As filed with the United States Securities and Exchange Commission on May 10, 2024

Registration No. 333-[*]

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

FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

TENON MEDICAL, INC.
(Exact name of registrant as specified in its charter)

Delaware	**3841**	**45-5574718**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

104 Cooper Court
Los Gatos, CA 95032
(408) 649-5760
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Steven M. Foster
Chief Executive Officer and President
Tenon Medical, Inc.
104 Cooper Court
Los Gatos, CA 95032
(408) 649-5760
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Ross D. Carmel, Esq.
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Approximate date of commencement of proposed sale to the public: **As soon as practicable after the effective date of this Registration Statement.**

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Securities Exchange Act of 1934.

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 to Section 7(a)(2)(B) of the Securities Act. ☐

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

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MAY 10, 2024

PRELIMINARY PROSPECTUS

Up to 5,014,654 Shares of Common Stock

Tenon Medical, Inc.

This prospectus relates to the resale, from time to time, of up to 5,014,654 shares of our common stock, par value $0.001 per share, by the selling stockholder, Lincoln Park Capital Fund, LLC ("Lincoln Park" or the "Selling Stockholder").

The shares of our common stock to which this prospectus relates includes (i) 14,654 outstanding shares held by Lincoln Park as of the date of the prospectus that were previously issued and sold to Lincoln Park pursuant to a Purchase Agreement between us and Lincoln Park dated as of July 24, 2023 (the "Purchase Agreement") prior to the date of this prospectus and (ii) 5,000,000 shares that may be issued to Lincoln Park pursuant to the Purchase Agreement.

We are not selling any securities under this prospectus and will not receive any proceeds from the sale of our shares of common stock by Lincoln Park. We have sold an aggregate of 89,847 shares of common stock to Lincoln Park under the Purchase Agreement for total gross proceeds of approximately $100,000 pursuant to Registration Statement on Form S-1 (File No. 333-274451) (the "Original Registration Statement") with the Securities and Exchange Commission ("SEC"), which was declared effective by the SEC on September 21, 2023. We may receive an additional aggregate gross proceeds of up to approximately $9.9 million from any sale of our common stock to Lincoln Park under the Purchase Agreement. See "*Lincoln Park Transaction*" herein.

Lincoln Park is deemed an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended, or the Securities Act.

Lincoln Park may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See " *Plan of Distribution*" on page 106 for more information about how Lincoln Park may sell the shares of common stock being registered pursuant to this prospectus.

We have agreed to bear all of the expenses incurred in connection with the registration of the shares to which this prospectus relates. Lincoln Park will pay or assume discounts, commissions, and fees of underwriters, selling brokers or dealer managers, if any, incurred in connection with the sale of shares of our common stock.

Our common stock is listed on The Nasdaq Capital Market under the symbol "TNON." On May 9, 2024, the closing sale price of our common stock as reported on The Nasdaq Capital Market was $0.8432. You are urged to obtain current market quotations for the common stock.

We are an "emerging growth company" and a "smaller reporting company" under applicable Securities and Exchange Commission rules and, as such, have elected to comply with certain reduced public company disclosure requirements for this prospectus and future filings. See "*Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company*."

Our business and investment in our common stock involve significant risks. These risks are described in the section titled " *Risk Factors*" beginning on page 10 of this prospectus.

Neither the SEC nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is , 2024.

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We have not, and the Selling Stockholder has not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give to you. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

You should rely only on the information contained in this prospectus. No dealer, salesperson or other person is authorized to give information that is not contained in this prospectus. This prospectus is not an offer to sell nor is it seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of these securities.

ABOUT THIS PROSPECTUS

Throughout this prospectus, unless otherwise designated or the context suggests otherwise,

- all references to the "Tenon," the "Company," the "registrant," "we," "our," or "us" in this prospectus mean Tenon Medical, Inc.;
- "year" or "fiscal year" means the year ending December 31 st; and
- all dollar or $ references, when used in this prospectus, refer to United States dollars.

MARKET DATA

Market data and certain industry data and forecasts used throughout this prospectus were obtained from internal company surveys, market research, consultant surveys, publicly available information, reports of governmental agencies and industry publications and surveys. Industry surveys, publications, consultant surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. To our knowledge, certain third-party industry data that includes projections for future periods does not consider the effects of any future coronavirus outbreaks or any geopolitical conflicts. Accordingly, those third-party projections may be overstated and should not be given undue weight. We have not independently verified any of the data from third party sources, nor have we ascertained the underlying economic assumptions relied upon therein. Similarly, internal surveys, industry forecasts and market research, which we believe to be reliable based on our management's knowledge of the industry, have not been independently verified. Forecasts are particularly likely to be inaccurate, especially over long periods of time. In addition, we do not necessarily know what assumptions regarding general economic growth were used in preparing the forecasts we cite. Statements as to our market position are based on the most currently available data. While we are not aware of any misstatements regarding the industry data presented in this prospectus, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under the heading "*Risk Factors*" in this prospectus. We are, however, liable for the information in the prospectus related to the market and industry data.

PROSPECTUS SUMMARY

This summary provides a brief overview of the key aspects of our business and our securities. The reader should read the entire prospectus carefully, especially the risks of investing in our common stock discussed under "Risk Factors." Some of the statements contained in this prospectus, including statements under "Summary" and "Risk Factors" as well as those noted in the documents incorporated herein by reference, are forward-looking statements and may involve a number of risks and uncertainties. Our actual results and future events may differ significantly based upon a number of factors. The reader should not put undue reliance on the forward-looking statements in this document, which speak only as of the date on the cover of this prospectus.

Unless the context otherwise requires, references in this prospectus to "Tenon," "Tenon Medical," "the Company," "our Company," "we," "us" and "our" refer to Tenon Medical, Inc.

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 has developed The Catamaran™ SI Joint Fusion System ("The CATAMARAN System") that offers a novel, less invasive approach to the sacroiliac joint (the "SI Joint") using a single, robust, titanium implant for treatment of the most common types of SI Joint disorders that cause lower back pain. The Company received U.S. Food and Drug Administration ("FDA") clearance in 2018 for The CATAMARAN System and is currently focused on the US market. Since the national launch of The CATAMARAN System in October 2022, the Company is focused on three commercial opportunities: 1) Primary SI Joint procedures, 2) Revision procedures of failed SI Joint implants and 3) SI Joint fusion adjunct to a spine fusion construct.

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 conservative options, including systemic oral medications, opioids, physical therapy and injection therapy.

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 spine 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 spine 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.

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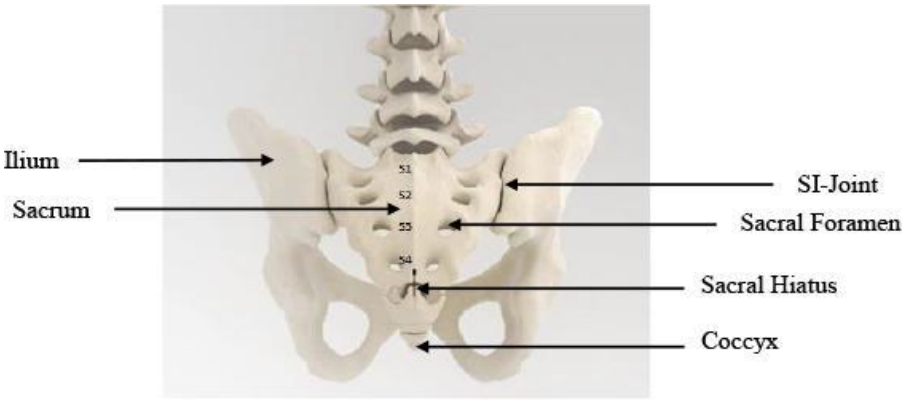
The SI-Joint



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 2-4mm 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.

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- **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.

Commercialization

Tenon initiated its national commercial launch of The CATAMARAN System in October 2022 to address what we believe is a large market opportunity. The CATAMARAN System includes instruments and implants designed to prepare and fixate the SI-Joint for fusion. The CATAMARAN System is distinct from other competitive offerings in the following ways:

- Transfixes the SI-Joint
- Inferior / Posterior Sacroiliac Fusion Approach
- 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 Lateral 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 address 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 transfix the SI-Joint and 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.

In October 2022, we received Institutional Review Board ("IRB") approval from WCG IRB for two separate Tenon-sponsored post market clinical studies of The CATAMARAN System. The approval by WCG allows designated Catamaran study centers to begin recruiting and enrolling patients into the clinical studies. The first approval from WCG IRB will support a prospective, multi-center, single arm post market study that will evaluate the clinical outcomes of patients with sacroiliac joint disruptions or degenerative sacroiliitis treated with The CATAMARAN System. Patients will be followed out to 24 months assessing various patient reported outcomes, radiographic assessments, and adverse events. The second prospective, multi-center, Catamaran study will evaluate 6-to-12-month radiographic outcomes to assess fusion of patients that have already undergone treatment with The CATAMARAN System. In addition, retrospective and prospective clinical outcomes will be evaluated. We anticipate completing enrollment by the end of the second quarter of 2024.

For a description of the challenges, we face and the risks and limitations that could harm our prospects, see *"Summary Risk Factors"* and *"Risk Factors."*

The Purchase Agreement with Lincoln Park

On July 24, 2023, we entered into the Purchase Agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park agreed to purchase from us up to an aggregate of $10.0 million of our common stock (subject to certain limitations) from time to time over the term of the Purchase Agreement. Also on July 24, 2023, we entered into a registration rights agreement with Lincoln Park, which we refer to in this prospectus as the Registration Rights Agreement, pursuant to which we filed with the SEC the registration statement that includes this prospectus to register for

resale under the Securities Act of 1933, as amended, or the Securities Act, the shares of our common stock that have been and may be issued to Lincoln Park under the Purchase Agreement. See "*Lincoln Park Transaction*."

Recent Developments

Nasdaq Notice of Failure to Comply with Continued Listing Standards

On May 7, 2024, we received a letter from the Nasdaq Listing Qualifications Staff of The Nasdaq Stock Market LLC ("Nasdaq") stating that for the 30 consecutive business day period between March 25, 2024 and May 6, 2024, our common stock had not maintained a minimum closing bid price of $1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"). Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until November 4, 2024 (the "Compliance Period"), to regain compliance with the Bid Price Rule.

To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive trading days, unless extended by Nasdaq under Nasdaq Rule 5810(c)(3)(H), prior to November 4, 2024.

If we do not regain compliance with the Bid Price Rule by November 4, 2024, we may be eligible for an additional 180-day period to regain compliance if we meet all of the other Nasdaq listing criteria and if Nasdaq does not believe we will not be able to regain compliance within such 180-day period. If we cannot regain compliance during the Compliance Period or any subsequently granted compliance period, our common stock will be subject to delisting.

Our common stock continues to be listed on The Nasdaq Capital Market under the symbol "TNON". We are currently evaluating our options for regaining compliance.

The notice from Nasdaq has no immediate effect on the listing or trading of our common stock on The Nasdaq Capital Market and does not affect our business, operations or reporting requirements with the SEC.

Exchange Offer

On April 8, 2024, we launched a one-time stock option exchange program (the "Option Exchange") pursuant to which eligible participants were able to exchange outstanding stock options for a lesser amount of new restricted stock units ("RSUs"). Our executive officers, non-employee directors and consultants were eligible to participate in the Option Exchange. Employees, non-employee directors and consultants received one RSU for every two shares of our common stock underlying the eligible options surrendered. This "exchange ratio" (2-for-1) was applied on a grant-by-grant basis. The Option Exchange expired on May 6, 2024 at 11:59 p.m., Eastern Time. At that time, stock options to purchase 83,391 shares of our common stock were surrendered and 41,698 new RSUs were issued under the Tenon Medical, Inc. 2022 Equity Incentive Plan (the "2022 Plan").

2024 Series A Offering

On February 20, 2024, we entered into a Securities Purchase Agreement (the "Series A Purchase Agreement") with certain investors (the "Series A Investors"), pursuant to which the Company agreed to sell, issue and deliver to the Series A Investors, in a private placement offering (the "Series A Offering"), a total of 172,239 shares of the Company's Series A Preferred Stock (the "Series A Preferred Stock") and warrants (the "Warrants") to purchase 258,374 shares of common stock, par value $0.001 per share, of the Company ("Common Stock") at an exercise price equal to $1.2705 per share for an aggregate offering price of $2,605,000. Under the Series A Purchase Agreement, each Series A Investor paid $15.125 for each share of Series A Preferred Stock and along with their shares of Series A Preferred Stock, received Warrants equal to 15% of the number of shares of our common stock initially underlying such shares of Series A Preferred Stock. In connection with the offering of the Series A Preferred Stock the Company exchanged the Notes (as defined below) for 84,729 shares of Series A Preferred Stock and Series A Warrants to purchase 157,094 shares of our common stock. There are a total of 256,968 shares of Series A Preferred Stock outstanding as of May 10, 2024.

2023 Note Offering

On November 21, 2023, we entered into securities purchase agreements with certain investors (the "Note Investors"), pursuant to which we agreed to sell, issue and deliver to the Note Investors, in a private placement offering (the "Note Offering"), a total of $1,250,000 in secured notes (the "Notes") and warrants (the "Note Warrants") to purchase 45,000 shares of our common stock at an exercise price equal to $1.94 per share. The Company received $1,125,000 from the Note Offering after payment of investor expenses.

The Notes beared an interest rate of 10% per annum with a default rate of 12% per annum and have a maturity date of November 21, 2024. All principal and accrued interest is payable at maturity. However, at any time during the term of the Notes, the principal amount of the Notes together with all accrued and unpaid principal thereon (the "Prepayment Amount") may be paid in full, but not in part, by us. The Prepayment Amount may be paid by us in cash or by the issuance to the Investors in shares of Series A Preferred Stock. The Notes are secured by a first priority security interest in all of our assets. The principal balance of the Note, including any accrued interest, was paid in full in shares of Series A Preferred Stock on February 20, 2024 and the security interest has been released.

November 2023 Stock Split

On November 2, 2023, the Company effected a 1-for-10 reverse stock split (the "2023 Reverse Stock Split") by filing an amendment to the Company's Second Amended and Restated Certificate of Incorporation, as amended, with the Delaware Secretary of State. The 2023 Reverse Stock Split combined every ten shares of our common stock issued and outstanding immediately prior to effecting the 2023 Reverse Stock Split into one share of common stock. No fractional shares were issued in connection with the 2023 Reverse Stock Split. All historical share and per share amounts reflected throughout this document have been adjusted to reflect the 2022 Reverse Stock Split and the 2023 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 2023 Reverse Stock Split.

Summary Risk Factors

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 the section titled "*Risk Factors*" below:

- 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;

- 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;
- 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;
- 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;
- Our sales volumes and our operating results may fluctuate over the course of the year;
- Various factors outside our direct control may adversely affect manufacturing and distribution of our product;

- 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;
- 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;
- 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;
- If we experience significant disruptions in our information technology systems, our business, results of operations, and financial condition could be adversely affected;
- 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;
- 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;
- We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks;
- 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;
- Inflation may adversely affect our operations and financial results;
- 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;
- 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 subject to environmental laws and regulations that can impose significant costs and expose us to potential financial liabilities;
- Our ability to protect our intellectual property and proprietary technology is uncertain;
- We may not be able to protect our intellectual property rights throughout the world;
- The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall; and
- Our management will have broad discretion over the use of the net proceeds from our sale of shares of common stock to Lincoln Park, and you may not agree with how we use the proceeds and the proceeds may not be invested successfully.

Corporate Information

Our principal executive offices are located at 104 Cooper Court, Los Gatos, CA 95032. Our website address is *www.tenonmed.com*. The information included on our website is not part of this prospectus.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). We will remain an emerging growth company until the earlier of (i) 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; (ii) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under applicable SEC rules. We expect that we will remain an emerging growth company for the foreseeable future, but cannot retain our emerging growth company status indefinitely and will no longer qualify as an emerging growth company on or before 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. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from specified disclosure requirements that are applicable to other public companies that are not emerging growth companies.

These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "*Management's Discussion and Analysis of Financial Condition and Results of Operations* " disclosure;
- not being required to comply with the requirement of auditor attestation of our internal controls over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of certain reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

An emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this extended transition period and, as a result, we will not be required to adopt new or revised accounting standards on the dates on which adoption of such standards is required for other public reporting companies.

We are also a "smaller reporting company" as defined in Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and have elected to take advantage of certain of the scaled disclosure available for smaller reporting companies.

SUMMARY OF THE OFFERING

Common stock being offered by the Selling Stockholder	Up to 5,014,654 shares of our common stock, consisting of: ● 14,654 shares of common stock previously issued and sold to Lincoln Park pursuant to the Purchase Agreement. ● Up to 5,000,000 shares of common stock that we may sell to Lincoln Park pursuant to the Purchase Agreement from time to time after the registration statement of which this prospectus forms a part is declared effective and all of the other conditions set forth in the Purchase Agreement are satisfied (the "Purchase Shares").
Common stock outstanding before this offering	3,726,974 shares.
Selling Stockholder	Lincoln Park Capital Fund, LLC. See "Selling Stockholder" on page 54 of this prospectus.
Use of Proceeds	We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. We may receive up to approximately $9.9 million in gross proceeds that remains available under the Purchase Agreement that we may sell to Lincoln Park pursuant to the Purchase Agreement from time to time after the registration statement of which this prospectus forms a part is declared effective. Any proceeds from Lincoln Park that we receive under the Purchase Agreement are expected to be used for general corporate purposes, capital expenditures, working capital and general and administrative expenses.
Risk Factors	See "*Risk Factors*" on page 10 and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Listing	Our common stock and tradeable warrants ("Tradeable Warrants") trade on The Nasdaq Capital Market under the symbols "TNON" and "TNONW," respectively.

The number of shares of our common stock to be outstanding after this offering is based on 3,726,974 shares of our common stock outstanding as of May 10, 2024 (including the 98,909 Commitment Shares previously issued to Lincoln Park and the 89,847 shares of common stock previously issued and sold to Lincoln Park pursuant to the Purchase Agreement (of which 14,654 are currently held by Lincoln Park) and excludes:

- 171,389 shares of our common stock issuable pursuant to options and restricted stock units granted pursuant to our equity incentive plan;
- 9,600 shares of our common stock issuable upon the exercise of warrants issued to the underwriters in our initial public offering that closed on April 29, 2022;
- Warrants to purchase up to 1,918,000 shares of our common stock at an exercise price equal to $3.146 per share issued to investors in our June 2023 public offering;
- Warrants to purchase up to 45,000 shares of our common stock at an exercise price equal to $1.94 per share issued to investors in our November 2023 private placement; and
- Warrants to purchase up to 415,468 shares of our common stock at an exercise price equal to $1.2705 per share issued to investors in our February 2024 private placement.

Unless otherwise indicated, this prospectus reflects and assumes no exercise of outstanding options or warrants described above.

RISK FACTORS

Our business is subject to many risks and uncertainties, which may affect our future financial performance. If any of the events or circumstances described below occur, our business and financial performance could be adversely affected, our actual results could differ materially from our expectations, and the price of our stock could decline. The risks and uncertainties discussed below are not the only ones we face. There may be additional risks and uncertainties not currently known to us or that we currently do not believe are material that may adversely affect our business and financial performance. You should carefully consider the risks described below, together with all other information included in this prospectus including our financial statements and related notes, before making an investment decision. The statements contained in this prospectus that are not historic facts are forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ materially from those set forth in or implied by forward-looking statements. If any of the following risks actually occurs, our business, financial condition or results of operations could be harmed. In that case, the trading price of our common stock could decline, and investors in our securities may lose all or part of their 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, 2023, 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.

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 COVID-19 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 any future COVID-19 outbreak 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. The increasing sophistication and frequency of cybersecurity threats, including targeted data breaches, ransomware attacks designed to encrypt our data for ransom and other malicious cyber activities, pose a significant risk to the integrity and confidentiality of our data systems. 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.

Our operations could be disrupted by geopolitical conditions, political and social instability, acts of war, terrorist activity or other similar events. In February 2022, 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 global trade, currency exchange rates, regional economies and the global economy. In addition, the ongoing conflicts in the Middle East may further impact global economic conditions and market sentiments. This, in turn, could adversely affect the trading price of our shares of common stock and investor interest in us. The outcome of the Russia-Ukraine war and conflicts in the Middle East remain 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.

Inflation may adversely affect our operations and financial results.

In periods of rising inflation, the cost of raw materials, components and labor essential for manufacturing The CATAMARAN System may increase and as a consequence, our overall profit margin may be adversely affected. In addition, inflation may result in limitations on healthcare spending, specifically for procedures that are deemed elective or non-critical, which may include treatments utilizing The CATAMARAN System. A decrease in demand for these procedures may significantly impact our financial condition and results of operations.

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 May 10, 2024, we owned eight issued patents (four domestic and four foreign), 20 pending patent applications (18 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 this Offering and Ownership of our Common Stock

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to decrease.

On July 24, 2023, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $10.0 million of our common stock. Upon the execution of the Purchase Agreement, we issued 98,909 Commitment Shares to Lincoln Park as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement (the “Commitment Shares”). The shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Lincoln Park at our sole discretion from time to time over a 24-month period commencing after the satisfaction of certain conditions set forth in the Purchase Agreement. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the trading price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to decrease. We generally have the right to control the timing and amount of any future sales of our shares to Lincoln Park. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

It is not possible to predict the actual number of shares we will sell under the Purchase Agreement to the Selling Stockholder, or the actual gross proceeds resulting from those sales.

On July 24, 2023, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $10.0 million in shares of our common stock, subject to certain limitations and conditions set forth in the Purchase Agreement. The shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over an approximately 24-month period commencing on the Commencement Date.

We generally have the right to control the timing and amount of any sales of our shares of common stock to Lincoln Park under the Purchase Agreement. Sales of our common stock, if any, to Lincoln Park under the Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the shares of our common stock that may be available for us to sell to Lincoln Park pursuant to the Purchase Agreement.

Because the purchase price per share to be paid by Lincoln Park for the shares of common stock that we may elect to sell to Lincoln Park under the Purchase Agreement, if any, will fluctuate based on the market prices of our common stock at the time we elect to sell shares to Lincoln Park pursuant to the Purchase Agreement, if any, it is not possible for us to predict, as of the date of this prospectus and prior to any such sales, the number of shares of common stock that we will sell to Lincoln Park under the Purchase Agreement, the purchase price per share that Lincoln Park will pay for shares purchased from us under the Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases by Lincoln Park under the Purchase Agreement.

Moreover, although the Purchase Agreement provides that we may sell up to an aggregate of $10.0 million of our common stock to Lincoln Park, only approximately $9.9 million remains available to us under the Purchase Agreement, and only 5,014,654 shares of our common stock are being registered for resale by Lincoln Park under the registration statement that includes this prospectus, consisting of (i) the 14,654 shares of our common stock that we previously issued and sold to Lincoln Park pursuant to the Purchase Agreement and (ii) up to 5,000,000 Purchase Shares that we may elect to sell to Lincoln Park, in our sole discretion, from time to time from and after the date of this prospectus. If after the date of this prospectus and for the remaining duration of the 24 month period after the Commencement Date we elect to sell to Lincoln Park all of the 5,000,000 shares of common stock being registered for resale under this prospectus that are available for sale by us to Lincoln Park in Regular Purchases under the Purchase Agreement, depending on the market prices of our common stock during the applicable Regular Purchase valuation period for each Regular Purchase made pursuant to the Purchase Agreement, the actual gross proceeds from the sale of all such shares may be substantially less than the approximately $9.9 million total purchase commitment that remains available to us under the Purchase Agreement, which could materially adversely affect our liquidity.

Furthermore, if we elect to issue and sell to Lincoln Park more than the 5,000,000 Purchase Shares, we must first file with the SEC one or more additional registration statements to register under the Securities Act for resale by Lincoln Park such additional shares of our common stock we wish to sell from time to time under the Purchase Agreement, which the SEC must declare effective, in each case before we may elect to sell any additional shares of our common stock to Lincoln Park under the Purchase Agreement.

The Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of our common stock if those shares of our common stock, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park having beneficial ownership of more than 4.99% of the total outstanding shares of our common stock, as calculated pursuant to Section 13(d) of the Exchange

Act and Rule 13d-3 thereunder (the "Beneficial Ownership Cap").

Any issuance and sale by us under the Purchase Agreement of a substantial amount of shares of common stock in excess of the 5,000,000 Purchase Shares that we may elect to issue and sell to Lincoln Park under the Purchase Agreement that are being registered for resale by Lincoln Park hereunder could cause additional substantial dilution to our stockholders. The number of shares of our common stock ultimately offered for resale by Lincoln Park is dependent upon the number of shares of our common stock we ultimately decide to sell to Lincoln Park under the Purchase Agreement.

Investors who buy shares at different times will likely pay different prices, and the sale of the shares of common stock acquired by Lincoln Park could cause the price of our common stock to decline.

Pursuant to the Purchase Agreement, we will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold to Lincoln Park. If and when we do elect to sell shares of our common stock to Lincoln Park pursuant to the Purchase Agreement, after Lincoln Park has acquired such shares, Lincoln Park may resell all, some or none of such shares at any time or from time to time in its discretion and at different prices. As a result, investors who purchase shares from Lincoln Park in this offering at different times will likely pay different prices for those shares, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results. Investors may experience a decline in the value of the shares they purchase from Lincoln Park in this offering as a result of future sales made by us to Lincoln Park at prices lower than the prices such investors paid for their shares in this offering. Further, the sale of a substantial number of shares of our common stock by Lincoln Park, or anticipation of such sales, could cause the trading price of our common stock to decline or make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise desire.

We may require additional financing to sustain our operations, without which we may not be able to continue operations, and the terms of subsequent financings may adversely impact our stockholders.

We may direct Lincoln Park to purchase up to $10.0 million worth of shares of our common stock, of which approximately $9.9 million remains available under the Purchase Agreement in a Regular Purchase from time to time under the Purchase Agreement after the date of this prospectus and over the remaining duration of the 24-month period generally in amounts up to 100,000 shares of our common stock, which may be increased to up to 150,000 shares of our common stock depending on the closing sale price of our common stock on Nasdaq at the time of sale; provided, however that Lincoln Park's maximum purchase obligation under any single Regular Purchase shall not exceed $500,000; provided, further, however, that we and Lincoln Park may mutually agree at any time to increase the maximum number of shares of common stock the Company may direct Lincoln Park to purchase in any single Regular Purchase to up to 1,000,000 shares or any number of shares that shall not exceed 4.99% of the then outstanding shares of common stock. Moreover, under certain circumstances as set forth in the Purchase Agreement, we may, in our sole discretion, also direct Lincoln Park to purchase additional shares of common stock in Accelerated Purchases and Additional Accelerated Purchases as set forth in the Purchase Agreement.

Depending on the prevailing market price of our common stock, we may not be able to sell shares to Lincoln Park for the maximum $10.0 million over the term of the Purchase Agreement, of which approximately $9.9 million is available under the Purchase Agreement from the date of this prospectus. In addition, Lincoln Park will not be required to purchase any shares of our common stock if such sale would result in Lincoln Park's beneficial ownership of our common stock exceeding the Beneficial Ownership Cap of 4.99% of the outstanding shares of our common stock. Our inability to access a portion or the full amount available under the Purchase Agreement, in the absence of any other financing sources, could have a material adverse effect on our business.

The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. Assuming a purchase price of $0.8432 per share (which represents the closing price of our common stock on May 9, 2024), the purchase by Lincoln Park of the entire 5,000,000 Purchase Shares issuable under the Purchase Agreement being registered for resale by Lincoln Park hereunder would result in gross proceeds to us of only $4,216,000. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all $10.0 million of shares of our common stock to Lincoln Park under the Purchase Agreement, of which approximately $9.9 million remains available under the Purchase Agreement, we may still need additional capital to finance our future commercialization plans and working capital needs, and we may have to raise funds through the issuance of equity or debt securities.

Depending on the type and the terms of any financing we pursue, stockholders' rights and the value of their investment in our common stock could be reduced. A financing could involve one or more types of securities including common stock, convertible debt or warrants to acquire common stock. These securities could be issued at or below the then prevailing market price for our common stock. In addition, if we issue secured debt securities, the holders of the debt would have a claim to our assets that would be prior to the rights of stockholders until the debt is paid. Interest on these debt securities would increase costs and negatively impact operating results. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock could be negatively impacted.

Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

Our management will have broad discretion over the use of the net proceeds from our sale of shares of common stock to Lincoln Park, and you may not agree with how we use the proceeds and the proceeds may not be invested successfully.

Our management will have broad discretion as to the use of the net proceeds from our sale of shares of common stock to Lincoln Park, and we could use them for purposes other than those contemplated at the time of commencement of this offering. Accordingly, you will be relying on the judgment of our management with regard to the use of those net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that, pending their use, we may invest those net proceeds in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flows.

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.

As initially disclosed on the Current Report on Form 8-K filed on May 8, 2024 with the SEC, we received written notification from Nasdaq notifying us that we had failed to comply with Nasdaq Listing Rule 5550(a)(2) because the bid price for our common stock for 30 consecutive business days prior to such

date had closed below the minimum $1.00 per share requirement for continued listing. Nasdaq initially granted us 180 calendar days, or until November 4, 2024, to regain compliance with the Minimum Bid Price Requirement.

The notice had no immediate effect on the listing or trading of the common stock on The Nasdaq Capital Market. If, at any time before November 4, 2024, the bid price of our common stock closes at or above $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written notification that we have achieved compliance with the Minimum Bid Price Requirement. If compliance with the Minimum Bid Price Requirement cannot be demonstrated by November 4, 2024, we may be eligible for an additional 180 calendar days to comply with Nasdaq Listing Rule 5550(a)(2), subject to us satisfying the continued listing requirement for the market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, subject to Nasdaq's approval.

Upon delisting from The Nasdaq Capital Market, our stock would be traded over-the-counter in the inter-dealer quotation system, more commonly known as the OTC. OTC transactions involve risks in addition to those associated with transactions in securities traded on the securities exchanges, such as The Nasdaq Capital Market (together, "Exchange-listed Stocks"). Many OTC stocks trade less frequently and in smaller volumes than Exchange-listed Stocks. Accordingly, our stock would be less liquid than it would be otherwise. Also, the values of OTC stocks are often more volatile than Exchange-listed Stocks. Additionally, institutional investors are usually prohibited from investing in OTC stocks, and it might be more challenging to raise capital when needed.

We will continue to monitor the closing bid price of our common stock and seek to regain compliance with the Minimum Bid Price Requirement within the allotted compliance period; however, there can be no assurance that we will regain compliance with the Minimum Bid Requirement.

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.

Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders.

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 price paid.

The trading price of our common stock may fluctuate substantially. The market price of our common stock may fluctuate higher or lower, 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;

- 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; and
- 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.

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.

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, a senior accountant, a cost accountant and external financial consultants, and plans to continue to add additional resources, technology and headcount as warranted by the growth of the Company. Management has taken initial steps to remedy this weakness by hiring a Chief Financial Officer as well as a Chief Executive Officer, and we are in the process of putting proper policies and procedures in place to ensure proper documentation is established and maintained for transactions that the Company enters into. 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 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 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 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, 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. However, prior to the effectiveness of the registration statement related to this prospectus, we will amend our Certificate of Incorporation to include a statement that this exclusive forum provision does not apply to claims arising under federal securities laws. 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.

IN ADDITION TO THE ABOVE RISKS, BUSINESSES ARE OFTEN SUBJECT TO RISKS NOT FORESEEN OR FULLY APPRECIATED BY MANAGEMENT. IN REVIEWING THIS FILING, POTENTIAL INVESTORS SHOULD KEEP IN MIND THAT OTHER POSSIBLE RISKS MAY ADVERSELY IMPACT THE COMPANY'S BUSINESS OPERATIONS AND THE VALUE OF THE COMPANY'S SECURITIES.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements." Forward-looking statements reflect the current view about future events. When used in this prospectus, the words "anticipate," "believe," "estimate," "expect," "future," "intend," "plan" or the negative of these terms and similar expressions, as they relate to us or our management, identify forward-looking statements. Such statements, include, but are not limited to, statements contained in this prospectus relating to our business strategy, our future operating results and liquidity and capital resources outlook. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward–looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees of assurance of future performance. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include, without limitation:

- Our ability to effectively operate our business segments;
- Our ability to manage our research, development, expansion, growth, and operating expenses;
- Our ability to evaluate and measure our business, prospects, and performance metrics;
- Our ability to compete, directly and indirectly, and succeed in the highly competitive medical devices industry;
- Our ability to respond and adapt to changes in technology and customer behavior;
- 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 prospectus entitled " *Risk Factors*") relating to our industry, our operations and results of operations.

Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

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 PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Lincoln Park. We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. We may receive up to $10 million in gross proceeds under the Purchase Agreement from any sales we make to Lincoln Park pursuant to the Purchase Agreement after the date of this prospectus.

Any net proceeds from the sale of our common stock to Lincoln Park that we receive under the Purchase Agreement are expected to be used for general corporate purposes, including working capital. As we are unable to predict the timing or amount of potential issuances of all of the additional shares issuable to the Purchase Agreement, we cannot specify with certainty all of the particular uses for the net proceeds that we will have from the sale of such shares. Accordingly, our management will have broad discretion in the application of the net proceeds. We may use the proceeds for purposes that are not contemplated at the time of this offering. It is possible that no additional shares will be issued under the Purchase Agreement.

DIVIDEND POLICY

We have not declared any cash dividends since inception and we do not anticipate paying any dividends in the foreseeable future. Instead, we anticipate that all of our earnings will 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. The payment of dividends is within the discretion of the Board and will depend on our earnings, capital requirements, financial condition, prospects, applicable Delaware law, which provides that dividends are only payable out of surplus or current net profits, and other factors our Board might deem relevant. There are no restrictions that currently limit our ability to pay dividends on our common stock other than those generally imposed by applicable state law.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock and Tradeable Warrants are listed on The Nasdaq Capital Market under the symbols “TNON” and “TNONW,” respectively. As of May 10, 2024, we have issued and outstanding 3,726,974 shares of common stock issued and outstanding held by 62 stockholders of record.

We also have outstanding:

- 171,389 shares of our common stock issuable pursuant to options and restricted stock units granted pursuant to our equity incentive plan;
- 9,600 shares of our common stock issuable upon the exercise of warrants issued to the underwriters in our initial public offering that closed on April 29, 2022;
- Warrants to purchase up to 1,918,000 shares of our common stock at an exercise price equal to $3.146 per share issued to investors in our June 2023 public offering;
- Warrants to purchase up to 45,000 shares of our common stock at an exercise price equal to $1.94 per share issued to investors in our November 2023 private placement; and
- Warrants to purchase up to 415,468 shares of our common stock at an exercise price equal to $1.2705 per share issued to investors in our February 2024 private placement.

Securities Authorized for Issuance under Equity Incentive Plan

On October 1, 2012, the Board adopted the 2012 Plan. The 2012 Plan terminated in April 2022. There are 1,175 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 2022, our Board 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 is equal to (i) 160,000 plus (ii) the lesser of (a) 75,000 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 canceled, 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 Plan is subject to an annual increase equal to the lesser of (i) 110,000 shares of our common stock, (ii) a number of shares of our common stock equal to 4% of the prior year’s maximum number and (iii) such number of shares of our common stock as determined by the 2022 Plan administrator. For a more detailed description of the 2022 Plan see “*Description of Securities—2022 Equity Incentive Plan.* ”

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 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.

THE LINCOLN PARK TRANSACTION

General

On July 24, 2023, we entered into the Purchase Agreement with Lincoln Park pursuant to which Lincoln Park has agreed to purchase from us up to an aggregate of $10.0 million of our common stock (subject to certain limitations) from time to time over the term of the Purchase Agreement. We have sold an aggregate of 89,847 shares of common stock to Lincoln Park under the Purchase Agreement for total gross proceeds of approximately $100,000. We may receive an additional aggregate gross proceeds of up to approximately $9.9 million from any sale of our commons tock to Lincoln Park under the Purchase Agreement after the date of this prospectus.

Also on July 24, 2023, we entered into the Registration Rights Agreement, pursuant to which we filed the Original Registration Statement with the SEC. Under the Original Registration Statement, we registered 598,909 shares of our common stock comprised of: (i) 98,909 Commitment Shares that we

issued to Lincoln Park as consideration for making its irrevocable commitment to purchase shares of our common stock under the Purchase Agreement at our direction, and (ii) up to 500,000 that we may issue and sell to Lincoln Park under the Purchase Agreement from time to time from thereafter at our determination. As of May 10, 2024, we have issued and sold an aggregate of 89,847 shares of common stock for total gross proceeds of approximately $100,000 pursuant to the Purchase Agreement and under the Original Registration Statement.

Also, pursuant to the Registration Rights Agreement, the registration statement of which this prospectus forms a part registers under the Securities Act for resale by Lincoln Park up to 5,014,654 shares of common stock, consisting of (i) the 14,654 shares of common stock that we previously issued and sold to Lincoln Park pursuant to the Purchase Agreement and (ii) up to 5,000,000 Purchase Shares that we may elect to sell to Lincoln Park, in our sole discretion, from time to time from and after the date of this prospectus.

We did not have the right to commence sales of our common stock to Lincoln Park under the Purchase Agreement until the Commencement Date and for a period of 24 months thereafter, under the terms and subject to the conditions of the Purchase Agreement, from time to time, at the Company's discretion, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $10 million of shares of common stock, subject to certain limitations set forth in the Purchase Agreement. Specifically, from time to time from and after the Commencement Date, the Company may, at its discretion, direct Lincoln Park to purchase on any single business day on which the closing price of its common stock on Nasdaq is equal to or greater than $0.15 up to 100,000 shares of common stock in a Regular Purchase, which share limit may be increased to up to 150,000 shares of common stock, depending on the closing sale price of our common stock on Nasdaq on the applicable purchase date for such Regular Purchase. In no case, however, will Lincoln Park's commitment with respect to any single Regular Purchase exceed $500,000; provided, that the parties may mutually agree at any time to increase the maximum number of shares of common stock the Company may direct Lincoln Park to purchase in any single Regular Purchase to up to 1,000,000 shares or any number of shares that shall not exceed 4.99% of the then outstanding shares of common stock. We will control the timing and amount of any sales of our common stock to Lincoln Park. The purchase price per share for each such Regular Purchase will be based on prevailing market prices of the Company's common stock immediately preceding the time of sale, as determined under the Purchase Agreement.

If the Company directs Lincoln Park to purchase the maximum number of shares of common stock that the Company may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the Purchase Agreement, the Company may direct Lincoln Park to purchase additional shares of common stock in an Accelerated Purchase and an Additional Accelerated Purchase (including multiple Additional Accelerated Purchases on the same trading day) as provided in the Purchase Agreement. The purchase price per share for each Accelerated Purchase and Additional Accelerated Purchase will be based on market prices of the common stock on the applicable purchase date for such Accelerated Purchases and such Additional Accelerated Purchases. Lincoln Park has no right to require the Company to sell any common stock to Lincoln Park, but Lincoln Park is obligated to make purchases as the Company directs, subject to conditions and limitations set forth in the Purchase Agreement.

In accordance with applicable Nasdaq rules, initially we were not allowed to issue or sell to Lincoln Park under the Purchase Agreement shares of our common stock in excess of 432,260 shares (including the Commitment Shares), which represents 19.99% of the shares of our common stock outstanding immediately prior to the execution of the Purchase Agreement. However, on September 13, 2023 shareholder approval of the transactions contemplated by the Purchase Agreement became effective and we no longer are limited by Nasdaq rules on the amount of the shares we may sell to Lincoln Park under the Purchase Agreement.

However, the Purchase Agreement does prohibit us from directing Lincoln Park to purchase any shares of our common stock if those shares of our common stock, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park having beneficial ownership of more than the Beneficial Ownership Cap of 4.99% of the outstanding shares of our common stock.

We will control the timing and amount of any sales of our common stock to Lincoln Park. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business day notice. There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement or Registration Rights Agreement, other than restrictions on entering into committed equity financing facility transactions or transactions that are similar thereto with third parties as set forth in the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

As consideration for Lincoln Park's commitment to purchase shares of common stock from us at our direction from time to time from and after the Commencement Date pursuant to the Purchase Agreement, promptly following our execution of the Purchase Agreement and the Registration Rights Agreement, we issued 98,909 Commitment Shares to Lincoln Park on July 24, 2023. All 98,909 Commitment Shares that we issued to Lincoln Park were included in the Original Registration Statement and have been resold by Lincoln Park pursuant to the Original Registration Statement.

As of May 10, 2024, there were 3,726,974 shares of our common stock outstanding, of which 3,609,813 shares of our common stock were held by non-affiliates, including the 98,909 Commitment Shares that we previously issued to Lincoln Park and the 89,847 shares of our common stock that we previously issued and sold to Lincoln Park pursuant to the Purchase Agreement (of which 14,654 are currently held by Lincoln Park). Although the Purchase Agreement provides that we may sell up to an additional aggregate gross proceeds of approximately$9.9 million of our common stock to Lincoln Park after the date of this prospectus, only 5,014,654 shares of our common stock are being registered for resale under this prospectus, which represents the 14,654 shares of our common stock that we previously issued and sold to Lincoln Park pursuant to the Purchase Agreement and an additional 5,000,000 shares of our common stock that we may issue and sell to Lincoln Park as Purchase Shares in the future under the Purchase Agreement, if and when we sell shares of our common stock to Lincoln Park under the Purchase Agreement. If all of the 5,000,000 Purchase Shares that may be sold to Lincoln Park in the future under the Purchase Agreement that are being registered for resale hereunder were issued and outstanding as of the date of this prospectus without taking into consideration the Beneficial Ownership Cap, such shares of our common stock, together with the 14,654 shares of our common stock that we previously issued and sold to Lincoln Park upon execution of the Purchase Agreement that are outstanding as of the date of this prospectus, would represent approximately 57.5% of the total number of shares of our common stock outstanding and approximately 58.2% of the total number of outstanding shares of our common stock held by non-affiliates, in each case as of the date of this prospectus.

Purchase of Shares Under the Purchase Agreement

Regular Purchases

Under the terms and subject to satisfaction of the conditions in the Purchase Agreement, beginning on the Commencement Date and from time to time for a period of up to 24 months thereafter, the Company may, at its discretion, direct Lincoln Park to purchase on any single business day on which the closing price of our common stock on Nasdaq is equal to or greater than $0.15 up to 100,000 shares of common stock in a Regular Purchase; provided, that the Company may direct Lincoln Park to purchase in a Regular Purchase (i) up to 125,000 shares of common stock, if the closing sale price of our common stock on Nasdaq on such business day is at least $1.50 per share and (ii) up to 150,000 shares of common stock, if the closing sale price of our common stock on Nasdaq on such business day is at least $2.50 per share (each share amount limitation applicable to a Regular Purchase, the "Regular Purchase Share Limit"). The foregoing share amounts and per share prices used to determine the applicable Regular Purchase Share Limit are subject to proportionate adjustment in the event of a reorganization, recapitalization, non-cash dividend, stock split or other similar transaction; provided, that if after giving effect to such full proportionate adjustment, the adjusted Regular Purchase Share Limit would preclude us from requiring Lincoln Park to purchase shares of our common stock at an aggregate purchase price equal to or greater than $100,000 in any single Regular Purchase, then the Regular

Purchase Share Limit will not be fully adjusted, but rather the Regular Purchase Share Limit for such Regular Purchase shall be adjusted as specified in the Purchase Agreement, such that, after giving effect to such adjustment, the Regular Purchase Share Limit will be equal to (or as close as can be derived from such adjustment without exceeding) $100,000.

In no case, however, will Lincoln Park's commitment with respect to any single Regular Purchase exceed $500,000; provided, that we and Lincoln Park may mutually agree at any time to increase the maximum number of shares of common stock the Company may direct Lincoln Park to purchase in any single Regular Purchase to up to 1,000,000 shares or any number of shares that shall not exceed 4.99% of the then outstanding shares of common stock.

The purchase price per share for each such Regular Purchase will be equal to the lower of:

- the lowest sale price for our common stock on the purchase date of such shares; and
- the arithmetic average of the three lowest closing sale prices for our common stock during the 10 consecutive business days ending on the business day immediately preceding the purchase date of such shares.

Accelerated Purchases

In addition to Regular Purchases described above, we may also direct Lincoln Park, on any business day on which we have properly submitted a Regular Purchase notice directing Lincoln Park to purchase the maximum number of shares of our common stock that we are then permitted to include in a single Regular Purchase notice, to purchase on the next following business day an additional amount of our common stock (each, an "Accelerated Purchase"), not to exceed the lesser of:

- 25% of the aggregate number of shares of our common stock traded during all or, if certain trading volume or market price thresholds specified in the Purchase Agreement are crossed on the applicable Accelerated Purchase date, which is defined as the next business day following the purchase date for the corresponding Regular Purchase, the portion of the normal trading hours on the applicable Accelerated Purchase date prior to such time that any one of such thresholds is crossed, which period of time on the applicable Accelerated Purchase date we refer to as the Accelerated Purchase Measurement Period; and
- 300% of the number of purchase shares purchased pursuant to the corresponding Regular Purchase.

Notwithstanding the foregoing, we and Lincoln Park may mutually agree at any time to increase the maximum number of shares of our common stock the Company may direct Lincoln Park to purchase in any single Accelerated Purchase to up to 1,000,000 shares or any number of shares that shall not exceed 4.99% of the then outstanding shares of common stock.

The purchase price per share for each such Accelerated Purchase will be equal to 95% of the lower of:

- the volume weighted average price of our common stock during the applicable Accelerated Purchase Measurement Period on the applicable Accelerated Purchase date; and
- the closing sale price of our common stock on the applicable Accelerated Purchase date.

Additional Accelerated Purchases

We may also direct Lincoln Park, not later than 1:00 p.m., Eastern time, on a business day on which an Accelerated Purchase has been completed and all of the shares to be purchased thereunder (and under the corresponding Regular Purchase) have been properly delivered to Lincoln Park in accordance with the Purchase Agreement prior to such time on such business day, to purchase an additional amount of our common stock on the same business day (each, an "Additional Accelerated Purchase), of up to the lesser of:

- 25% of the aggregate shares of our common stock traded during a certain portion of the normal trading hours on such Accelerated Purchase date as determined in accordance with the Purchase Agreement, which period of time we refer to as the Additional Accelerated Purchase Measurement Period; and
- three times the number of purchase shares purchased pursuant to the Regular Purchase corresponding to the Accelerated Purchase that was completed on such Accelerated Purchase date on which an Additional Accelerated Purchase notice was properly received.

Notwithstanding the foregoing, we and Lincoln Park may mutually agree at any time to increase the maximum number of shares of our common stock the Company may direct Lincoln Park to purchase in any single Additional Accelerated Purchase to up to 1,000,000 shares or any number of shares that shall not exceed 4.99% of the then outstanding shares of common stock.

We may, in our sole discretion, submit multiple Additional Accelerated Purchase notices to Lincoln Park prior to 1:00 p.m., Eastern time, on a single Accelerated Purchase date, provided that all prior Accelerated Purchases and Additional Accelerated Purchases (including those that have occurred earlier on the same day) have been completed and all of the shares to be purchased thereunder (and under the corresponding Regular Purchase) have been properly delivered to Lincoln Park in accordance with the Purchase Agreement.

The purchase price per share for each such Additional Accelerated Purchase will be equal to 95% of the lower of:

- the volume weighted average price of our common stock during the applicable Additional Accelerated Purchase Measurement Period for such Additional Accelerated Purchase on the applicable Additional Accelerated Purchase date; and
- the closing sale price of our common stock on the applicable Additional Accelerated Purchase date.

In the case of Accelerated Purchases and Additional Accelerated Purchases, the purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the business days used to compute the purchase price.

Other than as described above, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park.

Suspension Events

Suspension events under the Purchase Agreement include the following:

- the effectiveness of the registration statement of which this prospectus forms a part lapses for any reason (including, without limitation, the issuance of a stop order), or any required prospectus supplement and accompanying prospectus are unavailable for the resale by Lincoln Park of our common stock offered hereby, and such lapse or unavailability continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period;

- suspension by our principal market of our common stock from trading for a period of one business day;

- the delisting of the common stock from The Nasdaq Capital Market (or nationally recognized successor thereto), provided, however, that our common stock is not immediately thereafter trading on the New York Stock Exchange; The Nasdaq Global Market, The Nasdaq Global Select Market, the NYSE American, the NYSE Arca, or the OTCQX Best Market or the OTCQB Venture Market operated by OTC Markets Group Inc. (or nationally recognized successor to any of the foregoing);

- the failure of our transfer agent to issue to Lincoln Park shares of our common stock within two business days after the applicable date on which Lincoln Park is entitled to receive such shares;

- any breach of the representations or warranties or covenants contained in the Purchase Agreement or the Registration Rights Agreement that has or could have a material adverse effect on us and, in the case of a breach of a covenant that is reasonably curable, that is not cured within five business days;

- any person commences a proceeding against us pursuant to or within the meaning of Title 11, U.S. Code, or any similar federal or state law for the relief of debtors ("Bankruptcy Law");

- a court of competent jurisdiction enters an order or decree under any Bankruptcy Law that (i) is for relief against us in an involuntary case, (ii) appoints a custodian for us or for all or substantially all of our property or (iii) orders the liquidation of us or our subsidiaries; or

- if at any time we are not eligible to transfer our common stock electronically as Deposit Withdrawal At Custodian shares.

Lincoln Park does not have the right to terminate the Purchase Agreement upon any of the suspension events set forth above. During a suspension event, all of which are outside of Lincoln Park's control, we may not direct Lincoln Park to purchase any shares of our common stock under the Purchase Agreement.

Our Termination Rights

We have the unconditional right, at any time, for any reason and without any payment or liability to us, to give notice to Lincoln Park to terminate the Purchase Agreement. In the event of bankruptcy proceedings by or against us, the Purchase Agreement will automatically terminate without action of any party.

No Short-Selling or Hedging by Lincoln Park

Lincoln Park has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

Prohibitions on Similar Transactions

There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement or Registration Rights Agreement other than a prohibition on our entering into other committed equity financing facility transactions or transactions that are similar thereto, except for certain Exempt Issuances (as defined by the Purchase Agreement).

Effect of Performance of the Purchase Agreement on Our Stockholders

All 5,014,654 shares of our common stock being registered for resale by Lincoln Park under the registration statement that includes this prospectus which have been or may be issued or sold by us to Lincoln Park under the Purchase Agreement are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold after the date of this prospectus and over the remainder duration of a period of up to 24 months that began on the Commencement Date.

The sale by Lincoln Park of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Sales of our common stock to Lincoln Park, if any, will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. In addition, if we sell a substantial number of shares to Lincoln Park under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Lincoln Park may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales. However, we have the right to control the timing and amount of any additional sales of our shares to Lincoln Park and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

If and when we do elect to sell shares of our common stock to Lincoln Park pursuant to the Purchase Agreement, after Lincoln Park has acquired such shares, Lincoln Park may resell all, some or none of such shares at any time or from time to time in its discretion and at different prices. As a result, investors who purchase shares from Lincoln Park in this offering at different times will likely pay different prices for those shares, and so may experience different levels of dilution and in some cases substantial dilution and different outcomes in their investment results. Investors may experience a decline in the value of the shares they purchase from Lincoln Park in this offering as a result of future sales made by us to Lincoln Park at prices lower than the prices such investors paid for their shares in this offering.

Pursuant to the Purchase Agreement, we will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold to Lincoln Park. Sales of our common stock, if any, to Lincoln Park under the Purchase Agreement will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the shares of our common stock that may be available for us to sell to Lincoln Park pursuant to the Purchase Agreement. Because the purchase price per share to be paid by Lincoln Park for the shares of common stock

that we may elect to sell to Lincoln Park under the Purchase Agreement, if any, will fluctuate based on the market prices of our common stock at the time we elect to sell shares to Lincoln Park pursuant to the Purchase Agreement, if any, it is not possible for us to predict, as of the date of this prospectus and prior to any such sales, the number of shares of common stock that we will sell to Lincoln Park under the Purchase Agreement, the purchase price per share that Lincoln Park will pay for shares purchased from us under the Purchase Agreement, or the aggregate gross proceeds that we will receive from those purchases by Lincoln Park under the Purchase Agreement.

Moreover, although the Purchase Agreement provides that we may, in our discretion, from time to time after the date of this prospectus and during the term of the Purchase Agreement, direct Lincoln Park to purchase shares of our common stock from us in one or more purchases under the Purchase Agreement, for a maximum aggregate purchase price of up to $10.0 million, of which we have sold approximately $100,000 in shares of our common stock and may only receive an additional aggregate gross proceeds of approximately $9.9 million from any sale of our common stock to Lincoln Park as of the date of this prospectus, only 5,014,654 shares of common stock (14,654 which represent shares of our common stock that have been previously issued and sold by us to Lincoln Park pursuant to the Purchase Agreement) are being registered for resale under the registration statement of which this prospectus forms a part. Therefore, only 5,000,000 of such shares of common stock represent shares that we may issue and sell to Lincoln Park for cash consideration in purchases under the Purchase Agreement from time to time, at our sole discretion, after the date of this prospectus and for the remaining duration of the 24-month period that began on the Commencement Date. If after the date of this prospectus we elect to sell to the Selling Stockholder all of the 5,000,000 shares of common stock being registered for resale under this prospectus that are available for sale by us to the Selling Stockholder in purchases under the Purchase Agreement, depending on the market prices of our common stock at the time of such sales, the actual gross proceeds from the sale of all such shares may be substantially less than approximately $9.9 million purchase commitment remains available to us under the Purchase Agreement, which could materially adversely affect our liquidity. Furthermore, if we elect to issue and sell to Lincoln Park more than the 5,000,000 shares of our common stock that we may elect to issue and sell to Lincoln Park under the Purchase Agreement that are being registered for resale by Lincoln Park hereunder, which we have the right, but not the obligation, to do, we must first file with the SEC one or more additional registration statements to register under the Securities Act for resale by Lincoln Park such additional shares of our common stock we wish to sell from time to time under the Purchase Agreement, which the SEC must declare effective, in each case before we may elect to sell any additional shares of our common stock to Lincoln Park under the Purchase Agreement. Any issuance and sale by us under the Purchase Agreement of a substantial amount of shares of common stock in addition to the 5,000,000 shares of common stock that we may elect to issue and sell to Lincoln Park under the Purchase Agreement that are being registered for resale by Lincoln Park hereunder could cause additional substantial dilution to our stockholders.

The number of shares of common stock ultimately resold by Lincoln Park through this prospectus is dependent upon the total number of shares of common stock, if any, we elect to issue and sell to Lincoln Park under the Purchase Agreement from and after Commencement and during the term of the Purchase Agreement. Issuances of our common stock to Lincoln Park under the Purchase Agreement will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted as a result of any such issuance. Although the number of shares of our common stock that our existing stockholders own will not decrease, the shares of our common stock owned by our existing stockholders will represent a smaller percentage of our total outstanding shares of our common stock after any such issuance of shares of our common stock to Lincoln Park under the Purchase Agreement.

The following table sets forth the amount of gross proceeds we would receive from Lincoln Park from our sale of up to 5,000,000 Purchase Shares that we are registering hereby that we may issue and sell to Lincoln Park in the future under the Purchase Agreement at varying purchase prices from and after the date of this prospectus:

Assumed Average Purchase Price Per Share	Number of Registered Shares to be Issued if Full Purchase[1]	Percentage of Outstanding Shares After Giving Effect to the Issuance to Lincoln Park[2]	Proceeds from the Sale of Shares to Lincoln Park Under the Purchase Agreement[1]
$ 0.50	5,000,000	57.3	$ 2,500,000
$ 0.75	5,000,000	57.3	3,750,000
$ 0.8432(3)	5,000,000	57.3	$ 4,216,000
$ 1.00	5,000,000	57.3	$ 5,000,000
$ 1.25	5,000,000	57.3	$ 6,250,000
$ 1.50	5,000,000	57.3	$ 7,500,000

(1) Although we may sell up to approximately $9.9 million in aggregate gross proceeds of our common stock that remains available under the Purchase Agreement and for resale under the registration statement of which this prospectus forms a part, we are only registering 5,014,654 shares of common stock, including the 14,654 shares of our common stock that we previously issued and sold to Lincoln Park pursuant to the Purchase Agreement. Therefore, only 5,000,000 of such shares represent Purchase Shares that we may issue and sell to Lincoln Park for cash consideration in purchases under the Purchase Agreement from time to time, at our sole discretion, after the date of this prospectus and for the remaining duration of the 24-month period that began on the Commencement Date, which may or may not cover all the shares of our common stock we ultimately sell to Lincoln Park under the Purchase Agreement, if any, depending on the purchase price per share. We have included in this column only the 5,000,000 Purchase Shares that we may issue and sell to Lincoln Park for cash consideration in purchases under the Purchase Agreement that are being registered for resale in the offering made by this prospectus, without giving effect to the Beneficial Ownership Cap. Accordingly, depending on the assumed average price per share, we may or may not be able to ultimately sell to Lincoln Park a number of shares of our common stock with a total value of approximately $9.9 million remains available under the Purchase Agreement.

(2) The denominator is based on 3,726,974 shares of our common stock outstanding as of May 10, 2024 (which includes the 98,909 shares of our common stock that we previously issued to Lincoln Park and the 89,847 shares of our common stock that we previously issued and sold to Lincoln Park pursuant to the Purchase Agreement (of which 14,654 are currently held by Lincoln Park), adjusted to include the number of shares of our common stock set forth in the adjacent column. The numerator is based on the number of shares of our common stock set forth in the adjacent column.

(3) The closing sale price of our shares on May 9, 2024.

SELLING STOCKHOLDER

This prospectus relates to the possible resale by the Selling Stockholder, Lincoln Park, of up to 5,014,654 shares of our common stock, consisting of: (i) 14,654 shares of our common stock that we previously issued and sold to Lincoln Park pursuant to the Purchase Agreement and (ii) up to 5,000,000 shares of common stock that we have reserved for issuance and sale to Lincoln Park as Purchase Shares under the Purchase Agreement from time to time from and after the date of this prospectus, if and when we determine to sell shares of our common stock to Lincoln Park under the Purchase

Agreement.

We are filing the registration statement of which this prospectus forms a part pursuant to the provisions of the Registration Rights Agreement, which we entered into with Lincoln Park on July 24, 2023 concurrently with our execution of the Purchase Agreement, in which we agreed to provide certain registration rights with respect to resales by Lincoln Park of the shares of our common stock that have been or may be issued to Lincoln Park under the Purchase Agreement. The Selling Stockholder may sell some, all or none of the shares of common stock included in this prospectus. We do not know how long the Selling Stockholder will hold the shares of our common stock before selling them, and we currently have no agreements, arrangements or understandings with the Selling Stockholder regarding the sale of any of the shares of common stock. See "*Plan of Distribution*."

The table below sets forth, to our knowledge, information concerning the beneficial ownership of shares of our common stock by the Selling Stockholder as of May 10, 2024. The percentages of shares owned before and after the offering are based on 3,726,974 shares of common stock outstanding as of May 10, 2024 (which includes the 98,909 Commitment Shares that we previously issued to Lincoln Park and the 89,847 shares of our common stock that we previously issued and sold to Lincoln Park pursuant to the Purchase Agreement (of which 14,654 are currently held by Lincoln Park). The information in the table below with respect to the Selling Stockholder has been obtained from the Selling Stockholder.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to shares. The inclusion of any shares in this table does not constitute an admission of beneficial ownership for the person named below.

Name of Selling Stockholder	Number of Shares of Common Stock Owned Prior to Offering		Maximum Number of Shares of Common Stock to be Offered Pursuant to this Prospectus[1]	Number of Shares of Common Stock Owned After Offering[2]	
	Number	Percent		Number	Percent
Lincoln Park Capital Fund, LLC(3)	14,654(4)	*%	5,014,654	0	—

* Less than 1%.

(1) Although we may sell up to approximately $9.9 million in aggregate gross proceeds of our common stock to Lincoln Park that remains available under the Purchase Agreement, we are only registering 5,014,654 shares of our common stock for resale under this prospectus, including the 14,654 shares of our common stock that we previously issued and sold to Lincoln Park pursuant to the Purchase Agreement. Therefore, only 5,000,000 of such shares represent shares that we may issue and sell to Lincoln Park for cash consideration in purchases under the Purchase Agreement from time to time, at our sole discretion, after the date of this prospectus and for the remaining duration of the 24-month period that began on the Commencement Date. Depending on the price per share at which we sell our common stock to Lincoln Park pursuant to the Purchase Agreement, we may need to sell to Lincoln Park under the Purchase Agreement more shares of our common stock than are offered under this prospectus in order to receive aggregate gross proceeds equal to the full $10.0 million available to us under the Purchase Agreement. If we choose to do so, we must first register for resale under the Securities Act such additional shares. The number of shares ultimately offered for resale by Lincoln Park is dependent upon the number of shares we sell to Lincoln Park under the Purchase Agreement.

(2) Assumes the sale of all shares of common stock registered pursuant to the registration statement that includes this prospectus, although the Selling Stockholder is under no obligation known to us to sell any shares of common stock at this time.

(3) Joshua Scheinfeld and Jonathan Cope, the Managing Members of Lincoln Park Capital, LLC, the manager of the Selling Stockholder, are deemed to be beneficial owners of all of the shares of our common stock owned by the Selling Stockholder. Messrs. Cope and Scheinfeld have shared voting and investment power over the shares of our common stock being offered under this prospectus. Neither Lincoln Park Capital, LLC, nor the Selling Stockholder, is a licensed broker-dealer or an affiliate of a licensed broker-dealer.

(4) Represents the 14,654 shares of our common stock previously issued and sold to Lincoln Park pursuant to the Purchase Agreement, all of which shares are being registered under the Securities Act under the registration statement that includes this prospectus. In accordance with Rule 13d-3(d) under the Exchange Act, we have excluded from the number of shares of our common stock beneficially owned prior to the offering all of the shares of our common stock that we may issue and sell to Lincoln Park pursuant to the Purchase Agreement from and after the date of this prospectus, because the issuance and sale of such shares of our common stock to Lincoln Park under the Purchase Agreement is solely at our discretion and is subject to certain conditions, the satisfaction of all of which are outside of Lincoln Park's control, including the registration statement of which this prospectus is a part becoming and remaining effective under the Securities Act. Furthermore, under the terms of the Purchase Agreement, issuances and sales of shares of our common stock to Lincoln Park under the Purchase Agreement are subject to certain limitations on the amounts we may sell to Lincoln Park at any time, including the Beneficial Ownership Cap. See "*The Lincoln Park Transaction*" for more information about the Purchase Agreement.

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 Registration Statement on Form S-1. 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 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 computerized tomography (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. As of December 31, 2023, we had an accumulated deficit of approximately $55.1 million. To date, we have financed our operations primarily through an initial public offering, 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 Splits

On April 6, 2022, the Company effected a 1-for-2 reverse stock split (the "2022 Reverse Stock Split") by filing an amendment to the Company's Amended and Restated Certificate of Incorporation, as amended, with the Delaware Secretary of State. The 2022 Reverse Stock Split combined every two shares of our common stock issued and outstanding immediately prior to effecting the 2022 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 2022 Reverse Stock Split.

On November 2, 2023, the Company effected a 1-for-10 reverse stock split by filing an amendment to the Company's Amended and Restated Certificate of Incorporation, as amended, with the Delaware Secretary of State. The 2023 Reverse Stock Split combined every ten shares of our common stock issued and outstanding immediately prior to effecting the 2023 Reverse Stock Split into one share of common stock. No fractional shares were issued in connection with the 2023 Reverse Stock Split. All historical share and per share amounts reflected throughout this document have been adjusted to reflect the 2022 Reverse Stock Split and the 2023 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 2022 Reverse Stock Split or the 2023 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 prospectus, 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 or liabilities 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, 2023 or 2022. 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 Catamaran Tray 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 and salaries, increased 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 information technology 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 Stock Market LLC on which our securities are 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:	**2023**	**2022**
Revenue	$ 2,928	$ 691
Cost of goods sold	1,687	1,332
Gross profit (loss)	1,241	(641)
Operating expenses:		
Research and development	3,163	2,828
Sales and marketing	6,778	7,833
General and administrative	7,027	7,423
Total operating expenses	16,968	18,084
Loss from operations	(15,727)	(18,725)
Interest and other income (expense), net:		
Gain on investments	167	180
Interest expense	(21)	(354)
Other expense	—	(18)
Net loss	$ (15,581)	$ (18,917)

	Years Ended December 31,	
Consolidated Statements of Operations Data as a Percent of Revenue:	**2023**	**2022**
Revenue	100%	100%
Cost of goods sold	58	193
Gross profit (loss)	42	(93)
Operating expenses:		
Research and development	108	409
Sales and marketing	231	1,134
General and administrative	240	1,074
Total operating expenses	580	2,617
Loss from operations	(537)	(2,710)
Interest and other income (expense), net:		
Gain on investments	6	26
Interest expense	(1)	(51)
Other expense	—	(3)
Net loss	(532)%	(2,738)%

Comparison of the years ended December 31, 2023 and 2022 (in thousands, except percentages)

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

	Years Ended December 31,			
	2023	**2022**	**$ Change**	**% Change**
Revenue	$ 2,928	$ 691	$ 2,237	324%
Cost of goods sold	1,687	1,332	355	27%
Gross profit (loss)	$ 1,241	$ (641)	$ 1,882	(294)%
Gross profit (loss) percentage	42%	(93)%		

Revenue. The increase in revenue for the year ended December 31, 2023 as compared to 2022 was primarily due to an increase of 312% in the number of surgical procedures in which The CATAMARAN System was used.

Cost of Goods Sold, Gross Profit, and Gross Margin. The increase in cost of goods sold for the year ended December 31, 2023 as compared to 2022 was due to an increase of 312% in the number of surgical procedures performed. Gross profit (loss) and gross margin percentage improved due to higher revenue associated with the increase in the number of surgical procedures, operating leverage created due to lower relative fixed costs and the absorption of more overhead into our standard cost.

Operating Expenses

	Years Ended December 31,			
	2023	**2022**	**$ Change**	**% Change**
Research and development	$ 3,163	$ 2,828	$ 335	12%
Sales and marketing	6,778	7,833	(1,055)	(13)%
General and administrative	7,027	7,423	(396)	(5)%

Total operating expenses	$ 16,968	$ 18,084	$ (1,116)	

Research and Development Expenses. Research and development expenses for the year ended December 31, 2023 increased as compared to 2022 primarily due to increased stock-based compensation ($509) and payroll expenses ($49), partially offset by decreased professional fees ($137).

Sales and Marketing Expenses. Sales and marketing expenses for the year ended December 31, 2023 decreased as compared to 2022 primarily due to payments in 2022 in association with the termination of the SpineSource sales agreement ($3,611) and decreased consulting and professional fees ($1,190), partially offset by increased payroll expenses ($2,388), sales commissions ($1,388) and stock-based compensation ($100). The increase in payroll and payroll related expenses is primarily due to the increased number of sales and marketing employees as we build out our sales function.

General and Administrative Expenses. General and administrative expenses for the year ended December 31, 2023 decreased as compared to 2022 primarily due to a legal settlement accrual in 2022 ($574) and decreased professional service fees ($852), partially offset by increased stock-based compensation ($639) and payroll expenses ($271).

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

	Years Ended December 31,			
	2023	2022	$ Change	% Change
Gain on investments	$ 167	$ 180	$ (13)	7%
Interest expense	(21)	(354)	333	(94)%
Other expense, net	—	(18)	18	100%
Total operating expenses	$ 146	$ (192)	$ 338	

Gain on Investments. Gain on investments for the year ended December 31, 2023 decreased as compared to 2022 due to interest on our lower amounts of investments in money market and corporate debt securities.

Interest Expense. Interest expense for the year ended December 31, 2023 decreased as compared to 2022 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, 2023 and 2022.

Liquidity and Capital Resources

As of December 31, 2023, we had cash and cash equivalents of $2.4 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, 2023, we had outstanding debt of $1.2 million.

As of December 31, 2023, we had an accumulated deficit of $55.1 million. During the years ended December 31, 2023 and 2022, we incurred net losses of $15.6 million and $18.9 million, respectively, and expect to incur additional losses in the future. We have not achieved positive cash flow from operations to date. Based upon our current operating plan, our existing cash and cash equivalents will not be sufficient to fund our operating expenses and working capital 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. 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.

On February 20, 2024, we entered into a Securities Purchase Agreement with certain investors, pursuant to which we agreed to sell, issue and deliver to these investors, in a private placement offering, a total of 172,239 shares of our Series A Preferred Stock and warrants to purchase 258,374 shares of our common stock, par value $0.001 per share, at an exercise price equal to $1.2705 per share for an aggregate offering price of $2,605,000.

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. 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. Due to the uncertainty in our ability to raise capital, management believes that there is substantial doubt in our ability to continue as a going concern for the next twelve months from the issuance of these consolidated financial statements.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2023:

	Payments Due By Period (In thousands)				
	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
Operating leases	$ 756	$ 302	$ 454	$ —	$ —

Convertible debt (1)	1,260	1,260	—	—	—
Total	$ 2,016	$ 1,562	$ 454	$ —	$ —

(1) Amount represents the principal and accrued interest on the convertible debt as of December 31, 2023. Per the terms of the convertible debt, the entire amount was converted to preferred stock in February 2024.

Obligations under Terminated Sales Representative Agreement : On October 6, 2022, we entered into the Terminating Amended and Restated Exclusive Sales Representative Agreement (the "Termination Agreement"). In accordance with the Termination Agreement, (i) we paid the Representative $1,000 in cash; and (ii) we 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 us, (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, we will pay the Representative $3,600 less previous amounts paid pursuant to clause (b) and clause (c) above. The timing of the payments under clause (b) and (c) is variable depending on the timing of our sales.

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,			
	2023	2022	$ Change	% Change
Net cash (used in) provided by:				
Operating activities	$ (12,183)	$ (12,025)	$ (158)	1%
Investing activities	6,142	(2,884)	9,026	(313)%
Financing activities	6,302	14,114	(7,812)	(55)%
Effect of foreign currency translation on cash flow	38	7	31	(443)%
Net increase (decrease) in cash and cash equivalents	$ 299	$ (788)	$ 1,087	(138)%

The increase in net cash used in operating activities for the year ended December 31, 2023 as compared to 2022 was primarily attributable to decreases in our accrued expenses ($2,387) and accounts payable ($189) and increases in prepaid expenses ($244) and accounts receivable ($138), partially offset by our decreased net loss ($3,336), adjusted for increases in non-cash stock-based compensation expenses ($1,248) and a decrease in common stock issued for services ($1,561).

Cash provided by investing activities for the year ended December 31, 2023 consisted primarily of the net sales of short-term investments of approximately $6.5 million as used those amounts to fund operations, partially offset by purchases of property and equipment of $0.4 million as we acquired the components for our surgical tray sets. 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 provided by financing activities for the year ended December 31, 2023 consisted of the $5.3 million, net of relevant expenses, received from our offerings of stock in 2023 in addition to $1.2 million from the issuance of the Convertible Notes. 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.

Off-Balance Sheet Arrangements

As of December 31, 2023 and 2022, 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.

BUSINESS

Introduction

Tenon Medical, Inc. 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 The Catamaran™ SI Joint Fusion System that offers a novel, less invasive approach to the sacroiliac joint (the "SI Joint") using a single, robust, titanium implant for treatment of the most common types of SI Joint disorders that cause lower back pain. The Company received U.S. Food and Drug Administration ("FDA") clearance in 2018 for The CATAMARAN System and is currently focused on the US market. Since the national launch of The CATAMARAN System in October 2022, the Company is focused on three commercial opportunities: 1) Primary SI Joint procedures, 2) Revision procedures of failed SI Joint implants and 3) SI Joint fusion adjunct to a spine fusion construct.

The Opportunity

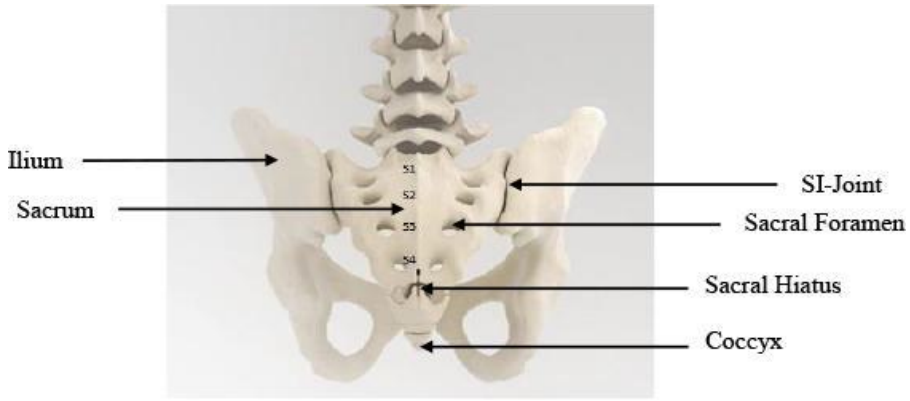
We estimate that over 30 million American adults have chronic lower back pain. Published clinical studies have shown that 15% to 30% of all chronic lower back pain is associated with the SI-Joint. For patients whose chronic lower back pain stems from the Sacroiliac Joint ("SI-Joint"), our experience 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 conservative options, including systemic oral medications, opioids, physical therapy and injection therapy.

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 spine 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 spine 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 2-4mm 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, we believe 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

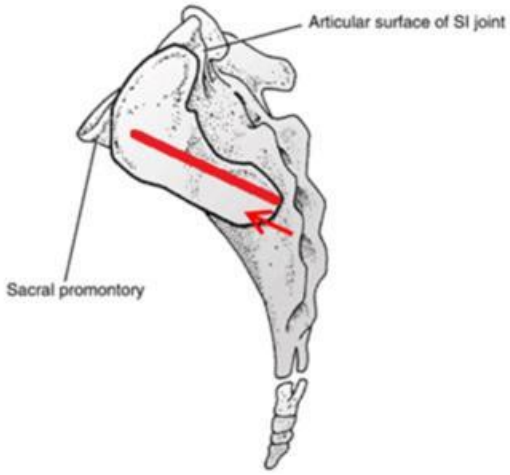
We believe we are the first company to develop and manufacture a novel Inferior Posterior approach featuring a dual pontoon fixation technology cleared by the FDA expressly for SI-Joint fusion. The approach, referred to as Inferior Posterior Sacroiliac Fusion is focused on these critical aspects of the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

We believe 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, we sold The CATAMARAN™ SI-Joint Fusion System to a limited number of clinician advisors to refine the product for a full commercial launch. In October 2022, we 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

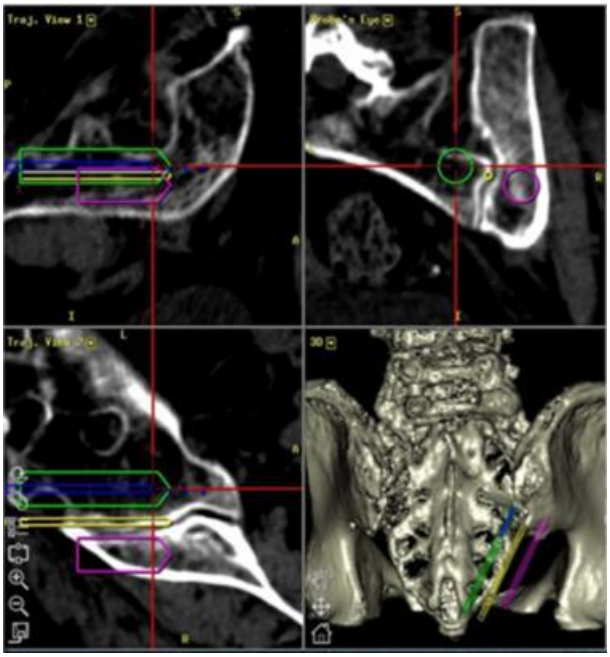
"Pontoon" in the ilium
"Pontoon" in the sacrum
"Pontoons and Bridge" filled with autologous bone from drilling process
Leading edge osteotome creates defect and facilitates ease of insertion

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.

We also have 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)

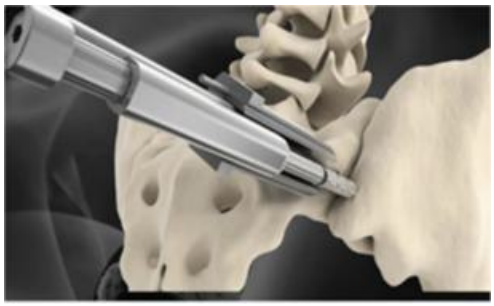
Notes:

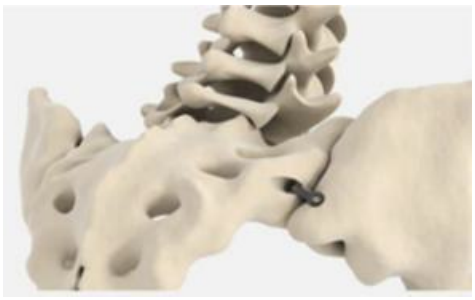
Upper Right Quadrant: The green and purple pontoons represent the placement in the dense bone inferior – contrasted with the dorsal gap superiorly where competitive systems are most often placed.

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.

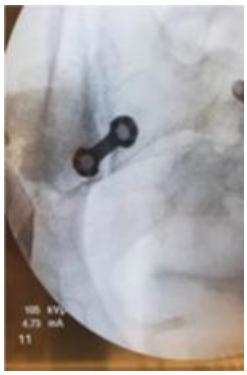




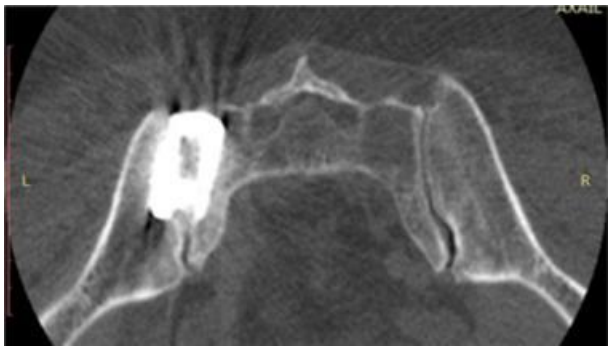
The CATAMARAN System procedure is typically performed under general anesthesia using a specially designed instrument set we provide to prepare for the Inferior Posterior access to the SI-Joint. Specially designed imaging and navigation protocols are designed to ensure the clinician has the proper Entry 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.

We believe 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. We have 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 2023 national average hospital inpatient payment for SI-Joint procedures ranges from approximately $25,661 to approximately $46,437

depending on the procedural approach and the presence of Complication and Comorbidity/Major Complication and Comorbidity.

The Medicare 2023 national average hospital outpatient clinic payment is $17,756. 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 us 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

We have 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.

Research & Development

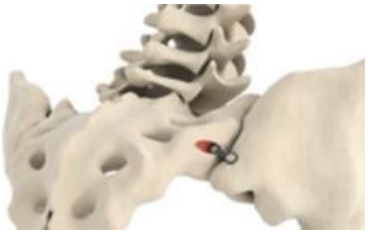
Our initial development of The CATAMARAN System has incorporated several differentiating features which we believe will make an important contribution for many patients suffering from SI-Joint pain. To our knowledge no other competitive product incorporates these Next Generation features:

- Dual Pontoon implant that transfixes the targeted joint;

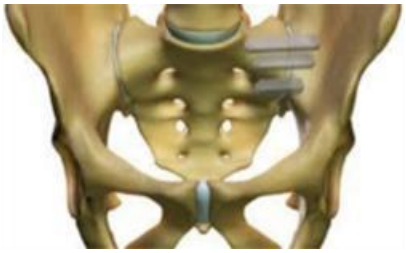
- Open cell design designed for utilizing the patient's own autologous bone for promotion of fusion;
- Bridge design between the dual pontoons for enhanced strength;
- Leading edge of the implant designed to function as an osteotome providing a self-creating defect feature not available with competitive 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. We believe, 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%. We believe that our 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.

Additionally, we 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 multi-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; pain scoring, 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 May 10, 2024, we own four (4) issued U.S. utility patents, eighteen (18) 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 May 10, 2024, 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.

Legal Proceedings

We may also from time to time be, party to litigation and subject to claims incident to the ordinary course of business. As our growth continues, we may become party to an increasing number of litigation matters and claims. 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.

Employees

As of May 10, 2024, we had a total of 23 employees, all of whom are full-time, and three senior consulting advisors of various specialty including product development, clinical affairs and reimbursement. None of our employees is subject to a collective bargaining agreement, and we consider our relationship with our employees to be good.

Property

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

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 prospectus. We have included our website address as an inactive textual reference only.

MANAGEMENT

The following are our executive officers and directors and their respective ages and positions as of May 10, 2024.

Name	Age	Position
Steven M. Foster	56	Chief Executive Officer and President, Director
Richard Ginn	58	Chief Technology Officer and Director

Steve Van Dick	69	EVP, Finance and Administration and Chief Financial Officer
Richard Ferrari	70	Executive Chairman of the Board
Ivan Howard	57	Director
Kristine M. Jacques	57	Director
Robert K. Weigle	64	Director
Stephen H. Hochschuler, M.D.	81	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.

Kristine M. Jacques was appointed as a director of the Company on March 25, 2024. From 2017 until 2023, Ms. Jacques was Vice President and General Manager, Interventional Pain Therapies at Vivex Biologics, Inc., a medical device company where she implemented a comprehensive strategic plan of a disruptive technology in the interventional spine market serving a significant unmet clinical need and potential $38 billion plus total addressable market, non-surgical treatment for chronic low back pain. From 2007 to 2017 Ms. Jacques was a Vice President at Alphatec Spine, Inc (Nasdaq:ATEC), a medical device company where she led the development and execution of a 3-year portfolio strategy to grow market share through identifying opportunities for innovation, maximizing product positioning and differentiation and delivering high quality products to meet the clinical and unmet needs of surgeons and their patients. From 1995 until 2007, Ms. Jacques served in various management positions at General Electric Corporation, prior to which she served from 1991 until 1994 at various management positions at Smith & Nephew, PLC, both of which are publicly traded. Previously, she was an Account Manager, Senior Investment Analyst for General Electric Capital Corporation from 1988 until 1991. Ms. Jacques received a Bachelor of Arts degree in Finance Administration from Michigan State University.

We believe that Ms. Jacques is well qualified to serve as a Director on our Board with her experience as a senior executive in the spine and medical device industries.

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. Our Board currently consists of seven members, four 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 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 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, Robert K. Weigle, Stephen H. Hochschuler, M.D. and Kristine Jacques are independent directors of the Company.

Board Committees

The Board has established three standing committees: (i) audit committee (the "Audit Committee"); (ii) compensation committee (the "Compensation Committee"); and (iii) nominating and corporate governance committee (the "Nominating and Corporate Governance Committee"). 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.

Audit Committee. The Audit Committee consists of three directors, Ivan Howard, Robert Weigle and Kristine Jacques, all of which 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.

The Audit Committee is 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 consists of three directors, Ivan Howard, Robert Weigle and Kristine Jacques, who are “independent” as defined by Nasdaq. 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 regarding, the compensation of our executive officers;
- administers our equity compensation plans;
- reviews and approves, or makes recommendations to our Board, 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 two directors, Robert Weigle and Stephen Hochschuler, both of which are “independent” as defined by Nasdaq. 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 consistent with criteria approved by our Board;
- evaluating director performance on our Board and applicable committees of our Board and determining whether continued service on our Board is appropriate;
- evaluating nominations by stockholders of candidates for election to our Board; and
- corporate governance matters.

Role of Board in Risk Oversight Process

Our Board 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 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.

EXECUTIVE COMPENSATION

The following summary compensation table provides information regarding the compensation paid during our fiscal years ended December 31, 2023 and December 31, 2022 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				
2023	$ 400,000	$ 87,600	$ —	$ 487,600
2022	$ 300,000	$ 70,000	$ 1,926,634	$ 2,296,634
Steven Van Dick, Chief Financial Officer				
2023	$ 325,000	$ 60,225	$ —	$ 385,225
2022	$ 275,000	$ 148,125	$ 808,998	$ 1,232,123
Richard Ginn, Chief Technology Officer				
2023	$ 290,000	$ 60,225	$ —	$ 350,225
2022	$ 275,000	$ 148,125	$ 3,995,603	$ 4,418,728

(1) In 2022 the named executives received restricted stock units ("RSUs").

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 a 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 the registration statement of which this prospectus is a part.

Foster Employment Agreement. Steven M. Foster, our Chief Executive Officer and President and a member of our Board, 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 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 the registration statement of which this prospectus forms a part.

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, 2023.

	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
Steven M. Foster[(1)]	9,687	1,563	$ 52.00	May 1, 2031	10,874	$ 17,181
Steven Van Dick[(2)]	4,865	785	$ 52.00	May 1, 2031	4,566	$ 7,214
	2,786	673	$ 70.60	July 19, 2031		
Richard Ginn[(3)]	4,865	785	$ 52.00	May 1, 2031	22,551	$ 35,631
	443	107	$ 70.60	July 19, 2031		

(1) 11,250 option shares were exchanged for 5,625 restricted stock units on May 6, 2024.

(2) 9,109 option shares were exchanged for 4,555 restricted stock units on May 6, 2024.

(3) 6,200 option shares were exchanged for 3,100 restricted stock units on May 6, 2024.

Stock Options

We granted Steven M. Foster (i) an option to purchase 11,250 shares of common stock at an exercise price of $52.00 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 (9,687 shares of which are vested), and (ii) a restricted stock unit consisting of 21,746 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.

We granted Steven Van Dick (i) an option to purchase 5,650 shares of common stock at an exercise of $52.00 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 (4,865 shares of which are vested), (ii) an option to purchase 3,459 shares of common stock at an exercise price of $70.60 per share with a grant date of July 19, 2021, subject to monthly equal vesting over a three-year period commencing July 19, 2021 (2,786 shares of which are vested), and (iii) a restricted stock unit consisting of 9,131 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.

We granted Richard Ginn (i) an option to purchase 5,650 shares of common stock at an exercise price of $52.00 per share with a grant date of May 1, 2021, subject to monthly equal vesting over a three-year period commencing April 1, 2021 (4,865 shares of which are vested), (ii) an option to purchase

550 shares of common stock at an exercise price of $70.60 per share with a grant date of July 19, 2021, subject to monthly equal vesting over a three-year period commencing July 19, 2021 (443 shares of which are vested) and (iii) a restricted stock unit consisting of 45,098 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, 2023 to our board members. Only our independent directors received compensation for being directors during fiscal year 2023.

Director	Cash Compensation[1]	Equity Compensation[2]	Total Compensation
Frank Fischer	$ 60,000	$ —	$ 60,000
Ivan Howard	$ 60,000	$ —	$ 60,000
Kristine M. Jacques[3]	$ —	$ —	$ —
Robert Weigle	$ 67,500	$ —	$ 67,500
Stephen Hochschuler	$ 45,000	$ —	$ 45,000
Total	232,500	$ —	$ 232,500

1 Frank Fischer received $40,000 as a board retainer and $20,000 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 No equity compensation was issued to board members in 2023.

3 Appointed as a director on March 25, 2024.

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 paid to Mr. Ferrari during the fiscal year ended December 31, 2023, totaled $247,500. On May 8, 2024, the Compensation Committee approved a two year extension to the Ferrari Consulting Agreement on the same terms.

2012 Equity Incentive Plan

On October 1, 2012, the Board adopted the 2012 Plan. The 2012 Plan terminated in April 2022. There are 727,394 options issued under the 2012 Plan that have not been exercised upon the 2012 Plan’s termination, these options will remain outstanding pursuant to the terms thereof.

2022 Equity Incentive Plan

Overview

On January 10, 2022, our Board approved the 2022 Plan and on February 2, 2020, our stockholders approved the 2022 Plan. 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 is equal to (i) 160,000 plus (ii) the lesser of (a) 75,000 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) 110,000 shares of our common stock, (ii) a number of shares of our common stock equal to 4% of the prior year’s maximum number and (iii) such number of shares of our common stock as determined by the 2022 Plan administrator.

The purpose of 2022 Plan is to attract and retain the best available personnel for positions of substantial responsibility, to provide additional incentive to employees, directors and consultants, and to promote the success of our business. The administrator of the 2022 Plan may, in its sole discretion, amend, alter, suspend or terminate the 2022 Plan, or any part thereof, at any time and for any reason. We will obtain stockholder approval of any Plan amendment to the extent necessary and desirable to comply with legal and regulatory requirements relating to the administration of equity-based awards. Unless earlier terminated by the administrator, the 2022 Plan will terminate ten years from the date it is adopted by our Board.

Authorized Shares

Initially, the maximum number of shares of our common stock that may be subject to awards under the 2022 Plan is equal to (i) 160,000 plus (ii) the lesser of (a) 75,000 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) 110,000 shares of our common stock, (ii) a number of shares of our common stock equal to 4% of the prior year’s maximum number and (iii) such number of shares of our common stock as determined by the 2022 Plan

administrator.

Additionally, if any award issued pursuant to the 2022 Plan expires or becomes unexercisable without having been exercised in full, is surrendered pursuant to an exchange program, as provided in the 2022 Plan, or, with respect to restricted stock, restricted stock units, performance units or performance shares, is forfeited to or repurchased by us due to the failure to vest, the unpurchased shares (or for awards other than stock options or stock appreciation rights the forfeited or repurchased shares) which were subject thereto will become available for future grant or sale under the 2022 Plan (unless the 2022 Plan has terminated). With respect to stock appreciation rights, only shares actually issued pursuant to a stock appreciation right will cease to be available under the 2022 Plan; all remaining shares under stock appreciation rights will remain available for future grant or sale under the 2022 Plan (unless the 2022 Plan has terminated). Shares that have actually been issued under the 2022 Plan under any award will not be returned to the 2022 Plan and will not become available for future distribution under the 2022 Plan; provided, however, that if shares issued pursuant to awards of restricted stock, restricted stock units, performance shares or performance units are repurchased by us or are forfeited to us due to the failure to vest, such shares will become available for future grant under the 2022 Plan. Shares used to pay the exercise price of an award or to satisfy the tax withholdings related to an award will become available for future grant or sale under the 2022 Plan. To the extent an award under the 2022 Plan is paid out in cash rather than shares, such cash payment will not result in reducing the number of shares available for issuance under the 2022 Plan. Notwithstanding the foregoing and, subject to adjustment as provided in the 2022 Plan, the maximum number of shares that may be issued upon the exercise of incentive stock options will equal the aggregate share number stated above, plus, to the extent allowable under Section 422 of the Code and regulations promulgated thereunder, any shares that become available for issuance under the 2022 Plan in accordance with the foregoing.

Plan Administration

One or more committees appointed by our Board will administer the 2022 Plan. Initially, the Compensation Committee shall administer the 2022 Plan. In addition, if we determine it is desirable to qualify transactions under the 2022 Plan as exempt under Rule 16b-3 of the Exchange Act, such transactions will be structured with the intent that they satisfy the requirements for exemption under Rule 16b-3. Subject to the provisions of the 2022 Plan, the administrator has the power to administer the 2022 Plan and make all determinations deemed necessary or advisable for administering the 2022 Plan, including the power to determine the fair market value of our common stock, select the service providers to whom awards may be granted, determine the number of shares covered by each award, approve forms of award agreements for use under the 2022 Plan, determine the terms and conditions of awards (including the exercise price, the time or times at which the awards may be exercised, any vesting acceleration or waiver or forfeiture restrictions and any restriction or limitation regarding any award or the shares relating thereto), construe and interpret the terms of the 2022 Plan and awards granted under it, prescribe, amend and rescind rules relating to the 2022 Plan, rules and regulations relating to sub-plans established for the purpose of facilitating compliance with applicable non-U.S. laws, easing the administration of the 2022 Plan and/or for qualifying for favorable tax treatment under applicable non-U.S. laws, in each case as the administrator may deem necessary or advisable and modify or amend each award (subject to the provisions of the 2022 Plan), including the discretionary authority to extend the post-termination exercisability period of awards and to extend the maximum term of an option or stock appreciation right (subject to the provisions of the 2022 Plan), to allow Participants to satisfy withholding tax obligations in a manner permissible under the 2022 Plan, to authorize any person to execute on behalf of us any instrument required to effect the grant of an award previously granted by the administrator and to allow a participant to defer the receipt of payment of cash or the delivery of shares that would otherwise be due to such participant under an award. The administrator also has the authority to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered or cancelled in exchange for awards of the same type which may have a higher or lower exercise price or different terms, awards of a different type or cash, or by which the exercise price of an outstanding award is increased or reduced. The administrator's decisions, interpretations and other actions are final and binding on all participants.

Eligibility

Awards under the 2022 Plan, other than incentive stock options, may be granted to our employees (including officers and directors) or a parent or subsidiary, members of our Board or consultants engaged to render bona fide services to us or a parent or subsidiary. Incentive stock options may be granted only to our employees or a subsidiary, provided the services (a) are not in connection with the offer or sale of securities in a capital-raising transaction, and (b) do not directly promote or maintain a market for our securities, in each case, within the meaning of Form S-8 promulgated under the Securities Act, and provided further, that a consultant will include only those persons to whom the issuance of Shares may be registered under Form S-8 promulgated under the Securities Act.

Stock Options

Stock options may be granted under the 2022 Plan. The exercise price of options granted under the 2022 Plan generally must at least be equal to the fair market value of our common stock on the date of grant. The term of each option will be as stated in the applicable award agreement; provided, however, that the term may be no more than 10 years from the date of grant. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, they may exercise their option for the period of time stated in their option agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the option will remain exercisable for six months. In all other cases, in the absence of a specified time in an award agreement, the option will remain exercisable for three months following the termination of service. An option may not be exercised later than the expiration of its term. Subject to the provisions of the 2022 Plan, the administrator determines the other terms of options.

Stock Appreciation Rights

Stock appreciation rights may be granted under the 2022 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding 10 years. After the termination of service of an employee, director or consultant, they may exercise their stock appreciation right for the period of time stated in their stock appreciation right agreement. In the absence of a specified time in an award agreement, if termination is due to death or disability, the stock appreciation rights will remain exercisable for six months. In all other cases, in the absence of a specified time in an award agreement, the stock appreciation rights will remain exercisable for three months following the termination of service. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of the 2022 Plan, the administrator determines the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock

Restricted stock may be granted under the 2022 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of the 2022 Plan, will determine the terms and conditions of such awards. The administrator may impose whatever conditions to vesting it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally will have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provides otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units

RSUs may be granted under the 2022 Plan. RSUs are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of the 2022 Plan, the administrator determines the terms and conditions of RSUs, including the vesting criteria and the form and timing of payment. The administrator may set vesting criteria based upon the achievement of Company-wide, divisional, business unit or individual goals (including continued employment or service), applicable federal or state securities laws or any other basis determined by the administrator in its discretion. The administrator, in its sole discretion, may pay earned RSUs in the form of cash, in shares of our common stock or in some combination thereof. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any vesting requirements will be deemed satisfied.

Performance Awards

Performance awards may be granted under the 2022 Plan. Performance awards are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will set objectives or vesting provisions, that, depending on the extent to which they are met, will determine the value the payout for the performance awards. The administrator may set vesting criteria based on the achievement of company-wide, divisional, business unit, or individual goals (including, but not limited to, continued employment or service), or any other basis determined by the administrator in its discretion. Each performance award's threshold, target, and maximum payout values are established by the administrator on or before the grant date. After the grant of a performance award, the administrator, in its sole discretion, may reduce or waive any performance objectives or other vesting provisions for such performance award. The administrator, in its sole discretion, may pay earned performance awards in the form of cash, in shares, or in some combination thereof.

Non-Employee Directors

The 2022 Plan provides that all non-employee directors will be eligible to receive all types of awards (except for incentive stock options) under the 2022 Plan. The 2022 Plan includes a maximum limit of $500,000 of equity awards that may be granted to a non-employee director in any fiscal year, increased to $750,000 in connection with his or her initial service. For purposes of this limitation, the value of equity awards is based on the grant date fair value (determined in accordance with accounting principles generally accepted in the United States). Any equity awards granted to a person for their services as an employee, or for their services as a consultant (other than as a non-employee director), will not count for purposes of the limitation. The maximum limit does not reflect the intended size of any potential compensation or equity awards to the Company's non-employee directors.

Non-transferability of Awards

Unless the administrator provides otherwise, the 2022 Plan generally does not allow for the transfer of awards other than by will or by the laws of descent and distribution and only the recipient of an award may exercise an award during their lifetime. If the administrator makes an award transferrable, such award will contain such additional terms and conditions as the administrator deems appropriate.

Certain Adjustments

In the event of certain changes in the Company's capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the 2022 Plan, the administrator will adjust the number and class of shares that may be delivered under the 2022 Plan or the number, and price of shares covered by each outstanding award and the numerical share limits set forth in the 2022 Plan.

Dissolution or Liquidation

In the event of the Company's proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and all awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Change in Control

The 2022 Plan provides that in the event of the Company's merger with or into another corporation or entity or a "change in control" (as defined in the 2022 Plan), each outstanding award will be treated as the administrator determines, including, without limitation, that (i) awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate thereof) with appropriate adjustments as to the number and kind of shares and prices; (ii) upon written notice to a participant, that the participant's awards will terminate upon or immediately prior to the consummation of such merger or change in control; (iii) outstanding awards will vest and become exercisable, realizable or payable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon consummation of such merger or change in control and, to the extent the administrator determines, terminate upon or immediately prior to the effectiveness of such merger or change in control; (iv) (A) the termination of an award in exchange for an amount of cash or property, if any, equal to the amount that would have been attained upon the exercise of such award or realization of the participant's rights as of the date of the occurrence of the transaction (and, for the avoidance of doubt, if as of the date of the occurrence of the transaction the administrator determines in good faith that no amount would have been attained upon the exercise of such award or realization of the participant's rights, then such award may be terminated by the Company without payment) or (B) the replacement of such award with other rights or property selected by the administrator in its sole discretion; or (v) any combination of the foregoing. The administrator will not be obligated to treat all awards, all awards a participant holds, or all awards of the same type, similarly. In the event that awards (or portion thereof) are not assumed or substituted for in the event of a merger or change in control, the participant will fully vest in and have the right to exercise all of their outstanding options and stock appreciation rights, including shares as to which such awards would not otherwise be vested or exercisable, all restrictions on restricted stock and RSUs or performance awards will lapse and, with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions met, in all cases, unless specifically provided otherwise under the applicable award agreement or other written agreement between the participant and the Company or any of the Company's subsidiaries or parents, as applicable. If an option or stock appreciation right is not assumed or substituted in the event of a merger or change in control, the administrator will notify the participant in writing or electronically that the option or stock appreciation right will be exercisable for a period of time determined by the administrator in its sole discretion and the vested option or stock appreciation right will terminate upon the expiration of such period.

For awards granted to an outside director, the outside director will fully vest in and have the right to exercise options and/or stock appreciation rights as to all of the shares underlying such award, including those shares which would not be vested or exercisable, all restrictions on restricted stock and RSUs will lapse, and, with respect to awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at one hundred percent (100%) of target levels and all other terms and conditions met, unless specifically provided otherwise under the applicable award agreement or other written agreement between the participant and the Company or any of its subsidiaries or parents, as applicable.

Clawback

Awards will be subject to any Company clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable laws. The administrator also may specify in an award agreement that the participant's rights, payments or benefits with respect to an award will be subject to reduction, cancellation, forfeiture or recoupment upon the occurrence of certain specified events. The administrator may require a participant to forfeit, return or reimburse the Company all or a portion of the award or shares issued under the award, any amounts paid under the award and any payments or proceeds paid or provided upon disposition of the shares issued under the award in order to comply with such clawback policy or applicable laws.

Amendment and Termination

The administrator has the authority to amend, suspend or terminate the 2022 Plan provided such action does not impair the existing rights of any participant. The 2022 Plan automatically will terminate on January 10, 2032, unless it is terminated sooner.

Equity Compensation Plan Information

The table below sets forth information as of December 31, 2023.

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	179,005	$ 42.54	37,486
Equity compensation plans not approved by security holders	—	$ —	—
Total	179,005	$ 42.54	37,486

Policies and Practices for Granting Certain Equity Awards

Our policies and practices regarding the granting of equity awards are carefully designed to ensure compliance with applicable securities laws and to maintain the integrity of our executive compensation program. The Compensation Committee is responsible for the timing and terms of equity awards to executives and other eligible employees.

The timing of equity award grants is determined with consideration to a variety of factors, including but not limited to, the achievement of pre-established performance targets, market conditions and internal milestones. The Company does not follow a predetermined schedule for the granting of equity awards; instead, each grant is considered on a case-by-case basis to align with the Company's strategic objectives and to ensure the competitiveness of our compensation packages.

In determining the timing and terms of an equity award, the Board or the Compensation Committee may consider material nonpublic information to ensure that such grants are made in compliance with applicable laws and regulations. The Board's or the Compensation Committee's procedures to prevent the improper use of material nonpublic information in connection with the granting of equity awards include oversight by legal counsel and, where appropriate, delaying the grant of equity awards until the public disclosure of such material nonpublic information.

The Company is committed to maintaining transparency in its executive compensation practices and to making equity awards in a manner that is not influenced by the timing of the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation. The Company regularly reviews its policies and practices related to equity awards to ensure they meet the evolving standards of corporate governance and continue to serve the best interests of the Company and its shareholders.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information, as of May 10, 2024, 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 3,726,974 shares of common stock and 256,968 shares of Series A Preferred Stock (which are entitled to vote with our common stock on a 1:1 as converted basis), in each case, issued and

outstanding on May 10, 2024, plus, for each individual, any common stock that individual has the right to acquire within 60 days of May 10, 2024.

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.

	Number of Shares Beneficially Owned		Beneficial Ownership Percentages		
Name and Address of Beneficial Owner[1]	Common Stock	Series A Preferred Stock[2]	Percent of Common Stock	Percent of Series A Preferred Stock	Percent of Voting Stock[3]
Officers and Directors					
Steven M. Foster, Chief Executive Officer and President	17,979[4]	—	*	—	*
Richard Ginn, Chief Technology Officer	81,580[5]	—	2.3%	—	*
Steven Van Dick, EVP, Finance and Admin and Chief Financial Officer	17,642[6]	—	*	—	*
Richard Ferrari, Chairman of the Board	48,421[7]	—	1.7%	—	*
Ivan Howard, Director	8,517[8]	—	*	—	*
Robert K. Weigle, Director	1,242[9]	—	*	—	*
Stephen H. Hochschuler, M.D., Director	6,133[10]	—	*	—	*
Kristine M. Jacques, Director	—	—	—	—	—
Officers and Directors as a Group	181,515[11]	—	5.6%	—	3.3%
5%+ Stockholders					
Zuhlke Ventures AG	244,773	—	9.4%	—	3.9%
TMD Wealth Management	870,237[12]	—	23.3%	—	13.8%
The Beckham-Shufeldt Family Trust	—	66,116	—	25.7%	10.5%
Ascent Special Ventures LLC	—	67,783	—	26.4%	10.8%

(1) The principal address of the named officers, directors and 5%+ stockholders of the Company is c/o Tenon Medical, Inc., 104 Cooper Court, Los Gatos, CA 95032.

(2) Entitles the holder to 10 votes per share and votes with the common as a single class.

(3) Represents total ownership percentage with respect to all shares of common stock and Series A Preferred Stock, as a single class.

(4) Includes 9,249 shares of our common stock underlying restricted stock units that have vested within 60 days of May 10, 2024.

(5) Includes 10,617 shares of our common stock underlying restricted stock units that have vested within 60 days of May 10, 2024.

(6) Consists of 1,999 shares held by the Van Dick Family Trust-1998 for which Steven Van Dick is trustee and 6,077 shares of our common stock underlying restricted stock units that have vested within 60 days of May 10, 2024.

(7) Consists of 9,222 shares held by the Ferrari Family Trust for which Richard Ferrari is trustee and 18,913 shares of our common stock underlying restricted stock units that have vested within 60 days of May 10, 2024 (includes 684 shares of our common stock underlying restricted stock units held by TCTIG, LLC for which Richard Ferrari is the beneficial owner) and 6,592 shares of our common stock held by TCTIG, LLC and for which Richard Ferrari has voting control.

(8) Consists of 621 shares of our common stock underlying restricted stock units that have vested within 60 days of May 10, 2024 (includes 684 shares of our common stock underlying restricted stock units held by TCTIG, LLC for which Ivan Howard is the beneficial owner) and 6,592 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.

(9) Includes 621 shares of our common stock underlying restricted stock units that have vested within 60 days of May 10, 2024.

(10) Includes 1,048 shares of our common stock underlying restricted stock units that have vested within 60 days of May 10, 2024; and 1,974 shares of our common that are held by SHKH, LLC, an entity for which Stephen H. Hochschuler has a controlling interest.

(11) Includes 47,829 shares of our common stock underlying restricted stock units that have vested within 60 days of May 10, 2024.

(12) Consists of (i) 358,137 shares of our Common Stock issued to individuals and entities that are clients of TMD Wealth Management and for which TMD Wealth Management has sole or shared power of disposition and (ii) 512,100 share of our common stock underlying warrants issued to individuals and entities that are clients of TMD Wealth Management that may be exercised within 60 days of May 10, 2024 and TMD Wealth Management has sole or shared power to dispose of the shares issued as result of any such exercise.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

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.

DESCRIPTION OF SECURITIES

The following summary description sets forth some of the general terms and provisions of our capital stock. Because this is a summary description, it does

not contain all of the information that may be important to you. For a more detailed description of our capital stock, you should refer to the applicable provisions of the General Corporation Law of the State of Delaware (the "DGCL"), our charter and our bylaws as currently in effect. Copies of our amended and restated certificate of incorporation, as amended, and our bylaws are included as exhibits to the registration statement of which this prospectus forms a part.

General

The total number of shares of stock which the Company is authorized to issue is 150,000,000 shares of capital stock, consisting of 130,000,000 shares of common stock, $0.001 par value per share, and 20,000,000 shares of preferred stock, $0.001 par value per share. As of May 10, 2024, there were 3,726,974 shares of common stock issued and outstanding.

Common Stock

The holders of our common stock are entitled to the following rights:

Voting Rights. Each share of our common stock entitles its holder to one vote per share on all matters to be voted or consented upon by the stockholders. Holders of our common stock are not entitled to cumulative voting rights with respect to the election of directors.

Election of Directors. The holders of our common stock, voting as a separate class, shall be entitled to elect one member of our Board.

Dividend Rights. Subject to limitations under Delaware law and preferences that may apply to any shares of preferred stock that we may decide to issue in the future, holders of our common stock are entitled to receive ratably such dividends or other distributions, if any, as may be declared by our Board out of funds legally available therefor.

Liquidation Rights. In the event of the liquidation, dissolution or winding up of our business, the holders of our common stock are entitled to share ratably in the assets available for distribution after the payment of all of our debts and other liabilities, subject to the prior rights of the holders of our preferred stock.

Other Matters. The holders of our common stock have no subscription, redemption or conversion privileges. Our common stock does not entitle its holders to preemptive rights. All of the outstanding shares of our common stock are fully paid and non-assessable. The rights, preferences and privileges of the holders of our common stock are subject to the rights of the holders of shares of any series of preferred stock which we may issue in the future.

Preferred Stock

Our Board also has the authority to issue up to 20,000,000 shares of preferred stock in one or more classes or series and to fix the designations, powers, preferences, and rights, and the qualifications, limitations, or restrictions thereof including dividend rights, dividend rates, conversion rights, voting rights, terms of redemption, redemption prices, liquidation preferences and the number of shares constituting any class or series, without further vote or action by the stockholders.

The issuance of preferred stock could adversely affect the rights of the holders of common stock and, therefore, reduce the value of the common stock. These effects may include:

- Restricting dividends on the common stock;
- Diluting the voting power of the common stock;
- Impairing the liquidation rights of the common stock; or
- Delaying or preventing a change in control of the Company without consent of the stockholders.

Series A Preferred Stock

The Certificate of Designations, Rights, and Preferences of the Series A Preferred Stock (the "Certificate of Designation") was filed in Delaware on February 20, 2024 and contains the terms of the Series A Preferred Stock. As of May 10, 2024, there were 256,968 shares of Series A Preferred Stock issued and outstanding.

Conversion. The Series A Preferred Stock is convertible, at any time, at the option of the holder into shares of Common Stock. Each share of Series A Preferred Stock shall be convertible, at any time after the date of issuance, at the option of the holder thereof (or, upon a Required Conversion (as defined below), at the option of the Company), into that number of shares of common stock determined by dividing the Stated Value (as defined below) for such share of Series A Preferred Stock by the Conversion Price (as defined below). "Stated Value" means for any share of Series A Preferred Stock, an amount equal to the product of (x) $15.125 multiplied by (y) the sum of 1 plus the product of (A) 0.06 multiplied by (B) a fraction equal to the number of days that such share of Series A Preferred Stock has been issued divided by 365. "Conversion Price" means (i) for the shares of Series A Preferred Stock issued on the Closing Date, $1.5125 and (ii) for each share of Series A Preferred Stock issued thereafter, an amount equal to the greater of (x) $1.5125 and the average of the VWAPs for the 10 Trading Days prior the issuance date of such share of Series A Preferred Stock, in each case subject to adjustment as set forth herein. On any date that ten out the last 15 daily VWAPs of the Common Stock is 250% higher than the Conversion Price on such date, then the Company will have the right to require 50% of the Preferred Stock to be converted into shares of Common Stock. Additionally, on and after the time on which the Company has $2.25 million in revenues in any single financial quarter, the Company will have the right to require 50% of the Preferred Stock to be converted into shares of Common Stock (a "Required Conversion"). The Conversion Price is subject to anti-dilution adjustment as the result of any subdivision, combination of shares or recapitalization, stock dividends, stock splits and similar transactions affecting the Common Stock. In addition, the Series A Preferred Stock will have weighted average anti-dilution protection providing for adjustment of the Conversion Price in the event of issuance of, or commitments to issue, Common Stock for less than the Conversion Price then in effect immediately prior to such issue or sale (a "Dilutive Issuance"), subject to customary exceptions; provided however the anti-dilution for Dilutive Issuances shall not be operative until the stockholders of the Company have approved the terms of the Series A Preferred Stock.

Dividends. No dividends are payable on the Series A Preferred Stock

Voting Rights. The Series A Preferred Stock will vote together with the Common Stock on all matters other than as required by law; provided however that any additional shares underlying the Series A Preferred Stock as a result of the anti-dilution provision described below shall not vote on an "as converted" basis and shall only vote when issued upon conversion. Notwithstanding the foregoing, the vote of an individual holder of Series A Preferred Stock (and underlying Common Stock) shall be capped at 9.99% (or 4.99% if selected by the holder). The holders of the Series A Preferred Stock are entitled to 10 votes for every share of Series A Preferred Stock held. Currently, the holders of the Series A Preferred Stock are entitled to 2,569,680 votes.

Liquidation. Upon any liquidation or winding up of the Company (a "Liquidation"), the holders of Series A Preferred Stock will be entitled to receive in preference to any other class or series of the Company's equity securities the greater of (i) the Stated Value plus accrued and unpaid dividends and (ii) what would be paid if the Series A Preferred Stock plus accrued and unpaid dividends had been converted into Common Stock. A consolidation or merger of the Company or sale or transfer of all or substantially all of its assets, or any transaction which results in the stockholders of the Company owning less than 50% of the equity or voting power of the surviving entity (excluding the issuance of Common Stock in any financing transaction unless more than 50% of the Company's shares are issued to one stockholder or a number of stockholders who act as a one group) shall be deemed a Liquidation (a "Deemed Liquidation") with respect to the shares of Series A Preferred Stock of any holder who opts to have such occurrence treated as a Deemed Liquidation; provided that if the liquidation preference payable on a Deemed Liquidation is less than 110% of the stated value of the Series A Preferred Stock, the dividend rate on any accrued and unpaid dividends payable with respect to such Deemed Liquidation will increase to 10%. All liquidation preferences payable in respect of a Deemed Liquidation will be payable in shares of Common Stock based on the closing price of the Common Stock on the date of such Deemed Liquidation.

Other Matters. Consent of the majority of the holders will be required to (i) amend the Certificate of Incorporation or Bylaws of the Company so as to adversely alter the rights, preferences, privileges of the Series A Preferred Stock, (ii) create any new class of shares *pari passu* or senior to the Series A Preferred Stock or increase or decrease the number of authorized shares of Common Stock or preferred stock, (iii) pay or declare any dividend on Common Stock or other junior securities, or incur indebtedness in any single transaction in excess of $1 million or (iv) redeem, purchase or otherwise acquire any share or shares of preferred stock or Common Stock (other than (a) the repurchase of shares of Common Stock pursuant to a written benefit plan or employment or consulting agreement, or (b) the repurchase of any equity securities in connection with the Company's right of first offer with respect to those securities contained in any written agreement with the Company).

Warrants Offered in February 2024 Private Placement

Exercisability. The Series A Warrants are exercisable at any time after their original issuance up to the date that is five years after their original issuance. The Series A Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of our common stock subscribed for upon such exercise (except in the case of a cashless exercise as discussed below). If a registration statement registering the issuance of the shares of our common stock underlying the Series A Warrants under the Securities Act is not effective or available, the holder may, in its sole discretion, elect to exercise the Series A Warrants through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of our common stock determined according to the formula set forth in the Series A Warrants, as applicable. No fractional shares of our common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Exercise Limitation. A holder will not have the right to exercise any portion of the Series A Warrants if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series A Warrants.

Exercise Price. The exercise price of the Series A Warrants is $1.2705 per share. The exercise price and number of shares of common stock issuable upon exercise will adjust in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications, dilutive issuances or similar events.

Rights as a Shareholder. Except as otherwise provided in the Series A Warrants or by virtue of such holder's ownership of our shares of common stock, the holder of a warrant does not have the rights or privileges of a holder of our shares of common stock, including any voting rights, until the holder exercises the warrant.

Transferability. Subject to applicable laws, the Series A Warrants may be offered for sale, sold, transferred or assigned without our consent.

Governing Law. The Series A Warrants are governed by New York law.

Warrants Offered in November 2023 Private Placement

Exercisability. The Note Warrants are exercisable at any time after their original issuance up to the date that is five years after their original issuance. The Note Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of our common stock subscribed for upon such exercise (except in the case of a cashless exercise as discussed below). If a registration statement registering the issuance of the shares of our common stock underlying the Note Warrants under the Securities Act is not effective or available, the holder may, in its sole discretion, elect to exercise the Note Warrants through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of our common stock determined according to the formula set forth in the Note Warrants, as applicable. No fractional shares of our common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Exercise Limitation. A holder will not have the right to exercise any portion of the Note Warrants if the holder (together with its affiliates) would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Note Warrants.

Exercise Price. The exercise price of Note Warrants is $1.94 per share. The exercise price and number of shares of common stock issuable upon exercise will adjust in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications, dilutive issuances or similar events.

Rights as a Shareholder. Except as otherwise provided in the Note Warrants or by virtue of such holder's ownership of our shares of common stock, the holder of a warrant does not have the rights or privileges of a holder of our shares of common stock, including any voting rights, until the holder exercises the warrant.

Transferability. Subject to applicable laws, the Note Warrants may be offered for sale, sold, transferred or assigned without our consent.

Governing Law. The Note Warrants are governed by New York law.

Warrants Offered in June 2023 Public Offering

Exercisability. The Tradeable Warrants are exercisable at any time after their original issuance up to the date that is five years after their original issuance. The Tradeable Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of our common stock subscribed for upon such exercise (except in the case of a cashless exercise as discussed below). If a registration statement registering the issuance of the shares of our common stock underlying the Tradeable Warrants under the Securities Act is not effective or available, the holder may, in its sole discretion, elect to exercise the Tradeable Warrants through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of our common stock determined according to the formula set forth in the Tradeable Warrants, as applicable. No fractional shares of our common stock will be issued in connection with the exercise of a Tradeable Warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Exercise Limitation. A holder will not have the right to exercise any portion of the Tradeable Warrants if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, upon election by a holder prior to the issuance of any Tradeable Warrants, 9.99%) of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Tradeable Warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, upon at least 61 days' prior notice from the holder to us with respect to any increase in such percentage.

Exercise Price. The exercise price of Tradeable Warrants is $3.146 per share. The exercise price and number of shares of common stock issuable upon exercise will adjust in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications, dilutive issuances or similar events.

Fundamental Transactions. In the event of a fundamental transaction, as described in the Tradeable Warrants, and generally including, with certain exceptions, any reorganization, recapitalization or reclassification of our shares of common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding shares of common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding shares of common stock, the holders of the Tradeable Warrants will be entitled to receive upon exercise thereof the kind and amount of securities, cash or other property that the holders would have received had they exercised the Tradeable Warrants immediately prior to such fundamental transaction. Additionally, as more fully described in the Tradeable Warrant, in the event of certain fundamental transactions, the holders of the Tradeable Warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the remaining unexercised portion of the Tradeable Warrants on the date of consummation of such fundamental transaction.

Rights as a Shareholder. Except as otherwise provided in the Tradeable Warrants or by virtue of such holder's ownership of our shares of common stock, the holder of a Warrant does not have the rights or privileges of a holder of our shares of common stock, including any voting rights, until the holder exercises the Warrant.

Warrant Agent; Global Certificate. Pursuant to warrant agent agreement between us and Vstock Transfer, LLC, as Warrant agent, the Tradeable Warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Transferability. Subject to applicable laws, the Tradeable Warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing. The Tradeable Warrants are listed on The Nasdaq Capital Market under the symbol "TNONW."

Governing Law. The Tradeable Warrants are governed by New York law.

Underwriters' Warrants

Upon the closing of our initial public offering, the underwriters were issued five-year warrants to purchase 9,600 shares of our common stock at an exercise price of $50 per share, which may be exercised at any time.

Options

In 2012, our Board and shareholders approved our 2012 Plan. From June 2014 to October 2021, we issued 10-year options to purchase a total of 72,740 (not including options to purchase 5,761 shares of our common stock that have been forfeited or cancelled) shares of our common stock pursuant to our 2012 Plan, which include outstanding options to purchase 9,100 shares of our common stock at an exercise price of $6.20; 37,130 shares of our common stock at an exercise price of $52; 24,311 shares of our common stock at an exercise price of $70.60; and 2,200 shares of our common stock at an exercise price of $75. In April 2022, we terminated the 2012 Plan, however, all of the options issued under the 2012 Plan remain outstanding and are now outstanding under the 2022 Plan. The following options were issued under the 2012 Plan:

On June 19, 2014, we granted three separate non-statutory options to purchase a total of 6,251 shares of our common stock under the 2012 Plan at an exercise price of $6.20 per share, 157 of the shares were subsequently forfeited. The options are fully vested and expire on June 19, 2024.

On November 15, 2016, we granted a non-statutory option to purchase 854 shares of our common stock under the 2012 Plan at an exercise price of $6.20 per share. The option is fully vested and expires on November 15, 2026.

On April 29, 2019, we granted a non-statutory option to purchase 854 shares of our common stock under the 2012 Plan at an exercise price of $6.20 per share, this option was subsequently forfeited.

On September 8, 2019, we granted a non-statutory option to purchase 2,152 shares of our common stock under the 2012 Plan at an exercise price of $6.20 per share. The option vests monthly over a four-year period and expires on September 8, 2029.

On May 1, 2021, we granted non-statutory options to 6 individuals to purchase in aggregate 37,450 shares of our common stock under the 2012 Plan at an exercise price of $52 per share, 2,250 of these shares were subsequently forfeited. All of the options are subject to three-year monthly vesting and expire on May 1, 2031.

On May 7, 2021, we granted non-statutory options to five individuals to purchase in aggregate 3,430 shares of our common stock under the 2012 Plan at an exercise price of $52 per share, 1,500 of these shares were subsequently forfeited. One option for 500 shares is subject to three-year vesting and the other options are subject to two-year vesting and both expire on May 7, 2031.

On July 8, 2021, we granted a non-statutory option to purchase 1,250 shares of our common stock under the 2012 Plan at an exercise price of $70.60 per

share. The option vests monthly over a two-year period and expires on July 8, 2031.

On July 19, 2021, we granted non-statutory options to two individuals to purchase 16,953 shares of our common stock and we granted incentive stock options to two individuals for 4,009 shares of our common stock under the 2012 Plan at an exercise price of $70.60 per share. The options are subject to three-year monthly vesting and expire on July 19, 2031.

On August 10, 2021, we granted non-statutory options to two individuals to purchase 1,350 shares of our common stock and we granted incentive stock options to two individuals for 750 shares of our common stock under the 2012 Plan at an exercise price of $70.60 per share. Three of these options vest 33% on the first anniversary with the balance of the shares vesting monthly over the next two years and one option is subject to two-year monthly vesting and all options expire on August 10, 2031. We also granted 6,175 of restricted shares of common stock to three individuals under the Plan, which vested immediately.

On October 8, 2021, we granted non-statutory options to three individuals to purchase 1,200 shares of our common stock and we granted incentive stock options to three individuals for 1,000 shares of our common stock under the Plan at an exercise price of $75 per share. Three of these options vest 33% on the first anniversary with the balance of the shares vesting monthly over the next two years and the remaining options are subject to two-year monthly vesting and all options expire on October 8, 2031.

Under the 2022 Plan, between May 2022 and September 2023 we granted (i) non-statutory options to 4 individuals to purchase in aggregate 9,895 shares of our common stock and (ii) incentive stock options to 15 individuals to purchase in aggregate 19,300 shares of our common stock at exercise prices between $2.90 and $27.50 per share. Fifteen of these options vest 33% on the first anniversary with the balance of the shares vesting monthly over the next two years, three of these options vest monthly over two years and the remaining option is subject to vesting 50% on the first anniversary with the balance of the shares vesting monthly over the next year. All options expire 10 years from the date of grant.

On May 6, 2024, a total of 83,391 options shares were exchanged for 41,698 restricted stock units.

RSUs

Under the 2022 Plan, between May 2022 and September 2023 we granted 23 restricted stock units to 20 individuals to purchase in aggregate 139,353 shares of our common stock under the Plan. Nine of these RSUs vest one third on the first anniversary with the balance vesting semi-annually over the next two years. Eight of these RSUs vest one sixth semi-annually over three years and four of these RSUs vest one third annually on their anniversary with one sixth of the balance vesting semi-annually over the next 2 years. One of these RSUs vests in 25% increments over seven months and one vested 100% upon grant. All RSUs expire 10 years from the date of grant.

From time to time, we expect to continue to issue options and RSUs under the 2022 Plan to various of our consultants, employees, officers and directors.

On May 6, 2024, we granted a total of 41,698 restricted stock units to our employees, non-employee directors and consultants.

Exclusive Forum

Our Certificate of Incorporation provides that, 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. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors or officers, which may discourage lawsuits against us or our directors or officers. Our Certificate of Incorporation also provides that this choice of forum provision does not apply to claims arising under federal securities laws.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. This statute prevents certain Delaware corporations, under certain circumstances, from engaging in a "business combination" with:

- a stockholder who owns 15% or more of our outstanding voting stock (otherwise known as an "interested stockholder");
- an affiliate of an interested stockholder; or
- an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

A "business combination" includes a merger or sale of more than 10% of our assets. However, the above provisions of Section 203 do not apply if:

- our Board approves the transaction that made the stockholder an "interested stockholder," prior to the date of the transaction; or
- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of common stock.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Vstock Transfer LLC.

Listing

Our common stock and Tradeable Warrants are listed on The Nasdaq Capital Market under the symbols "TNON" and "TNONW."

PLAN OF DISTRIBUTION

An aggregate of up to 5,014,654 shares of our common stock may be offered by this prospectus by Lincoln Park Capital Fund, LLC. The shares may be sold or distributed from time to time by the Selling Stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of our common stock offered by this prospectus could be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers or underwriters who may act solely as agents;
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the state's registration or qualification requirement is available and complied with.

Lincoln Park is deemed an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act.

Lincoln Park has informed us that it intends to use an unaffiliated broker-dealer to effectuate all sales, if any, of the common stock that it may purchase from us pursuant to the Purchase Agreement. Such sales will be made at prices and at terms then prevailing or at prices related to the then current market price. Each such unaffiliated broker-dealer will be an underwriter within the meaning of Section 2(a)(11) of the Securities Act. Lincoln Park has informed us that each such broker-dealer will receive commissions from Lincoln Park that will not exceed customary brokerage commissions.

Brokers, dealers, underwriters or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts or concessions from Lincoln Park and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions. Neither we nor Lincoln Park can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between Lincoln Park or any other stockholder, broker, dealer, underwriter or agent relating to the sale or distribution of the shares offered by this prospectus.

We may from time to time file with the SEC one or more supplements to this prospectus or amendments to the registration statement that includes this prospectus to amend, supplement or update information contained in this prospectus, including, if and when required under the Securities Act, to disclose certain information relating to a particular sale of shares of our common stock offered by this prospectus by the Selling Stockholder, including the names of any brokers, dealers, underwriters or agents participating in the distribution of such shares of our common stock by the Selling Stockholder, any compensation paid by Lincoln Park to any such brokers, dealers, underwriters or agents, and any other required information.

We will pay the expenses incident to the registration, offering and sale of the shares to Lincoln Park. We have agreed to indemnify Lincoln Park and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Lincoln Park has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Lincoln Park specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Lincoln Park has represented to us that at no time prior to the Purchase Agreement has it or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common stock or any hedging transaction, which establishes a net short position with respect to our common stock. Lincoln Park has agreed that during the term of the Purchase Agreement, it, its agents, representatives or affiliates will not enter into or effect, directly or indirectly, any of the foregoing transactions.

We have advised Lincoln Park that they are required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes Lincoln Park, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the securities offered by this prospectus.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Lincoln Park.

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

EXPERTS

Haskell & White LLP, an independent registered public accounting firm, audited our consolidated financial statements for the year ended December 31, 2023, and their related audit report included an explanatory paragraph expressing substantial doubt regarding our ability to continue as a going concern. Armanino LLP, an independent registered public accounting firm and our former auditor, audited our consolidated financial statements for the year ended December 31, 2022. We have included our consolidated financial statements with their report in this prospectus and elsewhere in the registration statement in reliance on the reports of Haskell & White LLP and Armanino LLP, given on their authority as experts in accounting and auditing.

CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

On July 28, 2023, we were informed by Armanino LLP ("Armanino"), our independent registered public accountant prior to September 7, 2023, that

Armanino would resign effective as of the earlier of (i) the date we engaged a new independent registered public accounting firm and (ii) the filing of our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2023, as a result of Armanino's determination to cease providing certain services to public companies. On September 5, 2023, the Audit Committee of the Board of Directors of the Company (the "Audit Committee") appointed Haskell & White LLP as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2023, effective September 7, 2023 (the "Engagement Date").

Armanino's audit reports on the Company's consolidated financial statements as of and for the fiscal years ended December 31, 2022 and December 31, 2021 did not contain an adverse opinion or a disclaimer of opinion, and were not qualified or modified as to uncertainty, audit scope or accounting principles, other than the explanatory paragraph regarding the Company's ability to continue as a going concern.

During the fiscal years ended December 31, 2022 and December 31, 2021, and subsequent interim periods through the Engagement Date, there were no disagreements with Armanino on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreement(s), if not resolved to the satisfaction of Armanino, would have caused it to make reference to the subject matter of the disagreement(s) in connection with its opinion or reportable events under Item 304(a)(1)(v) of Regulation S-K, except that Armanino concurred with the Company's assessment of a material weakness related to the Company's internal controls over financial reporting.

The Audit Committee of the Company approved the engagement of Haskell & White LLP. During the two most recent fiscal years and through the Engagement Date, the Company did not consult with Haskell & White LLP regarding either:

1. application of accounting principles to any specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, and neither a written report was provided to the Company nor oral advice was provided that Haskell & White LLP concluded was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issue; or

2. any matter that was either the subject of a disagreement (as defined in Regulation S-K, Item 304(a)(1)(iv) and the related instructions) or reportable event (as defined in Regulation S-K, Item 304(a)(1)(v)).

In accordance with Item 304(a)(3) of Regulation S-K, the Company provided Armanino with a copy of the disclosures made herein and requested from Armanino a letter addressed to the Securities and Exchange Commission indicating whether it agrees with such disclosures. A copy of Armanino's letter dated as of September 11, 2023 is attached as Exhibit 16.1 hereto.

LEGAL MATTERS

Sichenzia Ross Ference Carmel LLP, New York, New York, is acting as counsel in connection with the registration of our securities under the Securities Act, and as such, will pass upon the validity of the securities offered in this prospectus.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document is not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. You may obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is *www.sec.gov*.

We are subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, are required to file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information are available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at *www.tenonmed.com*. You may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

INCORPORATION OF DOCUMENTS BY REFERENCE

This prospectus incorporates by reference any future filings we make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act, until all of the securities are sold. Notwithstanding the foregoing, we will not be incorporating any document or portion thereof or information deemed to have been furnished and not filed in accordance with SEC rule.

We will provide you with a copy of any or all of the information that has been incorporated by reference in this prospectus, without charge, upon written or oral request directed to Tenon Medical, Inc., 104 Cooper Court, Los Gatos, CA 95032, telephone number (408) 649-5760. You may also access the documents incorporated by reference as described under "*Where You Can Find More Information*."

Tenon Medical, Inc.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of Tenon Medical, Inc. (the "Company") as of December 31, 2023, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity, and cash flows for the year then ended, and the related notes (collectively, the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2023, and the consolidated results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 2 to the consolidated financial statements, the Company has experienced recurring losses, negative cash flows from operations, and has limited capital resources. These matters raise substantial doubt about the Company's 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.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the consolidated financial statements based on our audit. 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 audit 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Haskell & White LLP

We have served as the Company's auditor since 2023.

Irvine, California
March 29, 2024

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 sheet of Tenon Medical, Inc and Subsidiary (collectively the "Company") as of December 31, 2022, 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 the year 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 the results of its operations and its cash flows for the year ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The 2022 consolidated financial statements were prepared assuming that the Company would continue as a going concern. As of December 31, 2022, the Company had suffered recurring losses from operations, incurred negative cash flows from operating activities, and had stated that substantial doubt exists about the Company's ability to continue as a going concern. The 2022 consolidated financial statements did not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. 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 audit 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.

Our audit of the consolidated financial statements 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. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

We began serving as the Company's auditor in 2021. In 2023, we became the predecessor auditor.

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 2,428	$ 2,129
Short-term investments	—	6,441
Accounts receivable	518	228
Inventory, net	554	415
Prepaid expenses	389	134
Total current assets	3,889	9,347
Fixed assets, net	961	793
Deposits	51	51
Operating lease right-of-use asset	646	873
Deferred offering costs	798	25
TOTAL ASSETS	$ 6,345	$ 11,089
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 433	$ 550
Accrued expenses	808	717
Current portion of accrued commissions	470	1,035
Current portion of operating lease liability	256	228
Convertible notes payable and accrued interest, net of debt discount of $ 77 and $0 at December 31, 2023 and 2022, respectively	1,173	—
Total current liabilities	3,140	2,530
Accrued commissions, net of current portion	1,999	1,624
Operating lease liability, net of current portion	428	683
Total liabilities	5,567	4,837
Commitments and contingencies (Notes 6 and 10)		
Stockholders' equity:		
Common stock, $0.001 par value; 130,000,000 shares authorized at December 31, 2023 and 2022; 2,600,311 and 1,123,680 shares issued and outstanding at December 31, 2023 and 2022, respectively	3	1
Additional paid-in capital	55,894	45,843
Accumulated deficit	(55,073)	(39,492)
Accumulated other comprehensive loss	(46)	(100)
Total stockholders' equity	778	6,252
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 6,345	$ 11,089

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

See Reports of Independent Registered Public Accounting Firms.

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

	Years Ended December 31,	
	2023	2022
Revenue	$ 2,928	$ 691
Cost of sales	1,687	1,332
Gross Profit (Loss)	1,241	(641)
Operating Expenses		
Research and development	3,163	2,828
Sales and marketing	6,778	7,833
General and administrative	7,027	7,423
Total Operating Expenses	16,968	18,084
Loss from Operations	(15,727)	(18,725)
Other Income (Expense)		
Gain on investments	167	180
Interest expense	(21)	(354)
Other expense, net	—	(18)
Total Other Income (Expense), net	146	(192)
Net Loss	$ (15,581)	$ (18,917)
Net Loss Per Share of Common Stock		
Basic and diluted	$ (8.59)	$ (23.62)
Weighted-Average Shares of Common Stock Outstanding		
Basic and diluted	1,814	801
Consolidated Statements of Comprehensive Loss:		
Net loss	$ (15,581)	$ (18,917)
Unrealized loss on investments	16	(16)
Foreign currency translation adjustment	38	7
Total Comprehensive Loss	$ (15,527)	$ (18,926)

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

See Reports of Independent Registered Public Accounting Firms.

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	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Total
Balance at December 31, 2021	2,550,763	$ 12,367	491,222	$ 1,272	98,995	$ —	$ 114	$ (20,575)	$ (91)	$ (20,552)
Stock-based compensation expense	—	—	—	—	—	—	2,897	—	—	2,897
Issuance of common stock and warrants, net of issuance costs	—	—	—	—	320,000	—	13,765	—	—	13,765
Common stock issued upon conversion of Series A preferred stock	(2,550,763)	(12,367)	—	—	244,773	—	12,367	—	—	12,367
Common stock issued upon conversion of Series B preferred stock	—	—	(491,222)	(1,272)	24,561	—	1,272	—	—	1,272
Common stock issued upon conversion of debt	—	—	—	—	395,542	1	13,867	—	—	13,868
Common stock issued for services	—	—	—	—	39,809	—	1,561	—	—	1,561
Other comprehensive loss	—	—	—	—	—	—	—	—	(9)	(9)
Net loss	—	—	—	—	—	—	—	(18,917)	—	(18,917)
Balance at December 31, 2022	—	$ —	—	$ —	1,123,680	$ 1	$ 45,843	$ (39,492)	$ (100)	$ 6,252
Stock-based compensation expense	—	—	—	—	—	—	4,145			4,145
Release of restricted stock units	—	—	—	—	61,200	—	—			—
Issuance of common stock and warrants, net of issuance costs	—	—	—	—	1,000,000	1	4,807			4,808
Issuance of common stock, net of issuance costs	—	—	—	—	232,100	1	494			495
Common stock issued for services	—	—	—	—	98,909	—	289			289
Issuance of common stock upon exercise of warrants	—	—	—	—	82,000	—	258			258

Warrants issued in connection with convertible debt	—	—	—	—	—	—	58			58
Shares issued for reverse stock split	—	—	—	—	2,422	—	—			—
Other comprehensive income	—	—	—	—	—	—	—		54	54
Net loss	—	—	—	—	—	—	—	(15,581)		(15,581)
Balance at December 31, 2023	—	$ —	—	$ —	2,600,311	$ 3	$ 55,894	$ (55,073)	$ (46)	$ 778

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

See Reports of Independent Registered Public Accounting Firms.

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

	Years Ended December 31,	
	2023	**2022**
Cash Flows from Operating Activities		
Net loss	$ (15,581)	$ (18,917)
Adjustments to reconcile net loss to net cash used in operating activities:		
Unrealized loss on investments	—	(16)
Non-cash interest expense	—	362
Stock-based compensation expense	4,145	2,897
Common stock issued for services	—	1,561
Depreciation and amortization	199	78
Loss on write-off of fixed assets	—	77
Amortization of operating right-of-use asset	227	211
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(290)	(152)
Inventory	(139)	(227)
Prepaid expenses and other assets	(301)	(57)
Accounts payable	(117)	72
Accrued expenses	(99)	2,288
Operating lease liability	(227)	(202)
Net cash used in operating activities	(12,183)	(12,025)
Cash Flows from Investing Activities		
Sales of short-term investments	6,996	8,079
Purchases of short-term investments	(493)	(10,116)
Purchases of property and equipment	(361)	(847)
Net cash provided by (used in) investing activities	6,142	(2,884)
Cash Flows from Financing Activities		
Proceeds from issuance of common stock and warrants, net of issuance costs	4,808	14,139
Proceeds from issuance of common stock, net of issuance costs	495	—
Proceeds from issuance of convertible notes payable	1,250	—
Proceeds from exercise of warrants	258	—
Deferred offering costs	(509)	(25)
Net cash provided by financing activities	6,302	14,114
Effect of foreign currency translation on cash flow	38	7
Net Increase (Decrease) in Cash and Cash Equivalents	299	(788)
Cash and Cash Equivalents at Beginning of Year	2,129	2,917
Cash and Cash Equivalents at End of Year	$ 2,428	$ 2,129
Cash at End of Year	$ 2,428	$ 480
Cash Equivalents at End of Year	$ —	$ 1,649
Supplemental Disclosures of Cash Flow Information		
Cash paid during the year for:		
Interest	$ —	$ —
Income taxes	$ —	$ —
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

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

See Reports of Independent Registered Public Accounting Firms.

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 The Catamaran™ SI Joint Fusion System ("the Catamaran System") that offers a novel, less invasive approach to the sacroiliac joint (the "SI Joint") using a single, robust, titanium implant for treatment of the most common types of SI Joint disorders that cause lower back pain. The Company received U.S. Food and Drug Administration ("FDA") clearance in 2018 for The Catamaran System and is currently focused on the U.S. market. Since the national launch of the Catamaran System in October 2022, the Company is focused on three commercial opportunities: 1) Primary SI Joint procedures, 2) Revision procedures of failed SI Joint implants and 3) SI Joint fusion adjunct to a spine fusion construct.

Basis of consolidation

The condensed financial statements of the Company include the accounts of the Company and its wholly-owned subsidiary, Tenon Technology AG ("TTAG"), a Swiss company. All intercompany balances and transactions have been eliminated in consolidation. The financial statements of TTAG are prepared for the same reporting period as the parent, using consistent accounting policies in all material respects.

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").

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 the commercialization of The Catamaran System. Based on the Company's expected level of revenues and expenditures, the Company believes that its existing cash and cash equivalents as of December 31, 2023 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 (see Note 13). The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 and stock-based compensation.

Reverse Stock Splits

On April 6, 2022, the Company effected a 1-for-2 reverse stock split (the "2022 Reverse Stock Split") by filing an amendment to the Company's Amended and Restated Certificate of Incorporation, as amended, with the Delaware Secretary of State. The 2022 Reverse Stock Split combined every two shares of our common stock issued and outstanding immediately prior to effecting the 2022 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 2022 Reverse Stock Split.

On November 2, 2023, the Company effected a 1-for-10 reverse stock split (the "2023 Reverse Stock Split") by filing an amendment to the Company's Amended and Restated Certificate of Incorporation, as amended, with the Delaware Secretary of State. The 2023 Reverse Stock Split combined every ten shares of our common stock issued and outstanding immediately prior to effecting the 2023 Reverse Stock Split into one share of common stock. No fractional shares were issued in connection with the 2023 Reverse Stock Split. All historical share and per share amounts reflected throughout this document have been adjusted to reflect the 2022 Reverse Stock Split and the 2023 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 2022 Reverse Stock Split or the 2023 Reverse Stock Split.

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 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.

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. As of December 31, 2023 and 2022, the Company's allowance for expected credit losses 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, 2023 and 2022, 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 future offerings, are capitalized, and are offset against proceeds received 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.

Leases

The Company leases its headquarters in Los Gatos, California. At the inception of a contract, the Company assesses whether that contract is, or contains, a lease. The Company's assessment is based on: (1) whether the contract involves the use of a distinct identified asset, (2) whether the Company obtains the right to substantially all the economic benefit from the use of the asset throughout the term, and (3) whether the Company has the right to direct the use of the asset. At inception of a lease, the Company allocates the consideration in the contract to each lease and non-lease component based on the component's relative stand-alone price to determine the lease payments. Lease and non-lease components are accounted for separately.

Leases are classified as either finance leases or operating leases based on criteria in FASB ASC 842, "Leases". The Company's facility lease is classified as an operating lease. Right-of-use 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 right-of-use 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. The Company has elected not to recognize ROU assets and lease liabilities for short-term operating leases that have a term of 12 months or less. Lease expense for operating leases is recognized on a straight-line basis over the lease term and is included in operating expenses in the consolidated statements of operations and comprehensive loss.

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 undiscounted cash flow in future periods as well as the strategic significance of the assets to the Company's business objectives.

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.

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, 2023 and 2022. 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.

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, 2023 and 2022, 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.

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 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 prior to that date, 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. 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.

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 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, 2023 and 2022 which were excluded from the calculation because their effect was anti-dilutive.

	December 31, 2023	December 31, 2022
Outstanding restricted stock units	76,916	131,858
Outstanding stock options	102,089	89,889
Outstanding warrants	1,927,600	9,600
Total	2,106,605	231,347

Adoption of New Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board issued Accounting Standards Update 2016-13, " *Financial Instruments-Credit Losses* (Topic 326): *Measurement of Credit Losses on Financial Instruments*". This standard requires an impairment model (known as the current expected credit loss ("CECL") model) that is based on expected losses rather than incurred losses. Under the new guidance, each reporting entity should estimate an allowance for expected credit losses, which is intended to result in more timely recognition of losses. The Company adopted this guidance effective January 1, 2023. The adoption of this guidance did not have a significant impact on the Company's consolidated financial statements or results of operations.

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, 2023 and 2022:

	Level 2
Corporate debt securities:	
December 31, 2023	$ —
December 31, 2022	$ 6,441

Cost and fair value of available-for-sale investments as of December 31, 2023 and 2022 are as follows:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate debt securities:				
December 31, 2023	$ —	$ —	$ —	$ —
December 31, 2022	$ 6,457	$ —	$ (16)	$ 6,441

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, 2023 and 2022, 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, 2023 and 2022, there were net gains of approximately $ 167 and $180, respectively, included in the Company's net loss. Accrued interest as of December 31, 2023 and 2022 was approximately $8 and $13, respectively, and is included in prepaid expenses in the Company's consolidated balance sheets.

4. Inventory, net

Inventory, net of reserves, consisted of the following:

	December 31, 2023	December 31, 2022
Raw materials	$ 22	$ 9
Finished goods	532	406
Inventory	$ 554	$ 415

5. Fixed Assets, net

Fixed assets, net, consisted of the following:

	December 31, 2023	December 31, 2022
Construction in progress	$ 602	$ 601
Catamaran tray sets	538	193
IT equipment	56	56
Leasehold improvements	15	—
Lab equipment	14	14
Office furniture	9	9
Fixed assets, gross	1,234	873
Less: accumulated depreciation	(273)	(80)
Fixed assets, net	$ 961	$ 793

Construction in progress is made up of reusable components that will become Catamaran Tray Sets. Depreciation expense was approximately $ 193 and $78 for the years ended December 31, 2023 and 2022, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following:

	December 31, 2023	December 31, 2022
Accrued compensation	$ 334	$ 452
Other accrued expenses	474	265
Total accrued expenses	$ 808	$ 717

7. Debt

Convertible notes payable

In November 2023, the Company entered into Securities Purchase Agreements with certain investors (the "Investors"), pursuant to which the Company sold to the Investors a total of $1,250,000 in secured notes (the "Convertible Notes") and warrants to purchase 45,000 shares of the Company's common stock at an exercise price equal to $1.94 per share.

The Convertible Notes bear an interest rate of 10% per annum with a default rate of 12% per annum and have a maturity date of November 21, 2024. All principal and accrued interest is payable at maturity. At any time during the term of the Convertible Notes, the principal amount together with all accrued interest thereon (the "Prepayment Amount") may be paid in full, but not in part, by the Company. The Prepayment Amount may be paid by the Company in cash or by the issuance to the Investors of shares of Series A Preferred Stock, if prior to such payment with Series A Preferred Stock (i) certain stockholder proposals described in the Convertible Notes are approved by the Company's stockholders; and (ii) the Company has commitments from investors other than the Investors to purchase shares of Series A Preferred Stock with a stated value of at least $3,750,000. The Convertible Notes are secured by a first priority security interest in all of the assets of the Company. The warrants expire five years from the issuance date. The warrants contain a "cashless exercise" feature and contain anti-dilution rights on subsequent issuances of equity or equity equivalents.

On February 20, 2024, the Investors agreed to a complete prepayment of the Company's obligations under the Convertible Notes, including accrued interest, in exchange for 84,729 shares of Series A Preferred Stock and warrants to purchase 157,094 shares of our common stock at $ 1.2705 per share and the Convertible Notes were cancelled. See Note 13.

8. Leases

In June 2021, the Company entered into a facility lease agreement for its company headquarters in Los Gatos, California. This non-cancellable operating lease expires in June 2026.

Operating lease costs for the facility lease were $292 and $292 for the years ended December 31, 2023 and 2022, respectively.

Supplemental balance sheet information related to leases was as follows:

	December 31, 2023	December 31, 2022
Operating lease right-of-use asset	$ 646	$ 873
Operating lease liability, current	$ (256)	$ (228)
Operating lease liability, noncurrent	(428)	(683)
Total operating lease liabilities	$ (684)	$ (911)

Future maturities of operating lease liabilities as of December 31, 2023 were as follows:

2024	302
2025	310
2026	144
Total lease payments	756
Less: imputed interest	(72)
Present value of operating lease liabilities	$ 684

Other information:

Cash paid for operating leases for the year ended December 31, 2023	$ 293
Cash paid for operating leases for the year ended December 31, 2022	$ 284
Remaining lease term - operating leases (in years)	2.50
Average discount rate - operating leases	8.0%

9. Stockholders' Equity

The Company's current Amended and Restated Certificate of Incorporation dated February 18, 2014 authorizes the issuance of 130,000,000 shares of common stock and 20,000,000 shares of preferred stock, both with a par value of $ 0.001 per share. With respect to the preferred stock, 4,500,000 shares

are designated Series A Preferred Stock and 491,222 shares are designated Series B Preferred Stock. As of December 31, 2023 and 2022, there were no shares of Series A Preferred stock or Series B Preferred Stock issued and outstanding.

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 320,000 shares of common stock, par value $0.001 per share at a public offering price of $ 50.00 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 9,600 shares of the Company's common stock at an exercise price of $ 50.00 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, the Company converted the entirety of the outstanding principal and accrued interest of the convertible notes payable to 395,542 shares of the Company's common stock.

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 269,334 shares of the Company's common stock at the conversion rate detailed below and issued the common stock to the preferred stockholders.

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 31,235 shares of the Company's common stock to the Representative, fully satisfying the Company's obligations. Also, as a result of the completion of the IPO, the Company issued 8,574 shares of its common stock to a consultant. The value of these shares issued at the IPO price of $50.00 per share was charged to operating expenses in the Company's consolidated financial statements.

Registered Offering

On June 16, 2023, the Company closed the Registered Offering of a total of 1,000,000 units (the "Units") for proceeds, net of issuance costs, of $ 4,808, with each Unit consisting of (i) one share of the Company's common stock, and (ii) two warrants, each warrant to purchase one share of the Company's common stock at an exercise price equal to $5.60 per share (the "Offering Warrants"). The Offering Warrants were exercisable upon issuance and will expire five years from the date of issuance. Per the terms of the Offering Warrants, the exercise price reset on July 16, 2023 to $ 3.146 per share.

At-the-Market Offering Program

On May 4, 2023, the Company entered into an Equity Distribution Agreement to establish an at-the-market offering program, under which the Company may sell from time to time, at its option, shares of its common stock having an aggregate gross sales price of $5.5 million. The Company is required to pay the Sales Agents a commission of 3% of the gross proceeds from the sale of shares and has also agreed to provide the Sales Agents with customary indemnification rights. During the year ended December 31, 2023, 232,100 shares of the Company's common stock were sold under the program at a weighted-average price of $2.27 per share with aggregate net proceeds of $ 495.

Equity Line of Credit

On July 24, 2023, the Company entered into a purchase agreement ("Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), under which, subject to specified terms and conditions, the Company may sell to Lincoln Park up to $10 million of shares of common stock from time to time during the term of the Purchase Agreement. On September 22, 2023 (the "Commencement Date"), the Company filed a registration statement with the Securities and Exchange Commission (the "SEC"), covering the resale of shares of common stock issued to Lincoln Park under the Purchase Agreement.

Beginning on the Commencement Date and for a period of 24 months thereafter, under the terms and subject to the conditions of the Purchase Agreement, from time to time, at the Company's discretion, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $10 million of shares of common stock, subject to certain limitations set forth in the Purchase Agreement. Specifically, from time to time from and after the Commencement Date, the Company may, at its discretion, direct Lincoln Park to purchase on any single business day on which the closing price of its common stock on The Nasdaq Capital Market ("Nasdaq") is equal to or greater than $1.50 up to 10,000 shares of common stock (a "Regular Purchase"); provided, that the Company may direct Lincoln Park to purchase in a Regular Purchase (i) up to 12,500 shares of common stock, if the closing sale price of its common stock on Nasdaq on such business day is at least $15.00 per share and (ii) up to 15,000 shares of common stock, if the closing sale price of its common stock on Nasdaq on such business day is at least $25.00 per share. In no case, however, will Lincoln Park's commitment with respect to any single Regular Purchase exceed $500,000; provided, that the parties may mutually agree at any time to increase the maximum number of shares of common stock the Company may direct Lincoln Park to purchase in any single Regular Purchase to up to 100,000 shares or any number of shares that shall not exceed 4.99% of the then outstanding shares of common stock. The foregoing share amounts and per share prices will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring after the date of the Purchase Agreement with respect to our common stock. The purchase price per share for each such Regular Purchase will be based on prevailing market prices of the Company's common stock immediately preceding the time of sale, as determined under the Purchase Agreement.

Voting rights

The holders of vested shares of common stock are entitled to vote on any matter submitted to a vote of the stockholders and each such holder is 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 provided 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.

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 initial number of shares of common stock subject to awards under the 2022 Plan was 160,000. The 2022 Plan calls for automatic annual increases in the number of shares available for issuance equal to the least of (a) 110,000 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.

Compensation expense for the years ended December 31, 2023 and 2022 includes the portion of awards vested in the periods for all equity-based awards granted, based on the grant date fair value. estimated using a Black-Scholes option valuation model. 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 using the weighted-average assumptions in the table below:

	Years ended December 31,	
	2023	2022
Expected volatility	63.89%	57.68%
Dividend yield	0%	0%
Risk-free interest rate	4.28%	3.34%
Expected term in years	5.85	5.85

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 (In Years)	Number of RSUs	Weighted Average Grant Date Fair Value per Share
Balance as of December 31, 2021	72,744	$ 53.18	7.12	—	
Granted	17,145	$ 22.98		131,858	$ 79.29
Balance as of December 31, 2022	89,889	$ 47.42	8.10	131,858	$ 79.29
Granted	15,050	$ 12.91		7,500	$ 2.91
Released	—	—		(61,200)	$ 82.04
Canceled	(2,850)	$ 39.87		(1,242)	$ 88.60
Balance as of December 31, 2023	102,089	$ 42.54	7.41	76,916	$ 69.50
Exercisable at December 31, 2023	70,634	$ 48.66	6.86		

The weighted-average grant-date fair value of options granted during the years ended December 31, 2023 and 2022 was $ 7.63 and $12.90, respectively. The aggregate intrinsic value of outstanding options at December 31, 2023 was $0. The aggregate intrinsic value is equal to the difference between the exercise price of the underlying option and the fair value of the Company's common stock for in-the-money options. As of December 31, 2023, total compensation cost not yet recognized related to unvested options was $414, which is expected to be recognized over a weighted-average period of 0.99 years, and total compensation costs not yet recognized related to unvested RSUs was $4,773, which is expected to be recognized over a weighted-average period of 1.40 years.

The following table sets forth stock-based compensation expense recognized for the years ended December 31, 2023 and 2022:

	Years ended December 31,	
	2023	2022
Research and development	$ 1,504	$ 995
Sales and marketing	217	117
General, and administrative	2,424	1,785
Total stock-based compensation expense	$ 4,145	$ 2,897

At December 31, 2023, there were 37,486 shares available for issuance under the 2022 Plan.

Warrants

In April 2022, as noted above, the Company granted the Underwriters warrants to purchase a total of 9,600 shares of the Company's common stock. The warrants are immediately exercisable at an exercise price of $50.00 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 $27.50 per warrant, which was calculated using a Black-Scholes option valuation model with an 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.

In June 2023, as noted above, in connection with the Registered Offering, the Company issued Offering Warrants to purchase a total of 2,000,000 shares of the Company's common stock. The Offering Warrants were exercisable upon issuance at an exercise price of $5.60 per share and will expire five years from the date of issuance. Per the terms of the Offering Warrants, the exercise price of the Offering Warrants reset on July 16, 2023, to a price equal to the greater of (i) $2.80 per share and (ii) 100% of the last VWAP (as defined in the Warrants) on July 14, 2023, which was $ 3.146 per share. The fair value of the Offering Warrants on the grant date was approximately $3,164, or $1.58 per warrant, which was calculated using a Monte-Carlo simulation to estimate the final exercise price, which is considered a Level 3 fair value measurement, using as inputs; the starting value of $3.00 per share, the

Company's VWAP on June 16; an assumed daily distribution of returns; a mean daily return of 5.18%; a short-term annual volatility of 100% and a standard deviation of 6.3%. The model used Black-Scholes to then calculate the estimated fair value of the Offering Warrants, using an estimated time to maturity of 4.9 years, a risk-free interest rate of 3.99% and a long-term volatility of 60%. Based on the accounting guidance under ASC 815, the Company determined that the Offering Warrants did not meet the criteria for classification as equity as of June 30, 2023. Accordingly, the Company classified the fair value of the Offering Warrants as a liability. As of July 16, 2023, with the resolution of the reset value, the Company has determined that the Offering Warrants do meet the criteria for classification as equity and the fair value of the Offering Warrants has been reclassified to additional paid-in capital on the Company's consolidated balance sheet as of that date.

In November 2023, in connection with the issuance of the Convertible Notes, the Company issued warrants to purchase a total of 45,000 shares of the Company's common stock at an exercise price equal to $1.94 per share. The warrants expire five years from the issuance date. The fair value of the warrants on the grant date was $1.29 per warrant, which was calculated using a Black-Scholes option valuation model with an expected term of 5.00 years, expected volatility of 68.89%, dividend yield of 0%, and risk-free interest rate of 4.41%. The Company recorded the fair value of these warrants of approximately $58 as an issuance cost to additional paid-in capital in 2023.

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 4,445 shares of common stock with a fair value of approximately $333 to the Representative in accordance with the anti-dilution provision. In April 2022, the Company issued 31,235 shares of common stock to the Representative in accordance with the anti-dilution provision, fully satisfying the Company's obligations.

The Restated Sales 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 Restated Sales Agreement as long as the bonus paid to the Representative is at least $6,000.

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 recorded a charge of $ 1,000 for the payment to the Representative in the fourth quarter of 2022 and expensed the $85 per month 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 total of $ 2,611 was charged to sales and marketing expense in the consolidated statements of operations and comprehensive loss and recorded as accrued commissions in the consolidated balance sheets. A reconciliation of the liability under clause (b) and clause (c) for the year ended December 31, 2023 is as follows:

	2023
Balance at January 1, 2023	$ 2,560
Amounts paid during 2023	(592)
Accretion	409
Balance at December 31, 2023	$ 2,377

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 was from October 6, 2022, until October 5, 2023, when it terminated in accordance with the terms of the Consulting Agreement. In consideration for the services to be provided, the Company paid 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 were 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.

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, 2023 and 2022, approximately $741 and $8, 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,	
	2023	2022
United States	$ (15,570)	$ (18,886)
International	(11)	(30)
Loss before income taxes	$ (15,581)	$ (18,916)

The components of current income tax expense are as follows:

	Years ended December 31,	
	2023	2022
Federal	$ —	$ —
State	—	1
Foreign	—	—
Total income tax expense	$ —	$ 1

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, 2023 and 2022 is as follows:

	Years ended December 31,	
	2023	2022
Statutory rate	(21)%	(21)%
State taxes, net of federal benefit	(7)%	(7)%
Non-deductible differences	3%	1%
Change in valuation allowance	25%	27%
Provision for taxes	—	—

Significant components of the Company's net deferred tax assets at December 31, 2023 and 2022 are as follows:

	Years ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 9,504	$ 7,001
Credit carryforwards	220	109
Fixed assets	52	—
Accruals and reserves	111	126
Stock-based compensation	1,802	843
Intangibles	220	244
Operating lease liability	188	254
Capitalized research and development	514	274
Total deferred tax assets	12,611	8,851
Valuation allowance	(12,433)	(8,564)
Net deferred tax assets	178	287
Deferred tax liabilities:		
Fixed assets	—	(44)
Operating lease right of use	(178)	(243)
Total deferred tax liabilities	(178)	(287)
Net deferred tax assets	$ —	—

In assessing the realizability of deferred tax assets at December 31, 2023, 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, 2023, the Company has available net operating loss carryforwards of approximately $ 33,866 for federal income tax purposes, of which approximately $33,644 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, 2023, the net operating loss carryforwards for state purposes are approximately $ 32,147 and will begin to expire in 2032 if not utilized. In addition, the Company had foreign net operating loss carryforwards of approximately $1,378 at December 31, 2023 that will start to expire in 2024 if not utilized.

The Company had credit carryforwards of approximately $ 214 for federal income tax purposes. The federal tax credits will begin to expire in 2041.

The Company also had credit carryforwards of approximately $ 101 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.

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,	
	2023	2022
Unrecognized tax benefits, beginning of year	$ 38	$ —
Increases related to prior year tax positions	5	12
Decreases related to prior year tax positions	—	—
Increases related to current year tax positions	36	26
Unrecognized tax benefits, end of year	$ 79	$ 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 and comprehensive loss. 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, 2023, 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. Subsequent Events

On February 20, 2024, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain investors, pursuant to which the Company agreed to sell, issue and deliver to these investors, in a private placement offering (the "Offering"), a total of 172,239 shares of the Company's Series A Preferred Stock and warrants (the "Warrants") to purchase 258,374 shares of common stock, par value $ 0.001 per share, of the Company ("Common Stock") at an exercise price equal to $1.2705 per share for an aggregate offering price of $ 2,605,000.

Additionally, on February 20, 2024, the Investors agreed to a complete prepayment of the Company's obligations under the Convertible Notes, including accrued interest, in exchange for 84,729 shares of Series A Preferred Stock and warrants to purchase 157,094 shares of our common stock at $ 1.2705 per share and the Convertible Notes were cancelled. The Warrants are immediately exercisable and expire five years from the date of issuance.

The Series A Preferred Stock is convertible, at any time, at the option of the holder into shares of Common Stock. Each share of Series A Preferred Stock shall be convertible, at any time after the date of issuance, at the option of the holder thereof (or, upon a Required Conversion (as defined below), at the option of the Corporation), into that number of shares of Common Stock determined by dividing the Stated Value (as defined below) for such share of Series A Preferred Stock by the Conversion Price (as defined below). "Stated Value" means for any share of Series A Preferred Stock, an amount equal to the product of (x) $15.125 multiplied by (y) the sum of 1 plus the product of (A) 0.06 multiplied by (B) a fraction equal to the number of days that such share of Series A Preferred Stock has been issued divided by 365. "Conversion Price" means (i) for the shares of Series A Preferred Stock issued on the Closing Date, $1.5125 and (ii) for each share of Series A Preferred Stock issued thereafter, an amount equal to the greater of (x) $ 1.5125 and the average of the VWAPs for the 10 Trading Days prior the issuance date of such share of Series A Preferred Stock, in each case subject to adjustment as set forth herein. On any date that ten out of the last 15 daily VWAPs of the Common Stock is 250% higher than the Conversion Price on such date, then the Company will have the right to require 50% of the Preferred Stock to be converted into shares of Common Stock. Additionally, on and after the time on which the Company has $2.25 million in revenues in any single financial quarter, the Company will have the right to require 50% of the Preferred Stock to be converted into shares of Common Stock (a "Required Conversion"). No dividends are payable on the Series A Preferred Stock. The Series A Preferred Stock will vote together with the Common Stock on all matters other than as required by law; provided however that any additional shares underlying the Series A Preferred Stock as a result of the anti-dilution provision described below shall not vote on an "as converted" basis and shall only vote when issued upon conversion. Notwithstanding the foregoing, the vote of an individual holder of Series A Preferred Stock (and underlying Common Stock) shall be capped at 9.99% (or 4.99% if selected by the holder).

The Conversion Price is subject to anti-dilution adjustment as the result of any subdivision, combination of shares or recapitalization, stock dividends, stock splits and similar transactions affecting the Common Stock. In addition, the Series A Preferred Stock will have weighted average anti-dilution protection providing for adjustment of the Conversion Price in the event of issuance of, or commitments to issue, Common Stock for less than the Conversion Price then in effect immediately prior to such issue or sale (a "Dilutive Issuance"), subject to customary exceptions; provided however the anti-dilution for Dilutive Issuances shall not be operative until the stockholders of the Company have approved the terms of the Series A Preferred Stock. Upon any liquidation or winding up of the Company (a "Liquidation"), the holders of Series A Preferred Stock will be entitled to receive in preference to any other class or series of the Company's equity securities the greater of (i) the Stated Value plus accrued and unpaid dividends and (ii) what would be paid if the Series A Preferred Stock plus accrued and unpaid dividends had been converted into Common Stock. A consolidation or merger of the Company or sale or transfer of all or substantially all of its assets, or any transaction which results in the stockholders of the Company owning less than 50% of the equity or voting power of the surviving entity (excluding the issuance of Common Stock in any financing transaction unless more than 50% of the Company's shares are issued to one stockholder or a number of stockholders who act as a one group) shall be deemed a Liquidation (a "Deemed Liquidation") with respect to the shares of Series A Preferred Stock of any holder who opts to have such occurrence treated as a Deemed Liquidation;

provided that if the liquidation preference payable on a Deemed Liquidation is less than 110% of the stated value of the Series A Preferred Stock, the dividend rate on any accrued and unpaid dividends payable with respect to such Deemed Liquidation will increase to 10%. All liquidation preferences payable in respect of a Deemed Liquidation will be payable in shares of Common Stock based on the closing price of the Common Stock on the date of such Deemed Liquidation. Consent of the majority of the holders will be required to (i) amend the Certificate of Incorporation or Bylaws of the Company so as to adversely alter the rights, preferences, privileges of the Series A Preferred Stock, (ii) create any new class of shares pari passu or senior to the Series A Preferred Stock or increase or decrease the number of authorized shares of Common Stock or preferred stock, (iii) pay or declare any dividend on Common Stock or other junior securities, or incur indebtedness in any single transaction in excess of $1 million or (iv) redeem, purchase or otherwise acquire any share or shares of preferred stock or Common Stock (other than (a) the repurchase of shares of Common Stock pursuant to a written benefit plan or employment or consulting agreement, or (b) the repurchase of any equity securities in connection with the Company's right of first offer with respect to those securities contained in any written agreement with the Company).

As of March 29, 2024, with the issuance of the Series A Preferred Stock, the conversion of the Convertible Notes, and proceeds from the Company's ATM and ELOC facilities, the Company believes that its Stockholders' Equity will exceed $2.5 million and will therefore meet the minimum stockholder equity amount required by the Nasdaq Stock Market, LLC.

5,014,654 Shares of Common Stock

Tenon Medical, Inc.

PRELIMINARY PROSPECTUS

, 2024

Part II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee.

		Amount
Securities and Exchange Commission registration fee	$	636.54
Accountants' fees and expenses	$	*
Legal fees and expenses	$	*
Miscellaneous	$	*
Total expenses	$	*

Item 14. Indemnification of Directors and Officers.

Section 102 of the General Company Law of the State of Delaware ("DGCL") permits a company to eliminate the personal liability of directors of a company to the company or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our charter, as amended provides that no director of the Company shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a company has the power to indemnify a director, officer, employee, or agent of the company, or a person serving at the request of the company for another company, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the company, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the company, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the company unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our charter, as amended provides that we will indemnify to the fullest extent permitted from time to time by the DGCL or any other applicable laws as presently or hereafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, including, without limitation, an action by or in the right of the Company, by reason of his acting as a director or officer of the Company or any of its subsidiaries (and the Company, in the discretion of the Board of Directors, may so indemnify a person by reason of the fact that he is or was an employee or agent of the Company or any of its subsidiaries or is or was serving at the request of the Company in any other capacity for or on behalf of the Company) against any liability or expense actually and reasonably incurred by such person in respect thereof; *provided*, *however*, the Company shall be required to indemnify an officer or director in connection with an action, suit or proceeding (or part thereof) initiated by such person only if (i) such action, suit or proceeding (or part thereof) was authorized by the Board of Directors and (ii) the indemnification does not relate to any liability arising under Section 16(b) of the Exchange Act, as amended, or any rules or regulations promulgated thereunder. Such indemnification is not exclusive of any other right to indemnification provided by law or otherwise.

If a claim is not paid in full by the Company, the claimant may at any time thereafter bring suit against the Company to recover the unpaid amount of the claim and, if successful in whole or in part, the claimant shall be entitled to be paid also the expense of prosecuting such claim. It shall be a defense to any such action (other than an action brought to enforce a claim for expenses incurred in defending any proceeding in advance of its final disposition where any undertaking required by the bylaws of the Company has been tendered to the Company) that the claimant has not met the standards of conduct which make it permissible under the DGCL for the Company to indemnify the claimant for the amount claimed, but the burden of proving such defense shall be on the Company. Neither the failure of the Company (including its Board of Directors, legal counsel or its stockholders) to have made a determination prior to the commencement of such action that indemnification of the claimant is proper in the circumstances because he or she has met the applicable standard of conduct set forth in the DGCL, nor an actual determination by the Company (including its Board of Directors, legal counsel or its stockholders) that the claimant has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that the claimant has not met the applicable standard of conduct. Indemnification shall include payment by the Company of expenses in defending an action or proceeding in advance of the final disposition of such action or proceeding upon receipt of an undertaking by the person indemnified to repay such payment if it is ultimately determined that such person is not entitled to indemnification.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act of 1933, as amended, or the Securities Act, against certain liabilities.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding shares of capital stock issued by us within the last three years which was not registered under the Securities Act of 1933, as amended.

(a) Issuance of Capital Stock.

Common Stock and Preferred Stock

On May 19, 2021, the Company issued 5,376 shares of common stock to SpineSource, Inc. pursuant to a Common Stock Purchase Agreement based on a value of $70.60 per share.

On August 10, 2021, the Company issued an aggregate of 6,175 shares of restricted common stock to several individuals under the Tenon Medical, Inc. 2012 Equity Incentive Plan.

During October 2021, the Company issued 4,445 shares of common stock to SpineSource, Inc. pursuant to an anti-dilution provision. The shares of common stock had a value of $74.90 per share.

On October 28, 2021, the Company issued 255,077 shares of Series A preferred stock to Zuhlke Ventures AG pursuant to an Exchange Agreement based on a deemed value of $0.98 per share.

In April of 2022, we issued 31,236 shares of common stock to SpineSource, Inc. The shares of common stock had a value of $50 per share.

In February 2024, we issued a total of 256,968 shares of Series A Preferred Stock to investors.

In July of 2023, we completed a private placement to Lincoln Park pursuant to which we have the right to sell to Lincoln Park up to $10.0 million in shares of common stock, subject to certain limitations, from time to time over the 24-month period commencing after the satisfaction of certain conditions set forth in the Purchase Agreement. We issued 98,909 Commitment Shares to Lincoln Park as consideration for its commitment to purchase our shares under the Purchase Agreement. In the Purchase Agreement, Lincoln Park represented to us, among other things, that it was an “accredited investor” (as such term is defined in Rule 501(a) of Regulation D under the Securities Act). The securities were and will be sold by us under the Purchase Agreement in reliance upon an exemption from the registration requirements under the Securities Act afforded by Section 4(a)(2) of the Securities Act.

The issuance of the capital stock listed above was deemed exempt from registration under 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 recipient 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.

(b) Option Grants.

On May 1, 2021, the Company issued a total of 37,450 options to various individuals at an exercise price of $52 per share. The options are subject to equal monthly vesting over a three-year period.

On May 7, 2021, the Company issued a total of 3,430 options to various individuals at an exercise price of $52 per share. The options are subject to either (i) equal monthly vesting over a two-year period or (ii) equal monthly vesting over a three-year period.

On July 8, 2021, the Company issued a total of 1,250 options to an individual at an exercise price of $70.60 per share. The options are subject to equal monthly vesting over a two-year period.

On July 19, 2021, the Company issued a total of 20,961 options to various individuals at an exercise price of $70.60 per share. The options are subject to equal monthly vesting over a three-year period.

On August 10, 2021 the Company issued a total of 2,100 options to various individuals at an exercise price of $70.60 per share. The options are subject to equal monthly vesting over a two or three-year period.

On October 8, 2021 the Company issued a total of 2,200 options to various individuals at an exercise price of $75 per share. The options are subject to equal monthly vesting over a two or three-year period.

The options 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.

(c) Warrants.

On December 31, 2020, the Company issued to Exchange Listing, LLC warrants to purchase a total of 2,500 shares of Company common stock at the exercise price $52 per share.

In April 2022, in connection with the Company's initial public offering, the Company granted the Underwriters warrants to purchase a total of 9,600 shares of the Company's common stock. The warrants are immediately exercisable at an exercise price of $50 per share and expire on the fifth anniversary of the commencement of sales under the IPO.

In November 2023, we issued warrants to purchase 45,000 shares of our common stock at an exercise price equal to $1.94 per share to investors.

In February 2024, we issued warrants to purchase 415,468 shares of our common stock at an exercise price equal to $1.2705 per share to investors.

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.

On January 27, 2021, the Company issued a promissory note in the amount of $130,560.34 to Wilson Sonsini Goodrich & Rosati. This note was paid in fully in May 2021.

On April 30, 2021, the Company issued the Amended and Restated 2015 Convertible Promissory Note with a principal amount of $117,530 and a per annum interest rate of 8%. The original note was issued on January 1, 2016 in the same principal amount. The principal amount of this note plus accrued and unpaid interest was subsequently converted in full into 4,426 shares the Company's common stock on the closing date of the Company's initial public offering at a conversion price of $40 per share.

On April 30, 2021, the Company issued the Amended and Restated 2019 Convertible Promissory Note with a principal amount of $70,000 and a per annum interest rate of 8%. The original note was issued on October 12, 2019 in the same principal amount. The principal amount of this note plus accrued and unpaid interest was subsequently converted in full into 2,408 shares the Company's common stock on the closing date of the Company's initial public offering at a conversion price of $35 per share.

On April 30, 2021, the Company issued the Convertible Promissory Note with a principal amount of $170,000 and a per annum interest rate of 8%. The principal amount of this note plus accrued and unpaid interest was subsequently converted in full into 5,245 shares the Company's common stock on the closing date of the Company's initial public offering at a conversion price of $35 per share.

On May 3, 2021, the Company issued the Amended and Restated 2019 Convertible Promissory Note with a principal amount of $200,000 and a per annum interest rate of 8%. The original note was issued on November 20, 2020 in the same principal amount. The principal amount of this note plus accrued and unpaid interest was subsequently converted in full into 6,372 shares the Company's common stock on the closing date of the Company's initial public offering at a conversion price of $35 per share.

On May 3, 2021, the Company issued the Amended and Restated 2019 Convertible Promissory Note with a principal amount of $50,000 and a per annum interest rate of 8%. The original note was issued on October 21, 2019 in the same principal amount. The principal amount of this note plus accrued and unpaid interest was subsequently converted in full into 1,717 shares of the Company's common stock on the closing date of the Company's initial public offering at a conversion price of $35 per share.

On May 7, 2021, the Company issued the Amended and Restated 2019 Convertible Promissory Note with a principal amount of $68,359 and a per annum interest rate of 8%. The original note was issued on June 12, 2019 in the same principal amount. The principal amount of this note, plus accrued and unpaid interest, was subsequently converted in full into 2,103 shares of the Company's common stock on the closing date of the Company's initial public offering at a conversion price of $40 per share.

During the period from May 17, 2021 to July 26, 2021, the Company issued an aggregate $12,177,328 of Convertible Promissory Notes to 125 investors, which accrues interest at 8% per annum from the date of issuance and are due one year from the date of issuance. Principal and interest is due in full at maturity on the notes. The notes are not prepayable without the consent of a majority of the holders. The principal amount of these notes plus accrued and unpaid interest was subsequently converted in full into 368,313 shares of the Company's common stock on the closing date of the Company's initial public offering at a conversion price of $35 per share.

In November 2023, we issued a total of $1,250,000 in secured notes to investors.

The notes 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.

Item 16. Exhibits and Financial Statement Schedules.

(a) ***Exhibits***:

EXHIBIT INDEX

Exhibit No.	Description
3.1**	Second Amended and Restated Certificate of Incorporation of the Registrant.
3.2*	Bylaws of The Registrant.
5.1	Opinion of Counsel to Registrant.
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**	Tenon Medical 2022 Equity Incentive Plan.
10.6***	Purchase Agreement dated as of July 24, 2023, by and between the Registrant and Lincoln Park Capital Fund, LLC.
10.7***	Registration Rights Agreement dated as of July 24, 2023, by and between the Registrant and Lincoln Park Capital Fund, LLC.
10.8****	Form of Securities Purchase Agreement entered into between the Registrant and investors in the February 2024 private placement.
10.9****	Form of Warrant issued in the February 2024 private placement issued by the Registrant.
10.10*****	Form of Securities Purchase Agreement entered into between the Registrant and investors in the November 2023 private placement.
10.11*****	Form of Note issued by the Registrant in the November 2023 private placement.
10.12*****	Form of Warrant issued by the Registrant in the November 2023 private placement.
16.1#	Letter from Armanino, LLP dated September 11, 2023, regarding change in accountant
21.1*	List of Subsidiaries of the Registrant.
23.1	Consent of Haskell & White LLP, dated May 10, 2024.
23.2	Consent of Armanino, LLP, dated May 10, 2024.
23.3	Consent of Counsel to Registrant (included in Exhibit 5.1).
24.1	Power of Attorney (included on the signature page hereto)
107	Filing Fee Table.

* Incorporated by reference to the Registrant's Registration Statement No. 333-260931, filed on November 10, 2021.
** Incorporated by reference to the Registrant's Registration Statement No. 333-271648, originally filed on May 4, 2023.
*** Incorporated by reference to the Registrant's Current Report on Form 8-K originally filed on July 28, 2023.
**** Incorporated by reference to the Registrant's Current Report on Form 8-K originally filed on February 22, 2024.
***** Incorporated by reference to the Registrant's Current Report on Form 8-K originally filed on November 28, 2023.

Previously filed.

(b) ***Financial Statement Schedules***: All schedules are omitted because the required information is inapplicable or the information is presented in the financial statements and the related notes.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933, as amended (the "Securities Act");

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first

use.

(5) That for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to any charter provision, by law or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of New York, State of New York, on May 10, 2024.

TENON MEDICAL, INC.

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Steven M. Foster and Steven Van Dick, or either of them, as his true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Registration Statement (including post-effective amendments and any related registration statements filed pursuant to Rule 462 and otherwise), and to file the same with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents and full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming that said attorney-in-fact and agent, or any substitute or resubstitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Position	Date
/s/ Steven M. Foster Steven M. Foster	Chief Executive Officer and President, Director (Principal Executive Officer)	May 10, 2024
/s/ Richard Ginn Richard Ginn	Chief Technology Officer and Director	May 10, 2024
/s/ Steven Van Dick Steven Van Dick	Chief Financial Officer (Principal Financial and Accounting Officer)	May 10, 2024
/s/ Richard Ferrari Richard Ferrari	Director	May 10, 2024

/s/ Ivan Howard Ivan Howard	Director	May 10, 2024
/s/ Kristine Jacques Kristine Jacques	Director	May 10, 2024
/s/ Robert K. Weigle Robert K. Weigle	Director	May 10, 2024
/s/ Stephen H. Hochschuler, M.D. Stephen H. Hochschuler, M.D.	Director	May 10, 2024

Exhibit 5.1

May 10, 2024

Tenon Medical, Inc.
104 Cooper Court
Los Gatos, CA 95032

RE: Registration Statement on Form S-1/A

Dear Ladies and Gentlemen,

We have acted as counsel to Tenon Medical, Inc., a Delaware corporation (the "Company"), in connection with the issuance of this opinion that relates to a Registration Statement on Form S-1 (the "Registration Statement") filed by the Company with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Securities Act"). The Registration Statement covers the resale, by the selling stockholder listed therein, from time to time pursuant to Rule 415 under the Securities Act as set forth in the Registration Statement, of 5,014,654 shares (the "Shares") of common stock, par value $0.001 per share, of the Company ("Common Stock") that have been or may be issued to Lincoln Park Capital Fund, LLC (the "Selling Stockholder") pursuant to the Purchase Agreement dated as of July 24, 2023 (the "Purchase Agreement"), by and between the Company and the Selling Stockholder. The Shares consist of: (i) 14,654 outstanding shares of Common Stock held by the Selling Stockholder as of May 9, 2024 (the "Selling Stockholder Shares") and (iii) 5,000,000 additional shares of Common Stock (the "Purchase Shares") that we may issue and sell to the Selling Stockholder from time to time at our discretion under the Purchase Agreement.

This opinion letter is being delivered in accordance with the requirements of Item 601(b)(5)(i) of Regulation S-K under the Securities Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement.

In connection with the issuance of this opinion letter, we have examined originals or copies, certified or otherwise identified to our satisfaction, of such records of the Company and such agreements, certificates and receipts of public officials, certificates of officers or other representatives of the Company and others, and such other documents as we have deemed necessary or appropriate as a basis for the opinions stated below. As to any facts relevant to the opinions stated herein that we did not independently establish or verify, we have relied upon statements and representations of officers and other representatives of the Company and of public officials.

In our examination, we have assumed (i) the genuineness of all signatures, including endorsements, (ii) the legal capacity and competency of all natural persons, (iii) the authenticity of all documents submitted to us as originals, (iv) the conformity to original documents of all documents submitted to us as facsimile, electronic, certified or photostatic copies, and the authenticity of the originals of such copies and (v) the accuracy, completeness and authenticity of certificates of public officials.

Based upon the foregoing and subject to the qualifications and assumptions stated herein, we are of the opinion that:

1. The Selling Stockholder Shares have been duly authorized and are validly issued, fully paid, and non-assessable.

2. The Purchase Shares have been duly authorized by all requisite corporate action on the part of the Company under the Delaware General Corporation Law ("DGCL") and, when the Purchase Shares are delivered and paid for in accordance with the terms of the Purchase Agreement and when evidence of the issuance thereof is duly recorded in the Company's books and records, the Purchase Shares will be validly issued, fully paid and non-assessable.

Our opinion is expressly limited to the matters set forth above, and we render no opinion, whether by implication or otherwise, as to any other matters relating to the Company, the Selling Stockholder Shares, the Purchase Shares, the Purchase Agreement or any other agreements or transactions that may be related thereto or contemplated thereby. We are expressing no opinion as to any obligations that parties other than the Company may have under or in respect of the Selling Stockholder Shares, the Purchase Shares or as to the effect that their performance of such obligations may have upon any of the matters referred to above. No opinion may be implied or inferred beyond the opinion expressly stated above.

The opinion we render herein is limited to those matters governed by the DGCL as of the date hereof and we disclaim any obligation to revise or supplement the opinion rendered herein should the above-referenced laws be changed by legislative or regulatory action, judicial decision or otherwise. We express no opinion as to whether, or the extent to which, the laws of any particular jurisdiction apply to the subject matter hereof.

This opinion letter is rendered as of the date first written above, and we disclaim any obligation to advise you of facts, circumstances, events or developments that hereafter may be brought to our attention or that may alter, affect or modify the opinion expressed herein.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement. We also hereby consent to the reference to our firm under the heading "Legal Matters" in the Registration Statement. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the General Rules and Regulations under the Securities Act. It is understood that this opinion is to be used only in connection with the offer and sale of the Selling Stockholder Shares and the Purchase Shares being registered while the Registration Statement is effective under the Securities Act.

Very truly yours,

/s/ Sichenzia Ross Ference Carmel LLP
Sichenzia Ross Ference Carmel LLP

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Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Form S-1 Registration Statement of Tenon Medical, Inc. (the "Company") of our report dated March 29, 2024, relating to our audit of the Company's consolidated financial statements as of December 31, 2023, and for the year then ended, included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which report includes an explanatory paragraph expressing substantial doubt regarding the Company's ability to continue as a going concern.

We also consent to the reference to us under the heading "Experts."

/s/ HASKELL & WHITE LLP

HASKELL & WHITE LLP

Irvine, California
May 10, 2024

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Registration Statement of Tenon Medical, Inc. on Form S-1 of our report dated March 10, 2023, with respect to our audits of the consolidated financial statements of Tenon Medical, Inc. and Subsidiary as of December 31, 2022, and for the year then ended. We also consent to the reference of our firm under the heading “Experts” in this Registration Statement.

Armanino LLP
San Jose, California

May 10, 2024

MOORE
An independent firm associated with Moore Global Network Limited

Exhibit 107

Calculation of Filing Fee Table

Form S-1

Tenon Medical, Inc.

Table 1: Newly Registered Securities

Security Type	Security Class Title	Fee Calculation Rule	Amount to be Registered[(1)]	Proposed Maximum Offering Price per Share[(2)]	Proposed Maximum Aggregate Offering Price[(2)]	Fee Rate	Amount of Registration Fee
Equity	Common Stock, $0.001 par value per share	457(c)	5,014,654	$ 0.86	$ 4,312,602.44	0.0001476	$ 636.54
	Total Offering Amounts				$ 4,312,602.44		$ 636.54
	Total Fee Offsets[(3)]						$ -
	Net Fee Due						$ 636.54

(1) Represents 5,014,654 shares that are issuable at the option of the Registrant pursuant to a purchase agreement with the selling stockholder. The shares will be offered for resale by the selling stockholder. Pursuant to Rule 416(a) under the Securities Act of 1933 (the "Securities Act"), the registration statement of which this Exhibit 107 is a part also covers any additional number of shares of common stock issuable upon stock splits, stock dividends, dividends or other distribution, recapitalization or similar events with respect to the shares of common stock being registered pursuant to this registration statement.

(2) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act, based on average of high and low price per share of the common stock as reported on The Nasdaq Capital Market on May 3, 2024.

(3) The Registrant does not have any fee offsets.