The amount of consolidated net loss attributable to the Company and ownership interests in TTAG held by parties other than the Company are both presented on the face of the Consolidated Statements of Operations. The Company purchased the non-controlling interest in TTAG as of October 28, 2021. As TTAG was a wholly-owned subsidiary for the full year ended December 31, 2022, the separate presentation was discontinued for the year then ended.

Going concern uncertainty and liquidity requirements

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. There is substantial doubt about the Company's ability to continue as a going concern for one year after the date that these financial statements are issued.

Since inception, the Company has incurred losses and negative cash flows from operations. Management expects to incur additional operating losses and negative cash flows from operations in the foreseeable future as the Company continues its product development programs and starts the commercial launch of The Catamaran System. On April 29, 2022, the Company closed an initial public offering (the "IPO") of its common stock for proceeds of $13,765, net of issuance costs. Based on the Company's current level of revenues and expenditures, the Company believes that its existing cash and cash equivalents and short-term investments as of December 31, 2022 will not provide sufficient funds to enable it to meet its obligations for a period of at least twelve months from the date of the filing of these consolidated financial statements. The Company plans to raise the necessary additional capital through one or a combination of public or private equity offerings, debt financings, and collaborations or licensing arrangements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Principles (cont.)

Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Accordingly, actual results could differ from those estimates. Significant estimates made by management include, but are not limited to, realization of deferred tax assets, accrued liabilities, obsolescence of inventory, the fair value of accrued commissions, stock-based compensation and the fair value of the Company's common stock and preferred stock.

Reverse Stock Split

On April 6, 2022, the Company effected a 1:2 reverse stock split (the "Reverse Stock Split") by filing an amendment to the Company's Amended and Restated Certificate Incorporation, as amended, with the Delaware Secretary of State. The Reverse Stock Split combined every two shares of our common stock issued and outstanding immediately prior to effecting the Reverse Stock Split into one share of common stock. Similarly, shares of Series A and Series B Preferred Stock became convertible into common stock at a conversion rate of one-to-0.5, subject to adjustments for stock dividends, splits, combinations, and similar events. No fractional shares were issued in connection with the Reverse Stock Split. All historical and per share amounts reflected throughout this document have been adjusted to reflect the Reverse Stock Split. The authorized number of shares and the par value per share of the Company's common stock were not affected by the Reverse Stock Split.

Impact of COVID-19

In March 2020, the World Health Organization declared the coronavirus ("COVID-19") outbreak to be a pandemic. During the years ended December 31, 2022 and 2021, the Company's financial results were not significantly affected by the COVID-19 outbreak. The Company has considered all information available as of the date of issuance of these consolidated financial statements and the Company is not aware of any specific events or circumstances that would require an update to its estimates or judgments, or a revision to the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information becomes available. The extent to which the COVID-19 outbreak affects the Company's future financial results and operations will depend on future developments which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the outbreak, and current or future domestic and international actions to contain and treat it.

Segments

The Company operates in one business segment. Although the Company's Swiss subsidiary is located in a different geographical area, management uses one measurement of profitability and does not segregate its business for internal reporting.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities of 90 days or less at the date of purchase to be cash equivalents.

Investments

The Company classifies its investments in marketable securities as available-for-sale and records them at fair value in its consolidated balance sheets. The net unrealized gains and losses are recorded as a separate component of stockholders' equity. Realized gains and losses are recorded in the consolidated statements of operations and comprehensive loss. The Company determines any realized gains or losses on the sale of marketable debt securities on a specific identification method and records such gains and losses as a component of other income (expense) net.

2. Summary of Significant Accounting Principles (cont.)

Accounts receivable and allowance for doubtful accounts

Accounts receivable are derived from products delivered to customers and are stated at their net realizable value. The Company records an allowance for estimated uncollectible accounts in an amount approximating anticipated losses. Individual uncollectible accounts are written off against the allowance when collection of the individual accounts appears doubtful. In determining the amount of the allowance, the Company considers its historical level of credit losses. The Company also makes judgments about the creditworthiness of significant customers based on ongoing credit evaluations, and the Company assesses current economic trends that might impact the level of credit losses in the future. Historically, the Company has had no significant write-offs of accounts receivable. However, since the Company cannot reliably predict future changes in the financial stability of its customers, it cannot guarantee that its allowances will continue to be adequate. If actual credit losses are significantly greater than the allowance, the Company would increase its general and administrative expenses and increase its reported net losses. Conversely, if actual credit losses are significantly less than the Company's reserve, this would eventually decrease the Company's general and administrative expenses and decrease its reported net losses. Allowances are recorded primarily on a specific identification basis. As of December 31, 2022 and 2021, the Company's allowance for doubtful accounts was $0.

Inventory

Inventory is stated at lower of cost or net realizable value. The Company establishes the inventory basis by determining the cost based on standard costs approximating the purchase costs on a first-in, first-out basis. The excess and obsolete inventory is estimated based on future demand and market conditions. Inventory write-downs are charged to cost of goods sold. As of December 31, 2022 and 2021, inventory consisted of finished goods and raw materials.

Deferred offering costs

Deferred offering costs, which consist of direct incremental legal, consulting, banking, and accounting fees relating to the Company's planned IPO in 2022 and future offerings in 2023, are capitalized, and are offset against proceeds upon the effectiveness of the offering. In the event an anticipated offering is terminated, deferred offering costs will be expensed.

Fixed assets, net

Fixed assets are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Equipment, computers, software, and furniture and fixtures are depreciated over periods ranging from three to seven years, and leasehold improvements over the shorter of the lease term or the life of the asset. Construction in progress pertains to the cost of individual components of a custom instrument set used for surgical placement of the Company's products that have not yet been placed into service. The cost of maintenance and repairs is charged to expense as incurred; significant renewals and betterments are capitalized. Deductions are made for retirements resulting from renewals or betterments.

Long-lived assets

The Company regularly reviews the carrying value and estimated lives of all of its long-lived assets, including property and equipment, to determine whether indicators of impairment may exist that warrant adjustments to carrying values or estimated useful lives. The determinants used for this evaluation include management's estimate of the asset's ability to generate positive income from operations and positive cash flow in future periods as well as the strategic significance of the assets to the Company's business objectives.

2. Summary of Significant Accounting Principles (cont.)

Fair value measurements

In accordance with Accounting Standards Codification ("ASC") 820, Fair Value Measurement, fair value is the price that would be received from selling an asset or paid to transfer a liability (i.e., the exit price) in an orderly transaction between market participants at the measurement date. ASC 820 establishes a fair value hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available.

Observable inputs are those that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability based on the best information available in the circumstances.

The fair value hierarchy is categorized into three levels based on the inputs as follows:

Level 1 — Quoted prices are available in active markets for identical assets or liabilities as of the reported date.

Level 2 — Pricing inputs are other than quoted prices in active markets, which are either directly or indirectly observable as of the reported date. The nature of these financial instruments includes cash instruments for which quoted prices are available but are traded less frequently, derivative instruments whose fair values have been derived using a model where inputs to the model are directly observable in the market and instruments that are fair valued using other financial instruments, the parameters of which can be directly observed.

Level 3 — Instruments that have little to no pricing observability as of the measurement date. These financial instruments are measured using management's best estimate of fair value, where the inputs into the determination of fair value require significant management judgment or estimation.

The degree of judgment exercised by the Company in determining fair value is greatest for assets categorized in Level 3. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, for disclosure purposes, the level in the fair value hierarchy within which the fair value measurement falls in its entirety is determined by the lowest level input that is significant to the fair value measurement.

Convertible preferred stock

The Company records convertible preferred stock at fair value on the dates of issuance, net of issuance costs. Convertible preferred stock is recorded as temporary stockholders' equity.

Income taxes

Income taxes are recorded in accordance with Financial Accounting Standards Board ("FASB") ASC Topic 740, Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. Under this method, the Company records deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect when the differences are expected to reverse. Valuation allowances are provided when necessary to reduce net deferred tax assets to the amount that is more likely than not to be realized. Based on the available evidence, the Company is unable, at this time, to support the determination that it is more likely than not that its deferred tax assets will be utilized in the future. Accordingly, the Company recorded a full valuation allowance as of December 31, 2022 and 2021. The Company intends to maintain valuation allowances until sufficient evidence exists to support its reversal.

Current income taxes are based upon the year's income taxable for federal, state, and foreign tax reporting purposes. Deferred income taxes are provided for certain income and expenses, which are recognized in different periods for tax and financial reporting purposes.

2. Summary of Significant Accounting Principles (cont.)

The Company's policy is not to record deferred income taxes on the undistributed earnings of foreign subsidiaries that are indefinitely reinvested in foreign operations.

Revenue recognition

The Company's revenue is derived from the sale of its products to medical groups and hospitals in the United States. Revenue is recognized when control is transferred to the customer, in an amount that reflects the consideration we expect to be entitled to in exchange for the goods or services, using the following five step approach: (1) identify the contract with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when a performance obligation is satisfied.

The Company generates revenue from the sale of products to hospitals or medical facilities where its products are delivered in advance of a procedure. The performance obligation is the delivery of the products along with the completion of the surgery and therefore, revenue is recognized upon delivery to the customers and completion of the surgery, net of rebates and price discounts. The Company accounts for rebates and price discounts as a reduction to revenue, calculated based on the terms agreed to with the customer. Historically, there have been no significant rebates or price discounts. Sales prices are specified prior to the transfer of control to the customer, via either the customer contract, agreed price list, purchase order, or written communication with the customer. Prior to October 2022, the Company had an agreement in place with a national distributor, which included standard terms that did not allow for payment contingent on resale of the product, obtaining financing, or other terms that could impact the distributor's payment obligation. The Company billed and collected directly with the end-user customers and recognized revenue based on the gross sales price. For direct sales to end-user customers, the Company's standard payment terms are generally net 30 days.

The Company offers its standard warranty to all customers and does not sell any warranties on a standalone basis. The Company's warranty provides that its products are free of material defects and conform to specifications, and includes an offer to replace or refund the purchase price of defective products. This assurance does not constitute a service and is not considered a separate performance obligation. The Company estimates warranty liabilities at the time of revenue recognition and records them as a charge to cost of goods sold.

Contract modifications generally do not occur during the performance of the Company's contracts.

Payments received prior to satisfying the revenue recognition criteria are recorded as deferred revenue on the consolidated balance sheets. As of December 31, 2022 and 2021, there were no remaining performance obligations that would give rise to deferred revenue.

Sales commissions are recorded in sales and marketing expenses during the same period as the corresponding revenues.

Research and development

The Company engages in improving existing products and new product development efforts. Research and development expenses relating to these efforts are expensed as incurred. For the years ended December 31, 2022 and 2021, the Company recognized research and development expense of approximately $2,828 and $1,718, respectively.

Stock-based compensation

The Company accounts for all stock-based compensation awards using a fair-value method on the grant date and recognizes the fair value of each award as an expense over the requisite service period.

The Company recognizes compensation costs related to stock-based awards granted to employees, directors, and consultants including stock options, based on the estimated fair value of the awards on the date of grant. We estimate

2. Summary of Significant Accounting Principles (cont.)

the grant date fair value, and the resulting stock-based compensation, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

The Black-Scholes option-pricing model requires the use of subjective assumptions to determine the fair value of stock-based awards. These assumptions include:

Expected Term — The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the expected term to be the midpoint between the vesting date and the contractual life of the stock-based awards.

Expected Volatility — Since the Company has only been publicly held since April 2022 and does not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, stage in the life cycle, or area of specialty.

Risk-Free Interest Rate — The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

Expected Dividends — The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, an expected dividend yield of zero is used.

The Company account for forfeitures as they occur.

The Company's board of directors intends all options granted to be exercisable at a price per share not less than the per share fair value of our common stock underlying those options on the date of grant.

Prior to the Company's initial public offering, the estimated fair value of its common stock was determined at each valuation date by a third-party independent valuation firm in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. These valuations took into account numerous factors, including developments at our company and market conditions.

The May 21, 2021 valuation used a hybrid method which combines the Probability Weighted Expected Return Method ("PWERM") with the OPM. The PWERM considers a set of discrete potential liquidity scenarios for the Company, the value common stock would receive in each scenario, and the time required and risk inherent in achieving those values. The May 21, 2021 valuation examined the following scenarios for the Company: (i) an IPO; (ii) remaining private and raising capital; and (iii) dissolution. Within the IPO scenario, 100% weighting was placed on the Market Approach for determining the enterprise value. The Market Approach assumes that businesses operating in the same industry will share similar characteristics, and therefore a comparison of the business to similar businesses whose financial information is publicly available may provide a reasonable basis to estimate a subject business's value. The equity value in the IPO scenario was estimated considering guideline IPOs, the anticipated size of the Company's offering, and forecasted cash and debt. The estimated common stock value as of the IPO was present valued using a discount rate of 22.4% based on Company's WACC, less an adjustment of 2.0% to reflect the risk reduction of an IPO event.

The August 31, 2021 valuation used a hybrid method which combines the Probability Weighted Expected Return Method ("PWERM") with the OPM. The PWERM considers a set of discrete potential liquidity scenarios for the Company, the value common stock would receive in each scenario, and the time required and risk inherent in achieving those values. The August 31, 2021 valuation examined the following scenarios for the Company: (i) an IPO; (ii) remaining private and raising capital; and (iii) dissolution. Within the IPO scenario, 100% weighting was placed on the Market Approach for determining the enterprise value. The Market Approach assumes that businesses operating in the same industry will share similar characteristics, and therefore a comparison of the business to similar businesses whose financial information is publicly available may provide a reasonable basis to estimate a subject business's value.

2. Summary of Significant Accounting Principles (cont.)

The equity value in the IPO scenario was estimated considering guideline IPOs, the anticipated size of the Company's offering, and forecasted cash and debt. The estimated common stock value as of the IPO was present valued using a discount rate of 32.0% based on Company's WACC, less an adjustment of 5.0% to reflect the risk reduction of an IPO event.

The October 28, 2021 valuation used a hybrid method which combines the Probability Weighted Expected Return Method ("PWERM") with the OPM. The PWERM considers a set of discrete potential liquidity scenarios for the Company, the value common stock would receive in each scenario, and the time required and risk inherent in achieving those values. The October 28, 2021 valuation examined the following scenarios for the Company: (i) an IPO; (ii) remaining private and raising capital; and (iii) dissolution. Within the IPO scenario, 100% weighting was placed on the Market Approach for determining the enterprise value. The Market Approach assumes that businesses operating in the same industry will share similar characteristics, and therefore a comparison of the business to similar businesses whose financial information is publicly available may provide a reasonable basis to estimate a subject business's value. The equity value in the IPO scenario was estimated considering guideline IPOs, the anticipated size of the Company's offering, and forecasted cash and debt. The estimated common stock value as of the IPO was present valued using a discount rate of 27.2% based on Company's WACC, less an adjustment of 5.0% to reflect the risk reduction of an IPO event.

In determining the enterprise value within the remain private scenario, 100% weighting was applied to the DCF Method under the income approach, in the same manner as in the December 31, 2018, 2019, and 2020 valuations. The discount rate in this scenario was determined to be 22.4% based on Company's WACC. Adjustments were made to the enterprise value for the Company's cash and debt as of the valuation date to determine the equity value in this scenario. The OPM was used to allocate the equity value to our common stock. The equity volatility rate was determined to be 70.0% based on the volatility rate of certain comparable public companies. DLOMs of (i) 10.0% in the IPO scenario and (ii) 30.0% in the remaining private scenario were applied to the common stock.

Following the closing of the initial public offering, the fair value of the Company's common stock was determined based on the closing price of its common stock on the Nasdaq Capital Market.

Foreign currency translation and other comprehensive income

The functional currency of Tenon Technology AG is the Swiss franc. Accordingly, TTAG's assets and liabilities are translated from their respective functional currency into U.S. Dollars at period-end rates, and TTAG's revenue and expenses are translated at the weighted-average exchange rate for the period. Adjustments resulting from this translation process are classified as other comprehensive income or loss and shown as a separate component of equity.

When intercompany foreign currency transactions between entities included in the consolidated financial statements are of a long-term investment nature (i.e., those for which settlement is not planned or anticipated in the foreseeable future) foreign currency translation adjustments resulting from those transactions are included in stockholders' equity (deficit) as accumulated other comprehensive loss or income. When intercompany transactions are deemed to be of a short-term nature, translation adjustments are required to be included in the consolidated statements of operations. The Company has determined that settlement of TTAG's intercompany balances is not anticipated in the foreseeable future, and therefore such translation adjustments are included in stockholders' deficit as accumulated other comprehensive income.

Net loss per share

Basic net loss per share is based upon the weighted-average number of common shares outstanding. Diluted net loss per share is based on the assumption that all potential common stock equivalents (convertible preferred stock, stock options, and warrants) are converted or exercised. The calculation of diluted net loss per share excludes potential

(in thousands, except share and per-share data)

2. Summary of Significant Accounting Principles (cont.)

common stock equivalents if the effect is anti-dilutive. For the periods presented, the Company's weighted-average common shares outstanding for basic and diluted are the same because the effect of the potential common stock equivalents is anti-dilutive.

The Company had the following dilutive common stock equivalents as of December 31, 2022 and 2021 which were excluded from the calculation because their effect was anti-dilutive.

	December 31, 2022	December 31, 2021
Outstanding restricted stock units	1,318,530	—
Outstanding stock options	898,844	727,394
Outstanding warrants	96,000	25,000
Common shares convertible from notes payable	—	2,079,510
Common shares convertible from preferred stock	—	1,520,996
Total	2,313,374	4,352,900

Adoption of New Accounting Pronouncements

There have been no accounting pronouncements or changes in accounting pronouncements in the year ended December 31, 2022 that are significant or potentially significant to the Company.

3. Investments

The following table sets forth by level, within the fair value hierarchy, the Company's investments at fair value as of December 31, 2022 and 2021:

	Level 2
Corporate debt securities:	
December 31, 2022	$ 6,441
December 31, 2021	$ 4,404

Cost and fair value of available-for-sale investments as of December 31, 2022 and 2021 are as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities:				
December 31, 2022	$ 6,457	$ —	$ (16)	$ 6,441
December 31, 2021	$ 4,404	$ —	$ —	$ 4,404

All of the investments with gross unrealized losses have been in a continuous loss position for less than 12 months.

During the years ended December 31, 2022 and 2021, the Company did not recognize any significant other-than-temporary impairment losses because the Company does not intend to sell the investments before recovery of their amortized cost bases.

During the years ended December 31, 2022 and 2021, there were net gains of approximately $180 and $2, respectively, included in the Company's net loss. Accrued interest as of December 31, 2022 and 2021 was approximately $13 and $18, respectively, and is included in prepaid expenses in the Company's consolidated balance sheet.

(in thousands, except share and per-share data)

4. Inventory

Inventory consisted of the following:

	December 31, 2022	December 31, 2021
Raw materials	$ 9	$ 15
Finished goods	406	173
Inventory	$ 415	$ 188

5. Fixed Assets, net

Fixed assets, net, consisted of the following:

	December 31, 2022	December 31, 2021
Construction in progress	$ 601	$ —
Catamaran tray sets	193	77
IT equipment	56	17
Lab equipment	14	—
Office furniture	9	9
Fixed assets, gross	873	103
Less: accumulated depreciation	(80)	(2)
Fixed assets, net	$ 793	$ 101

As of December 31, 2022, construction in progress pertains to cost of individual components of a custom instrument set used for surgical placement of the Company's products that have not yet been placed into service. Depreciation expense was approximately $78 and $2 for the years ended December 31, 2022 and 2021, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following:

	December 31, 2022	December 31, 2021
Accrued compensation	$ 452	$ 846
Other accrued expenses	265	228
Total accrued expenses	$ 717	$ 1,074

7. Debt

Convertible notes payable — parent company

During 2015, the Company issued a $53 convertible promissory note to a consultant that, along with accrued interest at an annual rate of 8.0%, was automatically convertible upon a preferred stock financing of at least $500, at a conversion price equal to 90% of the price per share paid by the other cash purchasers in the future financing. In June 2019, the note and its accrued interest to date was replaced by a $68 convertible promissory note that, along with accrued interest at an annual rate of 8.0%, was automatically convertible upon a preferred stock financing of at least $1,000, at a conversion price equal to 90% of the price per share paid by the other cash purchasers in the future financing. The note had a maturity date of June 12, 2021. In May 2021, the note was again replaced by a $68 convertible promissory note with a maturity date of May 7, 2022 that, along with accrued interest at an annual rate of 8.0%, was automatically

7. Debt (cont.)

convertible upon an IPO or a capital stock financing of at least $5,000. The conversion price was equal to 80% of the IPO price or $1.9565 per share in the event of a capital stock financing of at least $5,000. Accrued interest at December 31, 2022 and 2021 totaled approximately $0 and $14, respectively.

During 2016, the Company issued a $118 convertible promissory note to a vendor that, along with accrued interest at an annual rate of 8.0%, was automatically convertible upon a preferred stock financing of at least $500, at a conversion price equal to 90% of the price per share paid by the other cash purchasers in the future financing. The note had a maturity date of January 1, 2019 and remained unpaid during 2019 and 2020. In April 2021, the note was replaced by a $118 convertible promissory note with a maturity date of April 30, 2022 that, along with accrued interest at an annual rate of 8.0%, was automatically convertible upon an IPO or a capital stock financing of at least $5,000. The conversion price was equal to 80% of the IPO price or $1.9565 per share in the event of a capital stock financing of at least $5,000. Accrued interest at December 31, 2022 and 2021 totaled approximately $0 and $56, respectively.

In October 2019, the Company issued a $70 convertible promissory note to the Company's former Chief Executive Officer that, along with accrued interest at an annual rate of 8.0%, was automatically convertible upon a preferred stock financing of at least $500, at a conversion price equal to 80% of the price per share paid by the other cash purchasers in the future financing. The note had a maturity date of October 12, 2022. In April 2021, the note was replaced by a $70 convertible promissory note with a maturity date of April 30, 2022 that, along with accrued interest at an annual rate of 8.0%, was automatically convertible upon an IPO or a capital stock financing of at least $5,000. The conversion price was equal to 70% of the IPO price or $1.9565 per share in the event of a capital stock financing of at least $5,000. Accrued interest at December 31, 2022 and 2021 totaled approximately $0 and $12, respectively.

In October 2019, the Company issued a $50 convertible promissory note to an investor that, along with accrued interest at an annual rate of 8.0%, was automatically convertible upon a preferred stock financing of at least $500, at a conversion price equal to 80% of the price per share paid by the other cash purchasers in the future financing. The note had a maturity date of October 21, 2022. In May 2021, the note was replaced by a $50 convertible promissory note with a maturity date of May 3, 2022 that, along with accrued interest at an annual rate of 8.0%, was automatically convertible upon an IPO or a capital stock financing of at least $5,000. The conversion price was equal to 70% of the IPO price or $1.9565 per share in the event of a capital stock financing of at least $5,000. Accrued interest at December 31, 2022 and 2021 totaled approximately $0 and $9, respectively.

In November 2020, the Company issued a $200 convertible promissory note to the same investor that, along with accrued interest at an annual rate of 8.0%, was automatically convertible upon a preferred stock financing of at least $2,000, at a conversion price equal to 80% of the price per share paid by the other cash purchasers in the future financing. The note had a maturity date of November 16, 2022. In May 2021, the note was replaced by a $200 convertible promissory note with a maturity date of May 3, 2022 that, along with accrued interest at an annual rate of 8.0%, was automatically convertible upon an IPO or a capital stock financing of at least $5,000. The conversion price was equal to 70% of the IPO price or 70% of the price per share paid by the other cash purchasers in the future financing. Accrued interest at December 31, 2022 and 2021 was approximately $0 and $18, respectively.

In January 2021, the Company issued a promissory note of $131 to a law firm. The note bore interest at 3.0% per annum and had a maturity date of the earlier of July 27, 2021, the closing of a debt or equity financing, or the closing of a change in control transaction. The interest rate was to increase to 5.0% if all principal and interest had not been paid by the maturity date. The Company repaid this note and accrued interest in May 2021.

In April 2021, the Company issued two convertible promissory notes of $40 and $170 to the vendor described in the second paragraph above that, along with accrued interest at an annual rate of 8.0%, were automatically convertible upon an IPO or a capital stock financing of at least $5,000. The conversion price was equal to 70% of the IPO price or 70% of the price per share paid by the other cash purchasers in the future financing. Accrued interest at December 31, 2022 and 2021 totaled approximately $0 and $11, respectively.

(in thousands, except share and per-share data)

7. Debt (cont.)

From May through July 2021, in multiple rounds of closings the Company issued convertible promissory notes to multiple investors for aggregate proceeds of approximately $12,177, with maturity dates twelve months from the issuance dates. Of this amount, $620 of notes were issued to related officers, directors, and their family members, and a $50 note was issued to the Chief Executive Officer of the Representative described in Note 9. The notes, along with accrued interest at an annual rate of 8.0%, were automatically convertible upon an IPO, a capital stock financing of at least $5,000, or a change of control transaction. The conversion price upon an IPO or a capital stock financing was equal to the lesser of 70% of the price per share paid by the other cash purchasers, or the price per share at a Company valuation of $22,500. The Company recorded debt issuance costs of approximately $71 as a discount on the convertible notes payable balance. Accrued interest at December 31, 2022 and 2021 was approximately $0 and $527, respectively.

On April 29, 2022, as a result of the completion of the IPO and as required under the terms of the convertible notes payable described above, the Company converted the entirety of the outstanding principal and accrued interest of the outstanding convertible notes payable to 3,955,415 shares of the Company's common stock at the conversion price detailed above and issued the common stock to the noteholders, fully satisfying the Company's obligations.

Convertible notes payable — subsidiary

In June 2021, the Company's subsidiary issued a convertible promissory note for approximately $107 to TTAG's minority shareholder. This note, along with accrued interest at an annual rate of 8.0%, could be applied to future TTAG capital increases. The Company purchased this note and accrued interest of approximately $114 in October 2021 from TTAG's minority shareholder.

8. Leases

In June 2021, the Company entered into a facility lease agreement for its company headquarters in Los Gatos, California. This non-cancelable operating lease expires in June 2026. The Company includes options that are reasonably certain to be exercised as part of the determination of lease terms. The Company may negotiate termination clauses in anticipation of any changes in market conditions, but generally these termination options are not exercised. Residual value guarantees are generally not included within operating leases. In addition to base rent payments, leases may require the Company to pay directly for taxes and other non-lease components, such as insurance, maintenance, and other operating expenses, which may be dependent on usage or vary month-to-month. Non-lease components were considered and determined not to be material. The Company determined if an arrangement is a lease at inception of the contract in accordance with guidance detailed in the new standard and performed the lease classification test as of the lease commencement date. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease's commencement date based on the present value of lease payments over the lease term. When a lease did not provide an implicit rate, the Company used its estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of future payments.

Operating lease costs for the facility lease were $292 and $158 for the years ended December 31, 2022 and 2021, respectively. Lease costs are included in general and administrative expenses in the consolidated statements of operations and comprehensive loss.

Supplemental balance sheet information related to leases was as follows:

	December 31, 2022	December 31, 2021
Operating lease right-of-use assets	$ 873	$ 1,084
Operating lease liability, current	$ (228)	$ (202)
Operating lease liability, noncurrent	(683)	(911)
Total operating lease liabilities	$ (911)	$ (1,113)

(in thousands, except share and per-share data)

8. Leases (cont.)

Future maturities of operating lease liabilities as of December 31, 2022 were as follows:

2023	293
2024	301
2025	310
2026	144
Total lease payments	1,048
Less: imputed interest	(137)
Present value of operating lease liabilities	$ 911

Other information:

Cash paid for operating leases for the year ended December 31, 2022	$ 284
Cash paid for operating leases for the year ended December 31, 2021	$ 128
Remaining lease term – operating leases (in years)	3.50
Average discount rate – operating leases	8.0%

9. Stockholders' Equity

The Amended and Restated Certificate of Incorporation dated February 18, 2014 authorized the issuance of 3,937,550 shares of common stock and 2,099,525 shares of preferred stock, with a par value of $0.001 per share. In April 2021 the Company increased the number of authorized shares to 7,000,000 shares of common stock and 2,460,802 shares of preferred stock, and increased the number of authorized shares of Series A Convertible Preferred Stock ("Series A Preferred Stock") to 1,798,905. In October 2021 the Company increased the number of authorized shares to 10,487,904 shares of common stock and 3,297,061 shares of preferred stock. In February 2022, the Company increased the number of authorized shares to 130,000,000 shares of common stock and 20,000,000 shares of preferred stock, of which 4,500,000 are designated "Series A Preferred Stock" and 491,222 are designated "Series B Preferred Stock".

Initial Public Offering

On April 26, 2022, the Company's Registration Statement relating to the IPO was declared effective by the SEC. The IPO consisted of 3,200,000 shares of common stock, par value $0.001 per share at a public offering price of $5.00 per share. Pursuant to the Underwriting Agreement dated April 26, 2022, between the Company, The Benchmark Company, LLC ("Benchmark") and Valuable Capital Limited (together with Benchmark, the "Underwriters"), the Company granted the Underwriters warrants to purchase a total of 96,000 shares of the Company's common stock at an exercise price of $5.00 per share. The warrants expire on the fifth anniversary of the commencement of sales under the IPO. On April 27, 2022, the shares of the Company's common stock began trading on the Nasdaq Capital Market LLC under the symbol "TNON."

On April 29, 2022, the IPO closed, and the Company received approximately $13.8 million in net proceeds from the IPO after deducting the underwriting discount and commission and other estimated IPO expenses payable by the Company. As a result of the completion of the IPO and as required under the terms of the convertible notes payable described in Note 6, the Company converted the entirety of the related outstanding principal and accrued interest to 3,955,415 shares of the Company's common stock at the conversion price detailed in Note 6 and issued the common stock to the noteholders, fully satisfying the Company's obligations.

On April 29, 2022, as result of the completion of the IPO, the Company converted all shares of Series A and Series B Preferred Stock to 2,693,342 shares of the Company's common stock at the conversion rate detailed below and issued the common stock to the preferred stockholders, fully satisfying the Company's obligations. This includes 1,172,346 shares issued to TTAG's minority shareholder in accordance with the anti-dilution protection provisions of the Exchange Agreement.

9. Stockholders' Equity (cont.)

Concurrent with the completion of the IPO and in accordance with the Amended and Restated Exclusive Sales Representative Agreement executed in May 2021, the counterparty to the agreement received anti-dilution protections to maintain ownership of 3.0% of the fully diluted equity of the Company through the date of an initial public offering and was issued 312,351 shares of the Company's common stock to the Representative, fully satisfying the Company's obligations. The value of these shares issued at the IPO price of $5.00 per share was charged to operating expenses in the Company's consolidated statements of operations and comprehensive loss. Also, as a result of the completion of the IPO, the Company issued 85,739 shares of its common stock to a consultant, which were treated as issuance costs and netted against IPO proceeds.

Preferred Stock

On October 28, 2021, the Company entered into an Agreement (the "Exchange Agreement") with TTAG's minority shareholder. Pursuant to the Exchange Agreement, TTAG's minority shareholder agreed to exchange 574,033 shares of Series A Convertible Preferred Stock issued by TTAG, representing its entire ownership interest in TTAG, for the Company's Series A Preferred Stock, representing a 24% ownership interest in the Company's fully-diluted capital, which includes the pro forma conversion of all outstanding convertible preferred stock and promissory notes, options, and warrants. Pursuant to the terms of the Exchange Agreement, the Company issued TTAG's minority shareholder 2,550,763 shares of Series A Preferred Stock. These shares were subject to anti-dilution protection to maintain TTAG's minority shareholder's 24% ownership interest in the Company, excluding any shares issued by the Company in an IPO or a qualified offering of at least $5,000 at a per share price of at least $3.3737. Upon conversion of the Company's convertible notes payable as described in Note 6, the Company issued 1,172,346 shares of its common stock to TTAG's minority shareholder.

In accordance with ASC 810-10-45-23, the Company did not recognize any gain or loss in the consolidated statements of operations and comprehensive loss in conjunction with the Exchange Agreement. The carrying value of the non-controlling interest in TTAG was reduced to zero, and the value of the Company's investment in TTAG increased accordingly. The shares of Series A Preferred Stock issued were recorded at fair value. The difference between the increase in the Company's investment and the fair value of the Series A Preferred Stock issued was recorded as a decrease in Additional Paid in Capital ("APIC"). The resulting negative APIC was then reclassified to accumulated deficit.

In a series of closings from 2012 through 2015, the Company issued an aggregate of 491,222 shares of Series B Convertible Preferred Stock ("Series B Preferred Stock") at $2.795 per share for proceeds of $1,272, net of stock issuance costs.

The Company classified the convertible preferred stock outside of total stockholders' deficit because, in the event of certain deemed liquidation events that are not solely within the control of the Company, the shares would become redeemable at the option of the holders. The Company did not adjust the carrying values of the convertible preferred stock to the deemed liquidation values of such shares since a liquidation event was not probable of occurring.

Conversion

At the option of the holder, shares of Series A and Series B Preferred Stock were convertible into common stock at a conversion rate of one-to-0.5, subject to adjustments for stock dividends, splits, combinations, and similar events. Automatic conversion will occur in the event of a firmly underwritten public offering of common stock of the Company at a price of at least $4.00 per share, subject to appropriate adjustments for stock dividends, splits, combinations, and similar events, and with total gross proceeds to the Company of at least $15,000, before deduction of underwriters' commissions and expenses. As noted above, the Series A and Series B Preferred Stock were converted to common stock at the time of the Company's IPO.

9. Stockholders' Equity (cont.)

Redemption

The shares of the Series A and Series B Preferred Stock were redeemable only upon acquisition or liquidation of the Company.

Liquidation preference

With respect to any distributions in connection with a liquidation, dissolution or winding up of the Company, or in connection with the sale of voting control of all or substantially all of the assets of the Company, by way of merger, acquisition, consolidation or similar transaction, prior to any distribution to common stockholders, the holders of Series A and Series B Preferred Stock were entitled to receive $1.526 and $4.981 per share, respectively, plus any declared but unpaid dividends, adjusted to reflect any dividends previously paid. If, upon the occurrence of such event, the assets and funds distributed among the holders of Series A and Series B Preferred Stock shall be insufficient to permit the payment to such holders of the full liquidation preference amounts, the entire assets and funds of the Company legally available shall be distributed ratably among the preferred stockholders in proportion to the preferential amount to which each holder is entitled.

After payment of the liquidation preferences, the holders of common stock are entitled to receive the remaining assets of the Company available for distribution to its stockholders pro rata based on the number of shares of common stock held by each holder.

Voting rights

The holders of vested shares of common stock shall be entitled to vote on any matter submitted to a vote of the stockholders and each such holder shall be entitled to one vote per share of common stock held. The holders of Series A and Series B Preferred Stock were entitled to vote together with the common stock as a single class on any matter submitted to a vote of the stockholders. Holders of Series A and Series B Preferred Stock were entitled to the number of votes equal to the number of common stock issuable upon conversion of their respective Series A and Series B Preferred Stock at the time such shares are voted. The holders of a majority of the preferred stock had additional voting rights as specified in the Company's Amended and Restated Certificate of Incorporation, as amended.

Equity awards

In 2012, the Board of Directors of the Company (the "Board") approved the Tenon Medical, Inc. 2012 Equity Incentive Plan (the "2012 Plan"). The 2012 Plan provides for the issuance of common stock options, appreciation rights, and other awards to employees, directors, and consultants. Options issued under the 2012 Plan generally vest over a period of two to four years and have a 10-year expiration date. In April 2021, the Board increased the number of shares of common stock reserved for issuance under the 2012 Plan to 662,516. In July 2021, the Board increased the number of shares of common stock reserved for issuance under the 2012 Plan to 737,516. In August 2021, the Board increased the number of shares of common stock reserved for issuance under the 2012 Plan from 737,516 shares to 799,266 shares and approved the form of a 2022 Equity Incentive Plan.

On January 10, 2022 and February 2, 2022, the Board and stockholders, respectively, of the Company approved the Tenon Medical, Inc. 2022 Equity Incentive Plan (the "2022 Plan"), which was effective on April 25, 2022. The number of shares of common stock that may be subject to awards and sold under the 2022 Plan is equal to 1,600,000. Automatic annual increases in number of shares available for issuance under the 2022 Plan is equal to the least of (a) 1,100,000 shares, (b) 4% of the total number of shares of all classes of common stock outstanding on the last day of the immediately preceding fiscal year, or (c) such number determined by the 2022 Plan administrator no later than the last day of the immediately preceding fiscal year. Annual increases will continue until the tenth anniversary of the earlier of the Board or stockholder approval of the 2022 Plan, which is January 10, 2032. Upon the effective date of the 2022 Plan, the Board terminated the 2012 Plan such that no new equity awards will be issued by the 2012 Plan and all outstanding options under the 2012 plan are administered under the 2022 Plan.

(in thousands, except share and per-share data)

9. Stockholders' Equity (cont.)

The Company adopted the fair value recognition provisions in accordance with authoritative guidance related to equity-based payments. Compensation expense in 2022 and 2021 includes the portion of awards vested in the periods for all equity-based awards granted, based on the grant date fair value. Grant date fair value for restricted stock units is estimated using the fair value of the Company's common stock on the date of grant. Grant date fair value for stock options is estimated using a Black-Scholes option valuation model, consistent with authoritative guidance, using the weighted-average assumptions in the table below:

	Years ended December 31,	
	2022	2021
Expected volatility	57.68%	52.35%
Dividend yield	0%	0%
Risk-free interest rate	3.34%	0.99%
Expected term in years	5.85	5.76

Estimates of fair value are not intended to predict actual future events or the value ultimately realized by employees who receive equity awards, and subsequent events are not indicative of the reasonableness of the original estimates of fair value made by the Company in accordance with authoritative guidance.

A summary of the Company's share option and restricted stock unit activity under its plans is as follows:

	Options			RSUs	
	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (InYears)	Number of RSUs	Weighted Average Grant Date Fair Value per Share
Balance as of January 1, 2021	90,991	$ 0.62	4.93	—	
Granted	658,903	$ 5.96		—	
Canceled/forfeited/expired	(22,500)	$ 5.20		—	
Balance as of December 31, 2021	727,394	$ 5.32	7.12	—	
Granted	171,450	$ 2.30		1,318,530	$ 7.93
Balance as of December 31, 2022	898,844	$ 4.74	8.10	1,318,530	$ 7.93
Exercisable at December 31, 2022	456,874	$ 4.89	7.34		

The weighted-average grant-date fair value of options granted during the years ended December 31, 2022 and 2021 was $1.29 and $1.47, respectively. The aggregate intrinsic value of outstanding options at December 31, 2022 was $87. The aggregate intrinsic value is calculated as the difference between the exercise price of the option and the estimated fair value of the Company's common stock for in-the-money options at December 31, 2022. As of December 31, 2022, total compensation cost not yet recognized related to unvested share options was $9,389, which is expected to be recognized over a weighted-average period of 2.30 years.

The following table sets forth stock-based compensation expense recognized for the years ended December 31, 2022 and 2021:

	Years ended December 31,	
	2022	2021
Research and development	$ 995	$ 65
Sales and marketing	117	30
General, and administrative	1,785	282
Total stock-based compensation expense	$ 2,897	$ 377

At December 31, 2022, there were 110,020 shares available for issuance under the 2022 Plan.

9. Stockholders' Equity (cont.)

Warrants

During 2020, the Company issued warrants to purchase 25,000 shares of common stock to a consultant. The warrants, which are equity-classified, are immediately exercisable at an exercise price of $5.20 per share. The fair value of the warrants on the grant date was $2.30 per warrant, which was calculated based on the following weighted-average assumptions, using a Black-Scholes option valuation model: expected term of 5.00 years; expected volatility of 51.88%; dividend yield of 0%, and risk-free interest rate of 0.30%. The Company recorded deferred offering costs of approximately $58 associated with these warrants during 2020 which was recorded in additional paid-in capital in 2022. These warrants expired immediately prior to the IPO per the original terms of the warrants.

In April 2022, as noted above, the Company granted the Underwriters warrants to purchase a total of 96,000 shares of the Company's common stock. The warrants are immediately exercisable at an exercise price of $5.00 per share and expire on the fifth anniversary of the commencement of sales under the IPO. The fair value of the warrants on the grant date was $2.75 per warrant, which was calculated based on the following weighted-average assumptions, using a Black-Scholes option valuation model: expected term of 5.00 years; expected volatility of 62.55%; dividend yield of 0%, and risk-free interest rate of 2.92%. The Company recorded the fair value of these warrants of approximately $264 as an issuance cost to additional paid-in capital in 2022. As the IPO issuance costs were also recorded to additional paid-in capital, the net impact was $0.

10. Commitments and Contingencies

Sales Representative Agreement

In April 2020, the Company entered into an Exclusive Sales Representative Agreement, under which the counterparty to the agreement (the "Representative") received exclusive rights to market, promote, and distribute The Catamaran System in the United States and Puerto Rico. The agreement is for an initial period of five years, and automatically renews for an additional five years unless written notice is given by either party prior to April 27, 2023. The agreement provides for a bonus to be paid to the Representative upon an acquisition or IPO. In May 2021 the Company entered into an Amended and Restated Exclusive Sales Representative Agreement (the "Restated Sales Agreement"). In connection with the amended agreement, the Company paid $500 cash and issued 53,757 shares of common stock to the Representative, for which the Company recorded a combined total of approximately $880 as sales and marketing expense. In addition, the Representative received anti-dilution protections to maintain ownership of 3.0% of the fully diluted equity of the Company through the date of an initial public offering. In October, 2021, the Company issued 44,447 shares with a fair value of approximately $333 to the Representative in accordance with the anti-dilution provision. In April 2022, the Company issued 312,351 shares to the Representative in accordance with the anti-dilution provision, fully satisfying the Company's obligations.

The amended agreement restructured the calculation of the bonus paid to the Representative upon an acquisition, removed the bonus payable upon an IPO, and allows the Company to terminate the amended agreement as long as the bonus paid to the Representative is at least $6,000.

In June 2021, the Company issued a $50 convertible note payable to the Chief Executive Officer of the Representative, as part of the convertible debt offering described in Note 6.

On October 6, 2022, the Company entered into the Terminating Amended and Restated Exclusive Sales Representative Agreement (the "Termination Agreement") with the Representative, which terminated the Restated Sales Agreement. In accordance with the Termination Agreement, (i) the Company paid the Representative $1,000 in cash; and (ii) the Company agreed to pay the Representative (a) $85 per month during the six months after the date of the Termination Agreement in return for efforts by the Representative to transition operations to the Company, (b) 20% of net sales of the Product sold in the United States and Puerto Rico until December 31, 2023 and (c) after December 31, 2023, 10% of net sales until such time as the aggregate amount paid to the Representative under this clause (c) and clause (b) above equal $3,600. In the event of an acquisition of the Company, the Company will pay the Representative $3,600 less previous amounts paid pursuant to clause (b) and clause (c) above. The Company

(in thousands, except share and per-share data)

10. Commitments and Contingencies (cont.)

recorded a charge of $1,000 for the payment to the Representative in the fourth quarter of 2022 and is expensing the $85 per charges as incurred over the six month period. For payments under clause (b) and clause (c) above, the Company estimated the fair value of the liability using level 3 hierarchy inputs based on a Monte Carlo simulation of future revenues with a 25% quarterly estimated standard deviation of growth rates and a 10% probability of dissolution, discounted at an estimated discount rate of 15.4%. Based on the Company's fair value analysis, a charge of $2,611 was charged to Sales and marketing expense in the fourth quarter of 2022. A reconciliation of the liability under clause (b) and clause (c) is as follows:

	2022
Balance at January 1, 2022	$ —
Amount recorded upon signing of Termination Agreement	2,611
Amounts paid during 2022	(56)
Accretion	5
Balance at December 31, 2022	$ 2,560

Per the terms of the Termination Agreement, the Company ultimately expects to expense $3,600 under clause (b) and clause (c).

Simultaneously with the execution of the Termination Agreement, the Company entered into a Consulting Agreement dated October 6, 2022, with the Representative (the "Consulting Agreement"). Under the terms and conditions of the Consulting Agreement, the Representative is tasked with organizing, recruiting, training, and coordinating the Company's Clinical Specialist program, Physician Education program and Sales Education program as more specifically described in the Consulting Agreement.

The term of the Consulting Agreement is from October 6, 2022, until October 05, 2023, unless extended by mutual agreement of the parties in writing for additional one-year terms, or terminated in accordance with the terms of the Consulting Agreement. In consideration for the services to be provided, the Company shall pay the Representative a base consulting fee of $700 per year, payable in monthly instalments, along with additional compensation of $62.5 per quarter, if certain sales targets are met, for four quarters; along with any travel and related out-of-pocket expenses incurred by the Representative in connection with the performance of the services.

Litigation

In the normal course of business, the Company may possibly be named as a defendant in various lawsuits.

On September 2, 2021, Khalid Mentak, a former director and Chief Executive Officer of the Company filed an arbitration claim with the American Arbitration Association ("AAA") against the Company, asserting damages in excess of $3,000, plus attorneys' fees and other costs, for alleged unpaid wages, defamation, and other claims.The services provided by Mr. Mentak were governed by a Consulting Agreement between the Company and Key Medical Technologies, Inc ("Key Medical"), a company which Mr. Mentak served as Chief Executive Officer. The AAA proceeding was also initiated pursuant to the arbitration provision in the Consulting Agreement. The parties selected an arbitrator and the Company filed a motion to dismiss the proceeding as currently pled because the proper parties should be Key Medical and the Company, and not Mr.Mentak as an individual. The arbitrator ruled that Mr. Mentak was the real-party-in-interest and denied the motion, without prejudice to any arguments on the merits of the underlying claims. On March 1, 2022, Mr. Mentak filed a more detailed Statement of Claims, which the Company responded to on March 16, 2022. The Company also filed a cross-complaint for declaratory relief seeking to establish its rights and obligations under the Consulting Agreement with respect to the claimant and Key Medical, which was formally named a defendant in the cross complaint. The claimant objected to the cross-complaint as unnecessary. On July 21, 2022, the Company entered into a Settlement Agreement and General Release of All Claims (the "Settlement Agreement") with Key Medical and Mr. Mentak to settle all claims and counterclaims. Pursuant to the Settlement Agreement, the Company has agreed to pay Key Medical the total sum of $1,200. The settlement amount was fully paid as of December 31, 2022.

(in thousands, except share and per-share data)

11. Concentrations of Risk

Credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents.

The Company maintains cash balances at financial institutions located in California and Switzerland. Accounts at the U.S. financial institutions are secured by the Federal Deposit Insurance Corporation. At times, balances may exceed federally insured limits. The Company has not experienced any losses in such accounts. Management believes that the Company is not exposed to any significant credit risk with respect to its cash and cash equivalents.

The Company grants unsecured credit to its customers based on an evaluation of the customer's financial condition and a cash deposit is generally not required. Management believes its credit policies do not result in significant adverse risk and historically has not experienced significant credit-related losses.

Currency risk

The Company's subsidiary, Tenon Technology AG, realizes a portion of its expenses in Swiss francs. Consequently, certain assets and liabilities are exposed to foreign currency fluctuations. At December 31, 2022 and 2021, approximately $8 and $21, respectively, of the Company's net monetary assets were denominated in Swiss francs. The Company has not entered into any hedging transactions to reduce the exposure to currency risk.

12. Income Taxes

The components of loss before income taxes are as follows:

	Years ended December 31,	
	2022	2021
United States	$ (18,886)	$ (7,012)
International	(30)	(67)
Loss before income taxes	$ (18,916)	$ (7,079)

The components of current income tax expense are as follows:

	Years ended December 31,	
	2022	2021
Federal	$ —	$ —
State	1	1
Foreign	—	1
Total income tax expense	$ 1	$ 2

A reconciliation of the expected tax computed at the U.S. statutory federal income tax rate to the total provision for income taxes for the years ended December 31, 2022 and 2021 is as follows:

	Years ended December 31,	
	2022	2021
Statutory rate	(21)%	(21)%
State taxes, net of federal benefit	(7)%	(7)%
Non-deductible differences	1%	2%
Change in valuation allowance	27%	26%
Provision for taxes	—	—

(in thousands, except share and per-share data)

12. Income Taxes (cont.)

Significant components of the Company's net deferred tax assets at December 31, 2022 and 2021 are as follows:

	Years ended December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 7,001	$ 2,642
Credit carryforwards	109	48
Accruals and reserves	126	242
Stock-based compensation	843	109
Intangibles	244	265
Operating lease liability	254	310
Capitalized research and development	274	—
Total deferred tax assets	8,851	3,616
Valuation allowance	(8,564)	(3,315)
Net deferred tax assets	287	301
Deferred tax liabilities:		
Fixed assets	(44)	—
Operating lease right of use	(243)	(301)
Total deferred tax liabilities	(287)	(301)
Net deferred tax assets	$ —	—

In assessing the realizability of deferred tax assets at December 31, 2022, management considered whether it is more likely than not that some portion or all of the deferred tax assets will be realized, and determined that a valuation allowance was required for those deferred tax assets that are not expected to provide future tax benefits. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible.

At December 31, 2022, the Company has available net operating loss carryforwards of approximately $23,237 for federal income tax purposes, of which approximately $23,015 was generated after 2017 and can be carried forward indefinitely under the Tax Cuts and Jobs Act. The remaining federal net operating loss of approximately $222, which was generated prior to 2018, will start to expire in 2034 if not utilized.

At December 31, 2022, the net operating losses for state purposes are approximately $24,146 and will begin to expire in 2032 if not utilized. In addition, the Company had foreign net operating losses of approximately $1,896 at December 31, 2022 that will start to expire in 202 if not utilized.

The Company had credit carryforwards of approximately $114 for federal income tax purposes. The federal tax credits will begin to expire in 2041.

The Company also had credit carryforwards of approximately $41 for California income tax purposes. These credits have no expiration.

The Company has not completed a study to determine whether any ownership change per the provisions of Section 382 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions, has occurred. Utilization of the Company's net operating loss and income tax credit carryforwards may be subject to a substantial annual limitation due to ownership changes that may have occurred or that could occur in the future. These ownership changes may limit the amount of the net operating loss and income tax credit carryover that can be utilized annually to offset future taxable income. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders.

(in thousands, except share and per-share data)

12. Income Taxes (cont.)

Coronavirus Aid, Relief and Economic Security Act

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted and signed into law in response to the market volatility and instability resulting from the COVID-19 pandemic. It includes a significant number of tax provisions and lifts certain deduction limitations originally imposed by the Tax Cuts and Jobs Act of 2017 (the "2017 Act"). The changes are mainly related to: (1) the business interest expense disallowance rules for 2019 and 2020; (2) net operating loss rules; (3) charitable contribution limitations; (4) employee retention credit; and (5) the realization of corporate alternative minimum tax credits. The Company does not anticipate the application of the CARES Act provisions to materially impact the overall consolidated financial statements.

Uncertain tax positions

In accordance with authoritative guidance, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The following shows the changes in the gross amount of recognized tax benefits:

	Years ended December 31,	
	2022	2021
Unrecognized tax benefits, beginning of year	$ —	$ —
Increases related to prior year tax positions	12	—
Decreases related to prior year tax positions	—	—
Increases related to current year tax positions	26	—
Unrecognized tax benefits, end of year.	$ 38	$ —

The Company recognizes interest and penalties related to unrecognized tax positions within the income tax expense line in the accompanying consolidated statements of operations. The Company does not anticipate that its total unrecognized tax benefits will significantly change due to settlement of examination or the expiration of statute of limitations during the next 12 months. Due to the full valuation allowance at December 31, 2022, current adjustments to the unrecognized tax benefit will have no impact on our effective income tax rate.

The Company currently has no federal or state tax examinations in progress nor has it had any federal or state tax examinations since its inception. As a result of the Company's net operating loss and credit carryforwards all of its years are subject to federal and state examination.

13. Related Party Transactions

During 2018 through 2020, the Company's subsidiary issued convertible promissory notes to TTAG's minority shareholder. In November 2020, these notes payable and accrued interest were converted into TTAG shares. In June 2021, the Company's subsidiary issued a convertible promissory note for approximately $107 to TTAG's minority shareholder. The Company purchased this note and accrued interest of $114 in October 2021 from TTAG's minority shareholder. See Note 7.

The Company had a consulting agreement with a company owned by the former Chief Executive Officer of the Company. Under this consulting agreement, the Chief Executive Officer was to provide services from 2015 through June 1, 2021. Total payments under the consulting agreement of $600 are to be paid as follows: (a) $300 paid upon closing of financing round of at least $5,000, followed by twelve monthly payments of $25 per month; (b) $300 paid upon achieving at least $3,000 of annual revenue and a financing round of less than $5,000; or (c) the entire $600 payable immediately upon an acquisition of the Company. During the year ended December 31, 2022 and 2021, the Company recorded expense of $574 and $42, respectively, related to this agreement. As of December 31, 2022 and 2021, approximately $0 and $600, respectively, owed to this party was included in accrued expenses with respect of these services. See Note 10.

13. Related Party Transactions (cont.)

During 2021, the Company issued convertible promissory notes totaling $620 to officers, directors, and their family members. See Note 6. In addition, a note was issued to the Chief Executive Officer of the Representative described in Note.

On October 28, 2021, the Company entered into an agreement with TTAG's minority shareholder. See Note 8. Pursuant to the terms of the Exchange Agreement, the Company purchased the convertible note and accrued interest between TTAG and Zuhlke Ventures AG ("ZVAG"), TTAG's minority shareholder, in the amount of approximately $114.

On December 31, 2021, the Company and TTAG entered into the IP Sale and Purchase Agreement, whereby TTAG transferred certain patents and trademarks to the Company. In connection with this transfer, the Company issued an unsecured promissory note to TTAG in the amount of $818 which eliminates in consolidation.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures

None

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are the controls and other procedures that are designed to provide reasonable assurance that information required to be disclosed by the issuer in the reports that it files or submits under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including the principal executive and principal financial officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

We have carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of December 31, 2022. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have identified a material weakness in our disclosure controls and procedures due to lack of segregation of duties and have therefore concluded that our disclosure controls and procedures are not effective at the reasonable assurance level.

A material weakness is a deficiency, or combination of deficiencies, in our internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements would not be prevented or detected on a timely basis.

As of December 31, 2022, we have taken steps to remediate this material weaknesses by hiring a Chief Financial Officer, a director of SEC reporting and compliance, and a senior accountant, and engaging a cost accounting consultant and external financial consultants, and plan to continue to add additional resources, technology and headcount as warranted by the growth of the Company.

We assessed the impact of the material weaknesses to the consolidated financial statements to ensure that our consolidated financial statements were prepared in accordance with U.S. GAAP and accurately reflect our financial position and results of operation for the year ended December 31, 2022. As a result, management concluded that the consolidated financial statements included in this Annual Report present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Evaluation of Internal Controls over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The following are our executive officers and directors and their respective ages and positions as of March 10, 2023.

Name	Age	Position
Steven M. Foster	55	Chief Executive Officer and President, Director
Richard Ginn	57	Chief Technology Officer and Director
Steve Van Dick	68	EVP, Finance and Administration and Chief Financial Officer
Richard Ferrari	69	Executive Chairman of the Board
Ivan Howard	56	Director
Frank Fischer	81	Director
Robert K. Weigle	63	Director
Stephen H. Hochschuler, M.D.	80	Director

Steven M. Foster is our Chief Executive Officer and President, and is also a director of the Company. Mr Foster has over 30 years of marketing, sales, operations and general management experience. From 2015 to present Mr. Foster has been a principal with CTB Advisors, LLC in Brentwood, Tennessee. CTB Advisors was founded as a single member limited liability company for the purpose of providing medical device organizations and physicians with consultative assistance on commercialization focused projects. Projects included: CRM based clinician engagement program design, training and implementation for NuVasive (NUVA). Valuation assessment / business plan development of early-stage spine technology including IP assessment and regulatory pathway definition. M&A (SafeOp Surgical) integration project, Alphatec Spine (ATEC). Current Status: Exclusive to ATEC. From 2012 to 2014 Mr. Foster was Global Commercialization President of Safe Orthopedics SAS, Paris, FR (based in Michigan): There Mr Foster worked on early-stage commercialization of a novel single-use / sterile / traceable surgical kit for lumbar spine fusion. His focus included pre-clinical design, clinician advisor team development, early marketing, web design, convention presence and P&L preparation and management. Technology reached 200 global surgeries in first 12 months of commercialization. From 1992 to 2012 Mr. Foster was part of the Danek Group Inc., Sofamor Danek, Medtronic Spine organization where he held a variety of marketing, sales administration and general management roles, including as VP / GM of Medtronic Spine's Western Europe operations from 2007-2010. Mr. Foster received a Bachelor of Science, Business Administration with a concentration in Marketing and Management from Central Michigan University in 1990.

Richard Ginn is a founder, the Chief Technology Officer and a director of the Company. Mr. Ginn's focus is primarily on intellectual property and product development, he has travelled throughout the world to train physicians and participated in multiple FIH trials and is a named inventor on more than 300 patents for medical devices. Over the course of his career, he has helped raise more than $100 million in venture capital and has provided an average 10x return to his investors. Mr. Ginn is the founder of TransAortic Medical, an embolic protection device company, and is its President, CEO and a director from 2013 to present. At TransAortic, Mr. Ginn Managed all corporate operations, raised capital to support company needs; managed acquisition of technology by strategic partner; managed all Intellectual Property; and set up European distribution for CE Marked device. Mr. Ginn is the founder of Promed, a large hole femoral closure device company and was the CEO, President and a director from 2012 to 2019. At Promed he managed all corporate operations; raised capital to support company needs; and managed all intellectual property.

Steven Van Dick is our Executive Vice President, Finance and Administration and Chief Financial Officer. Mr. Van Dick has been the Chief Financial Officer for the Company since June 1, 2021. Mr. Van Dick is a strategic financial and accounting executive with a record of transitioning early-stage companies to commercialization through astute financial management. Respected in the medical device startup community, he develops and leads comprehensive, world-class financial and accounting groups credited for propelling startup companies forward. Across his career Steve has played a key role on the Executive Leadership Teams that successfully completed three separate Initial Public Offering (IPOs) and three mergers/integrations. From 2016 to 2017 Mr. Van Dick was the Chief Financial Officer for Benvenue Medical Inc., a minimally invasive spine company in Santa Clara, California. At Benvenue, Mr. Van Dick was responsible for all accounting, finance and IT functions with his primary focus on developing a long-range financial model and reducing cash burn. From 2010 to 2016, Mr Van Dick was the Vice President, Finance Administration — Chief Financial Officer for Spiracur Inc., a disposable/portable negative pressure wound therapy company in Sunnyvale California. At Spiracur, Mr. Van Dick was responsible for all accounting, finance and IT

functions. He managed growth of company from initial commercialization to $12 million annualized run rate, lead the conversion to fully integrated ERP system and developed controls to become Hipaa compliant. Mr Van Dick received a Bachelor of Science, Business Administration with a concentration in Accounting from San Jose University in 1977 and an MBA from Santa Clara University in 1984.

Richard Ferrari is a founder, a director and Executive Chairman of the Company. Since 2000, Mr. Ferrari has been and currently is a Managing Director of Denovo Ventures a $650Mill venture firm specializing in Medical Devices and Biotechnology. From January 2019 until April 2021 Mr. Ferrari was employed as CEO and Chairman of the Board of Directors of PQ Bypass which culminated is a successful acquisition by Endologix. During the last five years Mr. Ferrari has been and currently is a board member (Executive Chairman) of Medlumics, S.L., a medical device company founded in 2011; a board member (Vice Chairman) of ABS Interventional; a board member (Executive Chairman) of Heart Beam Inc.; a board member of Biomodex Corporation; a board member of Retriever Medical Inc.; a board member of RMx Medical; a board member of Hawthorne Effect, Inc.; a board member and co-founder of TransAortic acquired by Medtronic; Executive Chairman of Sentreheart acquired by Atricure, a board member of Spinal Modualtion sold to St Jude and a board member of Hands of Hope. Mr. Ferrari has raised over $1billion for the companies he has been involved with and been a key member of the various boards M&A teams achieving over $2Bill in Acquisitions. Mr. Ferrari continues to mentor and advise a number of CEO's and start-up companies on strategy and building organizations dedicated to delivering excellence. Mr. Ferrari is the creator of Excellence by Choice a series of lectures and presentations to help early-stage companies perform at the highest level of execution. Mr. Ferrari received a Bachelor's Degree in Education from Ashland University and a MBA from University of South Florida.

Ivan Howard is a director of the Company. Mr. Howard has been since 2019 and currently is a Vice President and Sr. Specialist in Alternative Investment Fiduciary Risk for Banco Santander, a multinational financial services company. From 2020 Mr. Howard has been and currently serves as Director on the Collier County Farm Bureau board of directors. From 2016, Mr. Howard has been and currently serves as Chairman of the Hendry/Glades County Farm Service Agency. From 2020 Mr. Howard has been and currently serves on the U.S. Department of Agriculture Advisory Committee on Minority Farmers. From 2018 Mr. Howard has been and is currently a member of the University of Florida College of Biomedical Engineering External Advisory board. Mr. Howard holds an MBA from Mercer University and a Master's Degree in Biomedical Engineering from the University of Florida.

We believe that Mr. Howard is well qualified to serve as a Director on our Board with his financial services and board membership experience.

Frank Fischer has more than 40 years of senior management experience in the medical device industry. He co-founded NeuroPace in December 1997, led the company as its President and Chief Executive Officer from January 2000 through July 2019, served on its Board of Directors since inception and is currently Chairman of the Board. Prior to joining NeuroPace, Mr. Fischer was President and Chief Executive Officer of Heartport, Inc., a cardiac surgery company, from May 1998 until September 1999 and served on Heartport's Board of Directors. Previously, Mr. Fischer was President and Chief Executive Officer and a director of Ventritex, Inc., a company that pioneered implantable cardiac defibrillators, from July 1987 until the sale of the company to St. Jude Medical, Inc. in 1997. Before joining Ventritex, he held various management positions at Cordis Corporation from 1977 to 1987 in the cardiac and neurosurgical device areas, serving most recently as President of the Implantable Products Division. Currently he is a member of the Board of Directors of Nevro, Inc., the Board of Trustees of both Rensselaer Polytechnic Institute and Babson College as well as the Board of Directors of the Epilepsy Foundation of America. Mr. Fischer holds B.S.M.E. and M.S. in Management degrees from Rensselaer Polytechnic Institute.

We believe that Mr. Fischer is well qualified to serve as a Director on our Board with his experience in leading medical device companies both as a senior executive and as a member of the board of directors.

Robert K. Weigle currently is and has been since October 2020, the CEO of Prime Genomics, a saliva-based diagnostics company utilizing Genomics. Mr Weigle is also currently an executive in residence with DigitalDX, a venture capital firm. Mr. Weigle was CEO and a director of Benvenue Medical from May 2009 until August 2020. Benvenue was a Silicon Valley based medical device company, which raised over $200 million in funding. At Benvenue Mr. Weigle led growth from pre-clinical to successful clinical trials to commercial launch of first-generation devices in two distinct markets, one for the treatment of compression fractures in the spine and the second for the treatment of degenerative disc disease, resulting in a first full-year run rate exceeding $1 million per month. Mr. Weigle oversaw all early aspects of corporate strategy, including defining, communicating and executing the company's overall business model; and represented Benvenue to the investment community. Mr. Weigle was also a senior executive at numerous

healthcare/medical device companies, including TherOx, Inc, Cardiac Pathways, Baxter Healthcare and Cardima Corporation. Mr. Weigle also has relevant experience at Johnson & Johnson. Mr. Weigle holds a BA in Political Science from University of California, Berkeley.

We believe that Mr. Weigle is well qualified to serve as a Director on our Board with his experience in leading medical device companies both as a senior executive and as a member of the board of directors.

Stephen H. Hochschuler, M.D. is a world-renowned orthopedic spine surgeon. Dr. Hochschuler is the co-founder of the Texas Back Institute and founder of Back Systems, Inc., and founding Chairman of Innovative Spinal Technologies, Dr. Hochschuler has severed on numerous boards of directors and advisory boards for medical and scientific institutions. Dr. Hochschuler is a member of numerous national and international professional organizations including the American Academy of Orthopedic Surgeons; the American Pain Society; North American Spine Society; and the Southwest Chapter of the Society of International Business Fellows. Internationally, he is a member of the International Intradiscal Therapy Society; the International Society for Minimal Intervention in Spinal Surgery; the International Society for the Study of the Lumbar Spine; and is a founding board member of the Spinal Arthroplasty Society. He has also been a founding board member of The American Board of Spine Surgery and The American College of Spine Surgery. He is published in a wide range of professional journals, and has delivered numerous presentations worldwide. Dr. Hochschuler holds a BA from Columbia College and his medical degree from Harvard Medical School.

We believe that Dr. Hochschuler is well qualified to serve as a Director on our Board with his experience in as an orthopedic spine surgeon and his service on boards of directors and advisory boards of medical and scientific institutions as a member of the board of directors.

Board Composition

Our business and affairs are managed under the direction of our board of directors. Our board of directors currently consists of seven (7) members, four (4) of whom qualify as "independent" under the listing standards of Nasdaq.

Directors serve until the next annual meeting and until their successors are elected and qualified. Officers are appointed to serve for one year until the meeting of the Board following the annual meeting of shareholders and until their successors have been elected and qualified.

Director Independence

Our board of directors is composed of a majority of "independent directors" as defined under the rules of Nasdaq. We use the definition of "*independence*" applied by Nasdaq to make this determination. Nasdaq Listing Rule 5605(a)(2) provides that an "*independent director*" is a person other than an officer or employee of the company or any other individual having a relationship which, in the opinion of the Company's Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The Nasdaq listing rules provide that a director cannot be considered independent if:

- the director is, or at any time during the past three (3) years was, an employee of the company;
- the director or a family member of the director accepted any compensation from the company in excess of $120,000 during any period of twelve (12) consecutive months within the three (3) years preceding the independence determination (subject to certain exemptions, including, among other things, compensation for board or board committee service);
- the director or a family member of the director is a partner in, controlling shareholder of, or an executive officer of an entity to which the company made, or from which the company received, payments in the current or any of the past three fiscal years that exceed 5% of the recipient's consolidated gross revenue for that year or $200,000, whichever is greater (subject to certain exemptions);
- the director or a family member of the director is employed as an executive officer of an entity where, at any time during the past three (3) years, any of the executive officers of the company served on the compensation committee of such other entity; or

- the director or a family member of the director is a current partner of the Company's outside auditor, or at any time during the past three (3) years was a partner or employee of the Company's outside auditor, and who worked on the company's audit.

Under such definitions, our Board has undertaken a review of the independence of each director. Based on the information provided by each director concerning his or her background, employment, and affiliations, our Board has determined that Ivan Howard, Frank Fischer, Robert K. Weigle and Stephen H. Hochschuler, M.D. are independent directors of the Company.

Board Committees

The Company's Board has established three standing committees: Audit, Compensation, and Nominating and Corporate Governance. Each of the committees operates pursuant to its charter. The committee charters will be reviewed annually by the Nominating and Corporate Governance Committee. If appropriate, and in consultation with the chairs of the other committees, the Nominating and Corporate Governance Committee may propose revisions to the charters. The responsibilities of each committee are described in more detail below.

Nasdaq permits a phase-in period of up to one year after an issuer's initial public offering to meet the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee independence requirements. Under the initial public offering phase-in period, only a majority of the members of each committee must satisfy the heightened independence requirements within 90 days following the effectiveness of our registration statement, and all members of each committee must satisfy the heightened independence requirements within one year from the effectiveness of our registration statement. We expect to fully comply with Nasdaq's corporate governance rules prior to April 29, 2023, which is the one year anniversary of our initial public offering.

Audit Committee. The audit committee consists of three directors, Ivan Howard, Steven Foster and Robert Weigle, two of which, Messrs. Howard and Weigle are currently "independent" as defined by Nasdaq and includes an audit committee financial expert, Mr. Howard, within the meaning of Item 407(d) of Regulation S-K under the Securities Act of 1933, as amended, or the Securities Act. The audit committee's duties are specified in a charter and include, but not be limited to:

- reviewing and discussing with management and the independent auditor the annual audited financial statements, and recommending to the board whether the audited financial statements should be included in our annual disclosure report;
- discussing with management and the independent auditor significant financial reporting issues and judgments made in connection with the preparation of our financial statements;
- discussing with management major risk assessment and risk management policies;
- monitoring the independence of the independent auditor;
- verifying the rotation of the lead (or coordinating) audit partner having primary responsibility for the audit and the audit partner responsible for reviewing the audit as required by law;
- reviewing and approving all related-party transactions;
- inquiring and discussing with management our compliance with applicable laws and regulations;
- pre-approving all audit services and permitted non-audit services to be performed by our independent auditor, including the fees and terms of the services to be performed;
- appointing or replacing the independent auditor;
- determining the compensation and oversight of the work of the independent auditor (including resolution of disagreements between management and the independent auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or related work;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or reports which raise material issues regarding our financial statements or accounting policies; and

- approving reimbursement of expenses incurred by our management team in identifying potential target businesses.

By April 2023 the audit committee will be composed exclusively of "independent directors" who are "financially literate" as defined under the Nasdaq listing standards. The Nasdaq listing standards define "financially literate" as being able to read and understand fundamental financial statements, including a company's balance sheet, income statement and cash flow statement.

Compensation Committee. The compensation committee of the board of directors consists of three directors, Frank Fischer, Richard Ferarri and Robert Weigle, two of which, Frank Fischer and Robert Weigle, are "independent" as defined by Nasdaq. By April 2023 the compensation committee will be composed exclusively of "independent directors." The compensation committee's duties are specified in a charter and include, but not be limited to:

- reviews, approves and determines, or makes recommendations to our board of directors regarding, the compensation of our executive officers;
- administers our equity compensation plans;
- reviews and approves, or makes recommendations to our board of directors, regarding incentive compensation and equity compensation plans; and
- establishes and reviews general policies relating to compensation and benefits of our employees.

Nominating and Corporate Governance Committee. The nominating and corporate governance committee consists of three directors, Robert Weigle, Richard Ginn and Stephen Hochschuler, two of which, Robert Weigle and Stephen Sochschuler, are "independent" as defined by Nasdaq. By April 2023 the nominating and corporate governance committee will be composed exclusively of "independent directors." The nominating and corporate governance committee's duties are specified in a charter and include, but not be limited to:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- evaluating director performance on our board of directors and applicable committees of our board of directors and determining whether continued service on our board of directors is appropriate
- evaluating nominations by stockholders of candidates for election to our board of directors; and
- corporate governance matters

Role of Board in Risk Oversight Process

Our board of directors has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board of directors to understand our risk identification, risk management, and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, cybersecurity, strategic, and reputational risk.

Code of Ethics

Our Board adopted a written code of business conduct and ethics ("Code") that applies to our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. Our website has a current copy of the Code and all disclosures that are required by law in regard to any amendments to, or waivers from, any provision of the Code.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Involvement in Certain Legal Proceedings

To our knowledge, none of our current directors or executive officers has, during the past ten (10) years:

- been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two (2) years prior to that time;
- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;
- been found by a court of competent jurisdiction in a civil action or by the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;
- been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
- been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Item 11. Executive Compensation

The following summary compensation table provides information regarding the compensation paid during our fiscal years ended December 31, 2022 and December 31, 2021 to our Chief Executive Officer (principal executive officer), our Chief Financial Officer and Chief Technology Officer. We refer to these individuals as our "named executive officers."

Summary Compensation Table

Name and Principal Position	(Salary $)	($)Bonus	Option/RSU Awards[(1)] ($)	Total ($)
Steven M. Foster, Chief Executive Officer				
2022	$ 300,000	$ 70,000	$ 1,926,634	$ 2,296,634
2021	$ 175,000	$	$ 284,840	$ 459,840
Steven Van Dick, Chief Financial Officer				
2022	$ 275,000	148,125	$ 808,998	$ 1,232,123
2021	$ 160,417	$	$ 261,182	$ 421,599
Richard Ginn, Chief Technology Officer				
2022	275,000	148,125	$ 3,995,603	4,418,728
2021	$ 160,417	$	$ 161,836	$ 322,253

(1) In 2022 the named executives received restricted stock units ("RSUs") and in 2021 the named executives received options.

Employment Agreements

We have executed the following employment agreements with our executive officers. The material terms of each of those arrangements are summarized below. The summaries are not complete description of all provisions of the employment arrangements and are qualified in their entirety by reference to the written employment arrangements, each filed as an exhibit to this annual report on form 10-K.

Foster Employment Agreement. Steven M. Foster, our Chief Executive Officer and President and a member of our Board of Directors, and the Company entered into an Employment Agreement dated as of June 1, 2021 (the "Foster Employment Agreement"). The Foster Employment Agreement provides Mr. Foster an annual base salary of $300,000, an annual bonus of up to $120,000 based upon achievement of mutually agreed upon milestones, options to purchase shares of our common stock in an amount sufficient to maintain Mr. Foster's equity ownership at 4%, which were granted at the closing of our initial public offering and employee benefits that are generally given to our senior executives.

Under the Foster Employment Agreement, in the event that Mr. Foster's employment is terminated by us without cause (as described in the Foster Employment Agreement) or by Mr. Foster for good reason (as described in the Foster Employment Agreement), Mr. Foster would be entitled to (1)severance equal to his base salary at termination, payable in instalments over the 12-month period following termination and (2)payments in respect of continuing health care coverage for up to twelve months following termination. In addition, upon a change in control of the Company, Mr. Foster would be entitled to (1) vesting of his options granted prior to the date of the Foster Employment Agreement and (2) a lump sum cash payment of one year of his base salary and bonus opportunity then in effect.

If Mr. Foster is terminated for cause or because of death or disability or resigns without good reason, then all vesting of Mr. Foster's equity awards and payments of compensation will immediately terminate and any severance benefits will be paid in accordance with established policies, if any, then in effect.

The Foster Employment Agreement contains restrictive covenants and other obligations relating to non-solicitation of our employees, non-disclosure of our proprietary information and assignment of inventions.

Ginn Employment Agreement. Richard Ginn, our founder, Chief Technology Officer and a director of the Company, and the Company entered into an Employment Agreement dated as of June 1, 2021 (the "Ginn Employment Agreement"). The Ginn Employment Agreement provides Mr. Ginn an annual base salary of $275,000, an annual bonus of up to 30% of base salary based upon achievement of mutually agreed upon milestones, a second bonus of up to $200,000 based on certain milestones determined by our board of directors and employee benefits that are generally given to our senior executives.

Under the Ginn Employment Agreement, in the event that Mr. Ginn's employment is terminated by us without cause (as described in the Ginn Employment Agreement) or by Mr. Ginn for good reason (as described in the Foster Employment Agreement), Mr. Ginn would be entitled to (1)severance equal to his base salary at termination, payable in instalments over the 12-month period following termination and (2)payments in respect of continuing health care coverage for up to twelve months following termination. In addition, upon a change in control of the Company, Mr. Ginn would be entitled to (1) vesting of his options granted prior to the date of the Ginn Employment Agreement and (2) a lump sum cash payment of one year of his base salary and bonus opportunity.

If Mr. Ginn is terminated for cause or because of death or disability or resigns without good reason, then all vesting of Mr. Ginn's equity awards and payments of compensation will immediately terminate and any severance benefits will be paid in accordance with established policies, if any, then in effect.

The Ginn Employment Agreement contains restrictive covenants and other obligations relating to non-solicitation of our employees, non-disclosure of our proprietary information and assignment of inventions.

Van Dick Employment Agreement. Steven Van Dick, our Executive Vice President, Finance and Administration and Chief Financial Officer, and the Company entered into that certain Employment Agreement dated as of June 1, 2021 (the "Van Dick Employment Agreement"). The Van Dick Employment Agreement provides Mr. Van Dick an annual base salary of $275,000, an annual bonus of up to 30% of base salary based upon achievement of mutually agreed upon milestones and employee benefits that are generally given to our senior executives.

Under the Van Dick Employment Agreement, in the event that Mr. Van Dick's employment is terminated by us without cause (as described in the Van Dick Employment Agreement) or by Mr. Van Dick for good reason (as described in the Van Dick Employment Agreement), Mr. Van Dick would be entitled to (1)severance equal to his base salary at termination, payable in instalments over the 12-month period following termination and (2) payments in respect of continuing health care coverage for up to twelve months following termination. In addition, upon a change in control of the Company, Mr. Van Dick would be entitled to (1) vesting of his options granted prior to the date of the Van Dick Employment Agreement and (2) a lump sum cash payment of one year of his base salary and bonus opportunity.

If Mr. Van Dick is terminated for cause or because of death or disability or resigns without good reason, then all vesting of Mr. Van Dick's equity awards and payments of compensation will immediately terminate and any severance benefits will be paid in accordance with established policies, if any, then in effect.

The Van Dick Employment Agreement contains restrictive covenants and other obligations relating to non-solicitation of our employees, non-disclosure of our proprietary information and assignment of inventions.

The above summary description of the named executives' employment agreement includes some of the general terms and provisions of those agreements. For a more detailed description of those employment agreements, you should refer to such agreements, which are included as exhibits to this Annual Report on Form 10-K.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the number of RSUs and shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2022.

	Option Awards				Equity Awards (RSUs)	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of RSUs that have not Vested	Market Value of RSUs
Seven M. Foster	34,375	78,125	$ 5.20	May 1, 2031	217,453	$ 1,926,633
Steven Van Dick	20,403	36,098	$ 5.20	May 1, 2031	91,309	$ 808,998
	4,803	29,781	$ 7.06	July 19, 2031		
Richard Ginn	12,556	43,945	$ 5.20	May 1, 2031	450,971	$ 3,995,603
	764	4,736	$ 7.06	July 19, 2031		

Stock Options[1]

The Company granted Steven M. Foster (i) an option to purchase 112,500 shares of common stock at an exercise price of $5.20 per share with a grant date of May 1, 2021, subject to monthly equal vesting over a three-year period and adjustment in certain circumstances as provided therein (37,497 shares of which are vested), and (ii) a restricted stock unit consisting of 217,453 shares of common stock with a grant date of May 12, 2022, subject to semi-annual vesting over a three-year period commencing May 22, 2022, with a one-year cliff.

The Company granted Richard Ginn (i) an option to purchase 56,500 shares of common stock at an exercise price of $5.20 per share with a grant date of May 1, 2021, subject to monthly equal vesting over a three-year period commencing April 1, 2021 (18,832 shares of which are vested), (ii) an option to purchase 5,499 shares of common stock at an exercise price of $7.06 per share with a grant date of July 19, 2021, subject to monthly equal vesting over a three-year period commencing July 19, 2021(1,833 shares of which are vested) and (iii) a restricted stock unit consisting of 450,971 shares of common stock with a grant date of May 12, 2022, subject to semi-annual vesting over a three-year period commencing May 22, 2022, with a one-year cliff.

1 Numbers are as of March 10, 2023

The Company granted Steven Van Dick (i) an option to purchase 56,500 shares of common stock at an exercise of $5.20 per share with a grant date of May 1, 2021, subject to monthly equal vesting over a three-year period that commenced on November 1, 2020 (37,663 shares of which are vested), (ii) an option to purchase 34,584 shares of common stock at an exercise price of $7.06 per share with a grant date of July 19, 2021, subject to monthly equal vesting over a three-year period commencing July 19, 2021 (11,537 shares of which are vested), and (iii) a restricted stock unit consisting of 91,309 shares of common stock with a grant date of May 12, 2022, subject to semi-annual vesting over a three-year period commencing May 22, 2022, with a one-year cliff.

The Company granted Richard Ferrari an option to purchase 112,500 shares of common stock at an exercise of $5.20 per share with a grant date of May 1, 2021, subject to monthly equal vesting over a three-year period that commenced on January 1 2021 (74,993 shares of which are vested), (ii) an option to purchase 160,751 shares of common stock at an exercise price of $7.06 per share with a grant date of July 19, 2021, subject to monthly equal vesting over a three-year period commencing July 19, 2021 (53,579 shares of which are vested), and (iii) a restricted stock unit consisting of 273,930 shares of common stock with a grant date of May 12, 2022, subject to semi-annual vesting over a three-year period commencing May 22, 2022, with a one-year cliff.

The Company granted Stephen Hochschuler (i) an option to purchase 8,586 shares of common stock at an exercise price of $0.62 per share with a grant date of November 15, 2016, all of which are vested, and (ii) a restricted stock unit consisting of 18,623 shares of common stock with a grant date of May 12, 2022, subject to semi-annual vesting over a three-year period commencing May 22, 2022, with a one-year cliff.

The Company granted Frank Fischer (i) an option to purchase 7,500 shares of common stock at an exercise price of $5.20 per share with a grant date of May 7, 2021, subject to monthly equal vesting over a two-year period that commenced immediately (6,250 shares of which are vested), and (ii) a restricted stock unit consisting of 18,623 shares of common stock with a grant date of May 12, 2022, subject to semi-annual vesting over a three-year period commencing May 22, 2022, with a one-year cliff.

RSUs

All of the RSUs were granted on May 12, 2022 and have the following vesting schedule: one-third vest on May 22, 2023 and the remaining two thirds vesting equally every six months over the following two years.

Board Compensation

The following summary board compensation table provides information regarding the board compensation paid during our fiscal year ended December 31, 2022 to our board members. Only our independent directors received compensation for being directors during fiscal year 2022.

Director	Cash Compensation[1]	Equity Compensation (RSUs)[2]	Total Compensation
Frank Fischer	$ 55,000	$ 165,000	$ 220,000
Ivan Howard	$ 60,000	$ 165,000	$ 225,000
Robert Weigle	$ 67,500	$ 165,000	$ 232,500
Stephen Hochschuler	$ 45,000	$ 165,000	$ 210,000
Total	227,500	$ 660,000	$ 227,500

(1) Frank Fischer received $40,000 as a board retainer and $15,000 for being Compensation Committee Chairman; Ivan Howard received $40,000 as a board retainer and $20,000 for being Audit Committee Chairman; Robert Weigle received $40,000 as a board retainer, $10,000 for being Nominating and Corporate Governance Committee Chairman, $7,500 for being a member of the Compensation Committee and $10,000 for being a member of the Audit Committee; and Stephen Hochschuler received $40,000 as a board retainer and $5,000 for being a member of the Nominating and Corporate Governance Committee.

(2) The RSUs were granted in May of 2022 and vest annually over a three-year period in equal amounts

Executive Chairman

On May 7, 2021, the Company entered into a Consulting Agreement (the "Ferrari Consulting Agreement") with Richard Ferrari, a founder of the Company and its Executive Chairman, pursuant to which Mr. Ferrari was to assume the role of Executive Chairman of the Company in exchange for compensation of $22,500 per month starting September 1,

2021. Under this consulting agreement Mr. Ferrari was paid a bonus of $350,000, as a result of the closing of our initial public offering in April 2022. In May of 2022 Mr. Ferrari was granted RSUs which had a grant date fair value of $2,427,020 and vest over three years, with one-third vesting in May of 2023 and the remaining two thirds vesting equally every six months over the following two years. The compensation (comprised of cash and RSUs) paid to Mr. Ferrari during the fiscal year ended December 31, 2022, totaled $3,047,020.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth certain information, as of March 10, 2023, with respect to the holdings of (1) each person who is the beneficial owner of more than 5% of a class of Company voting stock, (2) each of our directors, (3) each executive officer, and (4) all of our current directors and executive officers as a group.

Beneficial ownership of a class of voting stock is determined in accordance with the rules of the SEC and includes any shares of such class of the Company's voting stock over which a person exercises sole or shared voting or investment power, or of which a person has a right to acquire ownership at any time within 60 days. Except as otherwise indicated, we believe that the persons named in this table have sole voting and investment power with respect to all shares of voting stock held by them. Applicable percentage ownership in the following table is based on 11,251,299 shares of common stock, issued and outstanding on March 10, 2023 and, plus, for each individual, any common stock that individual has the right to acquire within 60 days of March 10, 2023.

To the best of our knowledge, except as otherwise indicated, each of the persons named in the table has sole voting and investment power with respect to the shares of our common stock beneficially owned by such person, except to the extent such power may be shared with a spouse. To our knowledge, none of the shares listed below are held under a voting trust or similar agreement, except as noted. To our knowledge, there is no arrangement, including any pledge by any person of securities of the Company, the operation of which may at a subsequent date result in a change in control of the Company.

The information contained in this table is as of March 10, 2023. At that date, 11,251,299 shares of our common stock were outstanding.

Name and Address of Beneficial Owner[1]	Title	Number of Shares Beneficially Owned	Beneficial Ownership Percentage
Officers and Directors			
Steven M. Foster	Chief Executive Officer and President	90,372[2]	*
Richard Ginn	Chief Technology Officer	613,041[3]	5.4%
Steven Van Dick	EVP, Finance and Admin and Chief Financial Officer	77,823[4]	*
Richard Ferrari	Chairman of the Board	340,572[5]	3.0%
Frank Fischer	Director Nominee	191,966[6]	1.7%
Ivan Howard	Director	79,587[7]	*
Robert K. Weigle	Director Nominee	—	—
Stephen H. Hochschuler, M.D.	Director Nominee	33,436[8]	*
Officers and Directors as a Group (total of 8 persons)		1,426,797[9]	12.7%
5% Stockholders of a Class of Voting Stock			
Zuhlke Ventures AG		2,447,728	21.8%

* Indicate less than 1% beneficial ownership.

(1) Unless otherwise indicated, the principal address of the named officers and directors and holders of 5% of a class of voting stock of the Company is c/o Tenon Medical, Inc., 104 Cooper Court, Los Gatos, CA 95032.

(2) Includes 75,000 shares of our common stock underlying stock options that have vested and are exercisable within 60 days of March 10, 2023.

(3) Includes 40,873 shares of our common stock underlying stock options that have vested and are exercisable within 60 days of March 10, 2023.

(4) Consists of 19,983 shares held by the Van Dick Family Trust-1998 for which Steven Van Dick is trustee and 57,840 shares of our common stock underlying stock options that have vested and are exercisable within 60 days of March 10, 2023.

(5) Consists of 92,214 shares held by the Ferrari Family Trust for which Richard Ferrari is trustee and 182,441 shares of our common stock underlying stock options that have vested and are exercisable within 60 days of March 10, 2023 (includes 13,670 shares of our common stock underlying options held by TCTIG, LLC for which Richard Ferrari is the beneficial owner) and 65,918 shares of our common stock held by TCTIG, LLC and for which Richard Ferrari has voting control.

(6) Includes 7,500 shares of our common stock underlying stock options that have vested and are exercisable within 60 days of March 10, 2023.

(7) Consists of 13,669 shares of our common stock underlying stock options that have vested and are exercisable within 60 days of March 10, 2023 and 65,918 shares of our common stock, in each case, held by TCTIG, LLC and for which Ivan Howard is either the beneficial owner or has voting control.

(8) Includes 8,536 shares of our common stock underlying options that have vested and are exercisable within 60 days of March 10, 2023; and 19,700 shares of our common that are held by SHKH, LLC, an entity for which Stephen H. Hochschuler has a controlling interest.

(9) Includes 385,859 shares of our common stock underlying stock options that have vested and are exercisable within 60 days of March 10, 2023.

Item 13. Certain Relationships and Related Party Transactions, and Director Independence

On May 7, 2021 the Company entered into the "Ferrari Consulting Agreement with Richard Ferrari, a founder of the Company and its Executive Chairman. See "*Executive Compensation — Board Compensation*" for a summary description of the terms of the Ferrari Consulting Agreement.

Item 14. Principal Accountant Fees and Services

Audit and Non-Audit Fees

Armanino LLP ("Armanino") served as the independent registered public accounting firm to audit our books and accounts for the fiscal years ending December 31, 2022 and 2021.

The table below presents the aggregate fees billed for professional services rendered by Armanino for the years ended December 31, 2022 and 2021.

	2022	2021
Audit fees	$ 338,253	$ 298,810
Audit-related fees	72,640	60,809
All other fees	—	—
Total fees	$ 410,893	$ 359,619

In the above table, "audit fees" are fees billed for services provided related to the audit of our annual financial statements, quarterly reviews of our interim financial statements, and services normally provided by the independent accountant in connection with regulatory filings or engagements for those fiscal periods. "Audit-related fees" are fees not included in audit fees that are billed by the independent accountant for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements. These audit-related fees also consist of the review of our registration statements filed with the SEC and related services normally provided in connection with regulatory filings or engagements. "All other fees" are fees billed by the independent accountant for products and services not included in the foregoing categories.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report:

(1) The consolidated financial statements are filed as part of this Annual Report under "Item 8. Financial Statements and Supplementary Data."

(2) The consolidated financial statement schedules are omitted because they are either not applicable or the information required is presented in the consolidated financial statements and notes thereto under "Item 8. Financial Statements and Supplementary Data."

(3) The exhibits listed in the following Exhibit Index are filed, furnished or incorporated by reference as part of this Annual Report.

(b) Exhibits

See the Exhibit Index immediately preceding the signature page of this Annual Report.

EXHIBIT INDEX

Exhibit No.	Description
3.1*	Amended and Restated Certificate of Incorporation of the Registrant.
3.2*	Bylaws of The Registrant.
3.3*	Amendment to Certificate of Incorporation of the Registrant
3.4*	Amendment to Certificate of Incorporation of the Registrant
3.5*	Amendment to Certificate of Incorporation of the Registrant
3.6*	Amendment to Certificate of Incorporation of the Registrant
3.7*	Amendment to Certificate of Incorporation of the Registrant
3.8*	Amendment to Certificate of Incorporation of the Registrant
4.1*	Form of Representative's Warrant in connection with the Registrant's Initial Public Offering
10.1*	Employment Agreement dated June 1, 2021 between Steven M. Foster and the Registrant
10.2*	Employment Agreement dated June 1, 2021 between Richard Ginn and the Registrant
10.3*	Consulting Agreement dated May 7, 2021 by and between Richard Ferrari and the Registrant
10.4*	Employment Agreement dated June 1, 2021 between Steven Van Dick and the Registrant
10.5*	Agreement and Consent of Director Nominee dated October 8, 2021 from Frank Fischer
10.6*	Agreement and Consent of Director Nominee dated October 8, 2021 from Ivan Howard
10.7*	Agreement and Consent of Director Nominee dated October 8, 2021 from Stephen H. Hochschuler
10.8*	Agreement and Consent of Director Nominee dated October 8, 2021 from Robert Weigle
10.9*	Exchange Agreement dated as of October 27, 2021 among Zuhlke Ventures AG, Tenon Technology AG and the Registrant
10.10*	Tennon Medical 2022 Equity Incentive Plan
10.11*	Exchange Agreement dated October 28, 2021 between the Registrant, Zuhlke Ventures AG and Tenon Technology AG
10.12*	IP Sale and Purchase Agreement dated January 21, 2022 between the Registrant and Tenon Technology AG
21.1*	List of Subsidiaries of the Registrant.
31.1**	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2**	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1***	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2***	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

* Incorporated by reference to the Registrant's Registration Statement No. 333-260931, filed on April 20, 2022

** Filed herewith

*** Exhibits 32.1 and 32.2 are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall such exhibits be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise specifically stated in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Tenon Medical , Inc.

Date: March 10, 2023

By: */s/ Steven M. Foster*
Steven M. Foster
Chief Executive Officer and President
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 10, 2023.

Name	Position	Date
/s/ Steven M. Foster Steven M. Foster	Chief Executive Officer and President, Director (Principal Executive Officer)	March 10, 2023
/s/ Richard Ginn Richard Ginn	Chief Technology Officer and Director	March 10, 2023
/s/ Steven Van Dick Steven Van Dick	Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2023
/s/ Richard Ferrari Richard Ferrari	Director	March 10, 2023
/s/ Ivan Howard Ivan Howard	Director	March 10, 2023
/s/ Frank Fischer Frank Fischer	Director	March 10, 2023
/s/ Robert K. Weigle Robert K. Weigle	Director	March 10, 2023
/s/ Stephen H. Hochschuler, M.D Stephen H. Hochschuler, M.D	Director	March 10, 2023