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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

Commission File Number 001-40355

TREACE MEDICAL CONCEPTS, INC.
(Exact name of Registrant as specified in its Charter)

Delaware	**47-1052611**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
203 Fort Wade Rd, Suite 150 Ponte Vedra, Florida	**32081**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (904) 373-5940

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value	TMCI	The Nasdaq Global Select Market

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Global Select Market on June 30, 2021, was $849.9 million.

The number of shares of Registrant's Common Stock outstanding as of February 23, 2022 was 54,748,200.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2022 annual meeting of stockholders (the "2022 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2022 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

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SPECIAL NOTES REGARDING FORWARD-LOOKING STATEMENTS

As used in this Annual Report on Form 10-K ("Annual Report"), unless expressly indicated or the context otherwise requires, references to "Treace Medical Concepts," "we," "us," "our," "the Company," and similar references refer to Treace Medical Concepts, Inc. This Annual Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as codified in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

These forward-looking statements include, but are not limited to, statements about:

- the expected use of our products by physicians;
- the expected growth of our business and our organization;
- our expected uses of the net proceeds from our initial public offering ("IPO") in April 2021 and our existing cash and cash equivalents and the sufficiency of such resources to fund our planned operations;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to retain and recruit key personnel, including the continued development of a sales and marketing infrastructure;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers, some of which are single-source suppliers;
- our plans and expected timeline related to our products, or developing new products, to address additional indications or otherwise;
- our ability to manufacture sufficient quantities of our products with sufficient quality;
- our ability to obtain and maintain intellectual property protection for our products;
- our ability to identify and develop new and planned products and/or acquire new products;
- our ability to obtain, maintain and expand regulatory clearances for our products and any new products we create;
- our ability to expand our business into new geographic markets;
- our compliance with extensive Nasdaq requirements and government laws, rules and regulations both in the United States and internationally;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- the effect of the COVID-19 pandemic and its impact on our business;
- developments and projections relating to our competitors or our industry; and
- our plans to conduct further clinical trials.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Annual Report may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under "Risk Factors" and elsewhere in this Annual Report. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements.

These forward-looking statements speak only as of the date of this Annual Report. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to actual results or to changes in our expectations.

You should read this Annual Report and the documents that we reference in this Annual Report and have filed with the Securities and Exchange Commission ("SEC") as exhibits to this Annual Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

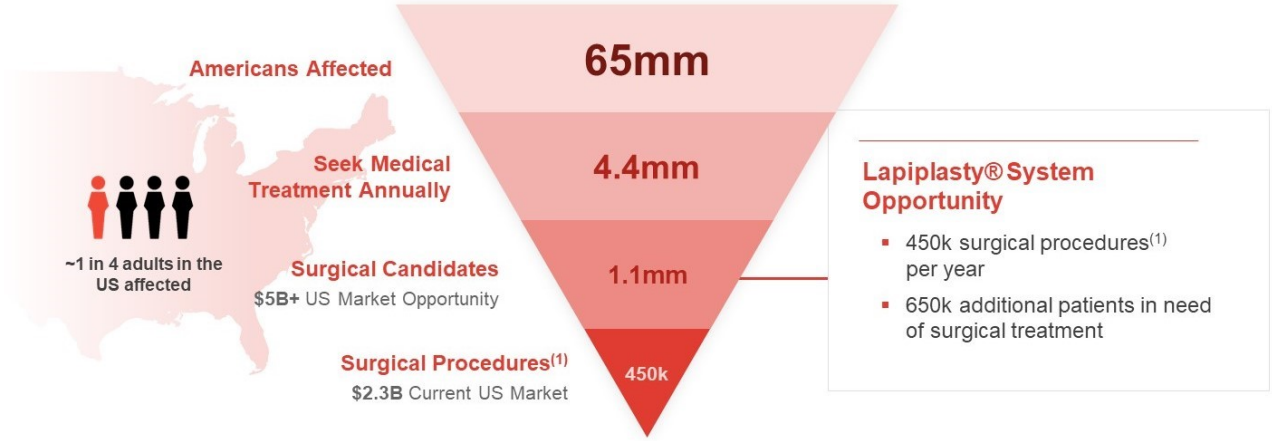
PART I

Item 1. Business.

Overview –

We are a medical technology company driving a paradigm shift in the surgical treatment of *Hallux Valgus* (commonly known as "bunions"). We have pioneered our proprietary Lapiplasty® 3D Bunion Correction System™—a combination of innovative instruments, implants and surgical methods designed to improve the inconsistent clinical outcomes of traditional approaches to bunion surgery. Although bunions are deformities typically caused by an unstable joint in the middle of the foot that leads to a three-dimensional ("3D") misalignment in the foot's anatomical structure, the majority of traditional surgical approaches focus on correcting the deformity from a two-dimensional ("2D") perspective and therefore fail to address the root cause of the disorder. To effectively restore the normal anatomy of bunion patients and improve clinical outcomes, we believe addressing the root cause of the bunion is critical and have developed the Lapiplasty System to correct the deformity across all three anatomic dimensions. Our mission is to be the leader in the surgical treatment of bunions by establishing the Lapiplasty System as the standard of care.

A bunion is a painful, disfiguring deformity characterized by a deviated position of the great toe, and easily identified visually by the "bump" at its base. Bunions affect approximately 65 million Americans, and generally increase in prevalence and severity over time. Nearly 25% of adults between the ages of 18 and 65, and over 35% of people over the age of 65, have bunions. Approximately 4.4 million patients in the United States seek medical attention for bunions annually; of these patients, an estimated 1.1 million are deemed surgical candidates, which represents a total annual addressable market opportunity of more than $5 billion. This large patient population often suffers from symptoms that worsen over time, including severe and debilitating pain, emotional burden and limited mobility, and is susceptible to further degeneration and common concomitant pathologies. Despite the significant limitations of traditional surgical treatment approaches, approximately 450,000 surgical bunion procedures are performed in the United States every year. We believe there is significant opportunity to convert these to our Lapiplasty System, representing a greater than $2.3 billion market opportunity. In addition, through better clinical outcomes and effective patient education, we believe we can increase the number of the patients who seek surgical treatment, representing the incremental opportunity of $3 billion. The chart below illustrates our annual addressable U.S. market opportunity:

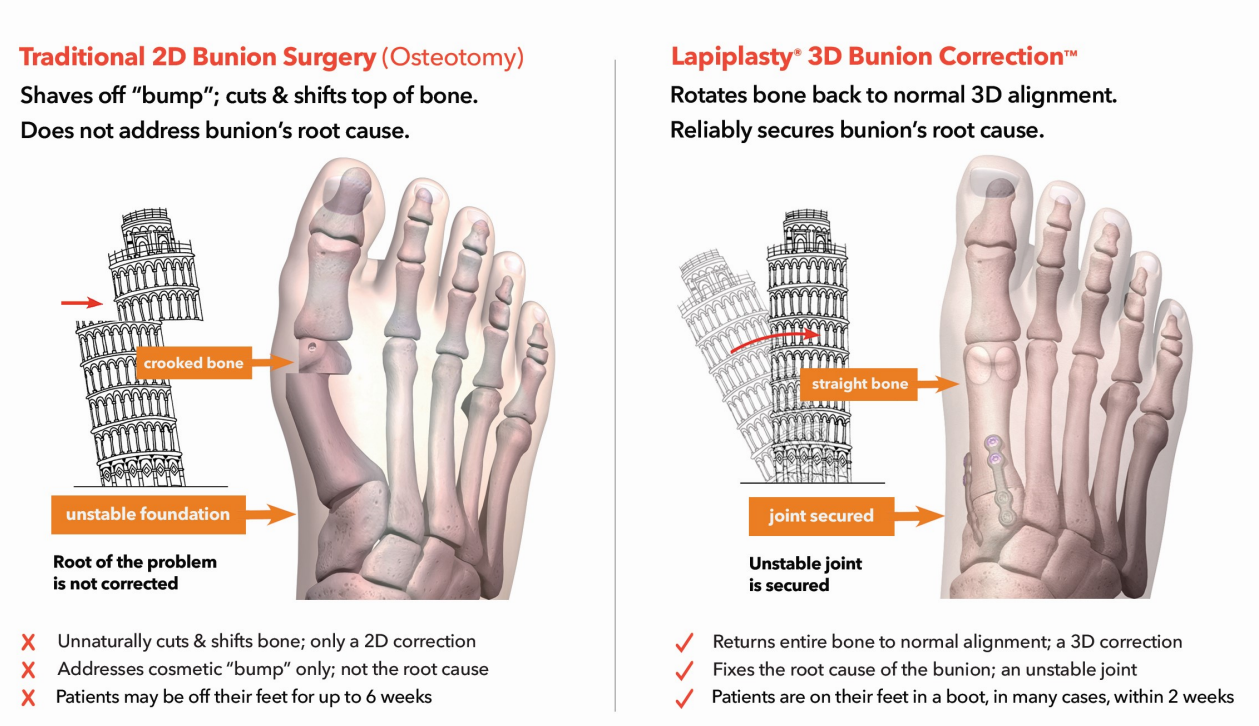


(1) Approximate number of surgical bunion procedures performed in the United States per year.

The goal of bunion surgery is to restore the normal anatomy of patients in order to return natural function and appearance in the foot and relieve pain. A common misconception is that a bunion is simply an overgrowth of bone that can be shaved off. In reality, a bunion is a complex 3D deformity caused by an unstable joint in the middle of the foot (which we may refer to as the "root cause") which causes the metatarsal bone in the foot to rotate out of alignment in all three anatomic dimensions. A 2015 study indicates that 87% of bunions have a 3D, rotational issue in addition to horizontal and vertical misalignments of the metatarsal bone. Traditional 2D approaches to bunion surgery, used in the majority of bunion surgical procedures, fail to correct this third "rotational" dimension of the bunion deformity, which has been reported to result in a 10 to 12 times increase in the chance of bunion recurrence as compared to 3D surgeries.

Historically, there have been two primary approaches to the surgical treatment of bunions, both of which fail to consistently meet patient needs and physician expectations. The first and most common approach is 2D Osteotomy surgery, which merely cuts and shifts the metatarsal bone in two dimensions, addressing the cosmetic bump rather than the root cause, which may result in high long-term recurrence rates (up to 78%) and low patient satisfaction with the procedure. The second approach, traditionally reserved for the

most advanced and severe bunion pathology is Lapidus Fusion surgery, which fuses the unstable joint but requires a technically challenging correction through a “freehand” technique which often results in inconsistent outcomes and has been reported to involve a protracted period of recovery, including approximately 6 to 8 weeks of non-weight-bearing. The freehand technique is highly dependent on the surgeon’s skill and requires the physician to perform complex corrections without the benefits of assistive instrumentation that are standard in most other orthopaedic joint procedures and, consequently, this surgery often results in inconsistent outcomes.



We believe our proprietary Lapiplasty System, the first of its kind, is the leading system designed to consistently and reliably correct all three dimensions of the bunion deformity, address the root cause of the bunion deformity, and allow rapid return to weight-bearing in a post-operative boot with low risk of recurrence (0.9% to 3.2% measured at 17 and 13 months, respectively). The Lapiplasty System combines our novel surgical approach, the Lapiplasty Procedure, with our procedural instrumentation and single-use implant kits. With help from our procedural instrumentation, the Lapiplasty Procedure is designed to rotate the entire metatarsal bone into normal anatomical position in all three dimensions, eliminating the bump and restoring normal anatomy. The unstable foundation in the foot is then secured with our titanium fixation plates and screws, allowing patients to get back on their feet quickly in a post-operative boot. The Lapiplasty Procedure can be performed in either hospital outpatient or ambulatory surgery center settings, and utilizes existing, well-established reimbursement codes. Since receiving 510(k) clearance for the Lapiplasty System in March 2015, more than 42,000 Lapiplasty procedures have been performed in the United States.

The safety, effectiveness and clinical advantages of the Lapiplasty System have been demonstrated in multiple post-market clinical outcome studies. This portfolio of studies is unique in the bunion correction field where comprehensive outcome studies are limited. Multiple peer-reviewed publications have demonstrated the ability of the Lapiplasty System to reproducibly correct all three dimensions of the deformity and allow the patient to quickly and safely return to weight-bearing in a post-operative boot while exhibiting a low rate of bunion recurrence (0.9% to 3.2% measured at 17 and 13 months, respectively). We have completed enrollment in our ALIGN3D prospective, multicenter study which is evaluating bunion correction status after two years and includes patient satisfaction scoring, range of motion results and radiographic outcomes. Interim analyses from the ALIGN3D clinical study have been presented at industry conferences, including at the American Orthopedic Foot and Ankle Society ("AOFAS") Annual Meeting in September 2021, and at the American College of Foot and Ankle Surgeons ("ACFAS") Annual Scientific Conference held on February 24-27, 2022.

To broaden our Lapiplasty offerings, we launched the Lapiplasty Mini-Incision System, which is designed to allow the Lapiplasty Procedure to be performed through a miniature, 3.5cm incision as compared to the current 6cm to 8cm incision. In addition, to address midfoot deformities, which may occur in up to 30% of bunion patients, we recently launched the Adductoplasty System. The Adductoplasty System brings together our implants and precision instrumentation for the first comprehensive system

designed for reproducible realignment, stabilization, and fusion of the midfoot. We have also commercialized new products that address ancillary surgical procedures performed routinely in connection with the Lapiplasty Procedure. We believe these ancillary product offerings will allow us to capture a higher percentage of the overall product revenue from the surgical case while also providing greater efficiency to the facility and operating room staff by reducing the number of vendors needed to support the case.

We market and sell our products in the United States through a combination of a direct employee sales force and independent sales agencies across 118 territories focused on driving adoption and supporting utilization of the Lapiplasty System among the approximately 7,800 surgical podiatrists and 2,600 orthopaedic surgeons with foot and ankle specializations in the United States. To improve clinical outcomes, we devote significant resources to training and educating physicians on the safe and effective use of the Lapiplasty System. Additionally, we have developed a differentiated direct-to-patient outreach program that educates patients on the benefits of the Lapiplasty System. We also offer a “Find a Doctor” tool on our website that allows potential patients to search for experienced Lapiplasty Procedure surgeons in their local markets. Our patient and surgeon education programs and specialized teams supporting surgeons in the field combined with the Lapiplasty System’s differentiated clinical outcomes lead to a significant increase in utilization of the Lapiplasty System per physician over time. For example, as of December 31, 2021, surgeons who performed their first Lapiplasty Procedure in the past 12 months, on average, performed 3.9 procedures during the year while surgeons who performed their first procedure in 2017 or prior, on average, performed 19.3 Lapiplasty Procedures in the past 12 months.

Our internal employee engineering personnel and our Surgeon Advisory Board help us to generate ideas and develop product innovations. Our Surgeon Advisory Board is comprised of both podiatrists and orthopaedic foot and ankle surgeons who provide us with holistic insights for developing products that fully meet the needs of each group. Our development team is focused on improving clinical outcomes by designing new procedure-specific products and by developing enhanced surgical techniques.

We have experienced considerable growth since receiving 510(k) clearance for the Lapiplasty System in March 2015. The number of Lapiplasty Procedure Kits sold increased from 7,714 in 2019 to 11,113 in 2020 to 17,490 in 2021, representing a compound annual growth rate of 50.6%, despite the adverse impact of the COVID-19 pandemic on elective procedures in 2020 and 2021. Correspondingly, our revenue increased from $39.4 million in 2019 to $94.4 million in 2021, representing a compound annual growth rate of 54.8%.

Overview of Bunions

Hallux Valgus (commonly known as "bunions") is a painful, disfiguring deformity characterized by a deviated position of the great toe. Bunions are easily identified visually by the “bump” on the joint at the base of the great toe (the metatarsophalangeal ("MTP") joint). While this “bump” is widely considered to be the source of pain in bunion sufferers, a structural defect causing misalignment in the middle of the foot is the root cause of the deformity.

Bunion deformities are most commonly considered to be the consequence of a hereditary predisposition. Prevalence increases with age, and one study found that 70% of bunion sufferers are female, and that the disorder occurs in both feet, or bilaterally, in 56% of bunion sufferers. Bunions are progressive deformities, with symptoms that typically grow in severity over time. For those with predispositions for developing bunions, constrained footwear, weight-bearing activities or occupations that aggravate the condition may accelerate progression of the joint deformity and cause symptoms to appear earlier in life. If left untreated, bunions can often have a significant long-term negative impact on sufferers, including:

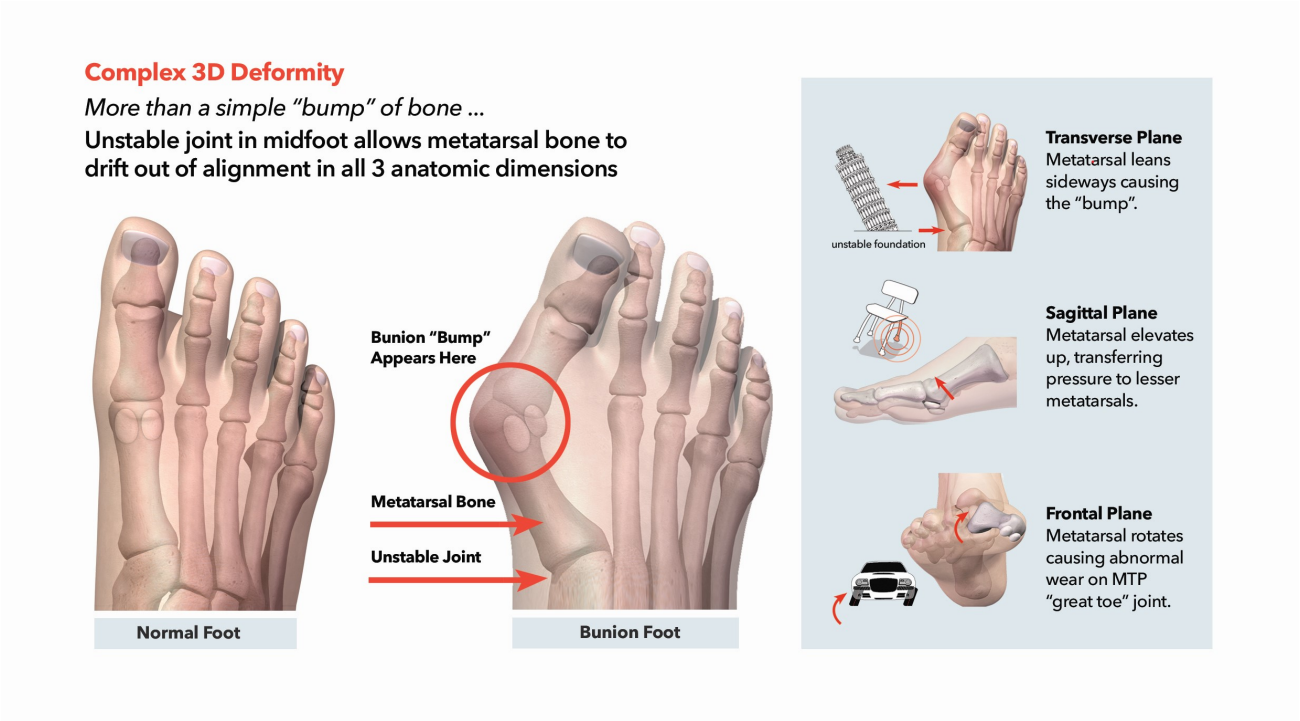
- **Severe and debilitating pain** in the bunion “bump” at the base of the great toe that can also develop in the ball of the foot.
- **Quality of life deterioration** with limited mobility, restrictions on footwear and an inability to participate in physical activities.
- **Susceptibility to additional pathologies**, such as hammertoes and arthritis of the great toe joint.
- **Increased risk of injury** as decreased stability leads to greater potential for falls.
- **Emotional burden** from becoming increasingly self-conscious about the bunions’ unsightly appearance.

A common misconception is that a bunion is simply an overgrowth of bone that can be shaved off. Bunions are in reality complex 3D deformities caused by an unstable joint in the middle of the foot (the first tarsometatarsal ("TMT") joint) which allows the metatarsal bone to drift out of alignment in three anatomic dimensions. These three anatomic dimensions and their associated misalignments are summarized below:

- **Dimension 1–Transverse Plane**: a horizontal misalignment, in which the metatarsal bone leans sideways causing the “bump.”

- **Dimension 2–Sagittal Plane**: a vertical misalignment, in which the metatarsal bone can elevate, transferring excessive pressure to other toes and ball of the foot.
- **Dimension 3–Frontal Plane**: a rotational misalignment, in which the metatarsal bone rotates causing abnormal wear on the great toe joint.

The shift in the metatarsal bone causes bone or tissue at the MTP joint to move out of place, resulting in the visual “bump” associated with bunions.



Traditional treatment options for bunion patients vary with the type and severity of each bunion. During the early stages of the disorder, pain can be managed but will typically worsen and additional symptoms may develop. The primary goal of most early treatment options is to relieve pressure on the bunion and halt the progression of the deformity. A physician may initially recommend various non-surgical treatments, including toe spacers, pads or splints, inserts or orthotics, medication or physical therapy. These options are prescribed to alleviate symptoms, but do not address the root cause of the deformity. When these non-surgical treatments fail, or when the severity of the bunion deformity progresses past the threshold for such options, surgery is often necessary.

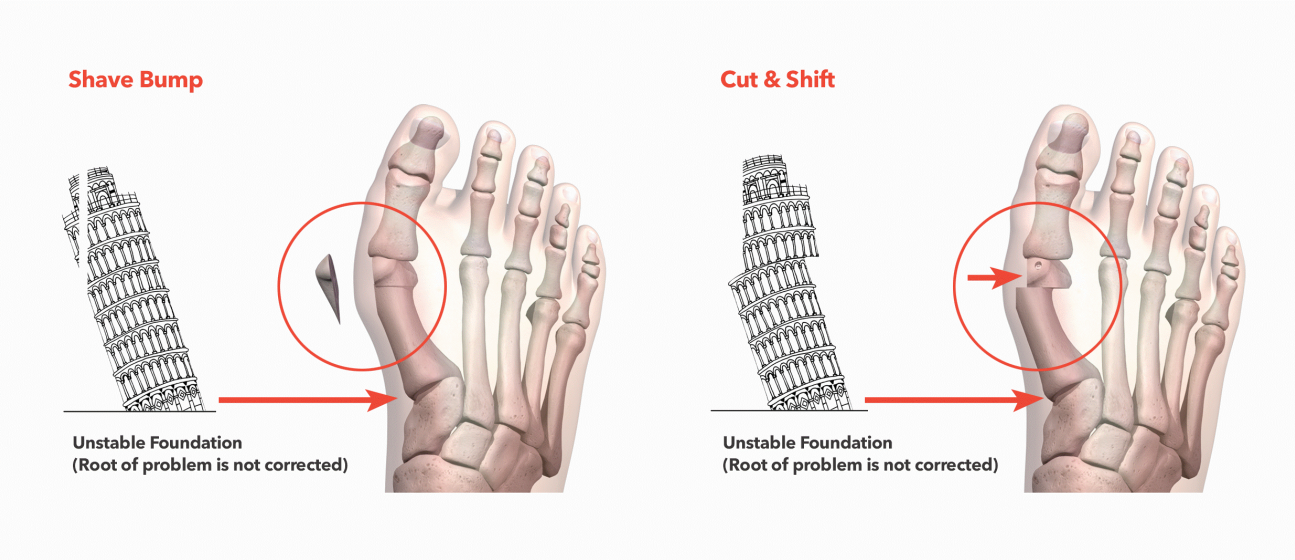
Limitations of Traditional Surgical Treatment Approaches

Historically, there have been two primary surgical approaches to bunion treatment, 2D Osteotomy and Lapidus Fusion. Between the two, approximately 450,000 bunion procedures are performed annually in the United States, of which approximately 75% are 2D Osteotomy procedures and approximately 25% are Lapidus Fusion procedures.

These traditional surgical treatment approaches are characterized by an approximately 30% patient dissatisfaction rate for 2D Osteotomy surgery and a 7% to 13% dissatisfaction rate for Lapidus Fusion following surgery. Clinical literature has identified the primary patient expectations for bunion surgery to be pain relief, shoe fit, mobility and improvement in cosmetic appearance. Certain published long-term clinical studies have demonstrated complication rates as high as 78% following 2D Osteotomy surgery and 46% following Lapidus Fusion surgery, with deformity recurrence being among the most common complications in each. While not all patients with recurrence require a secondary surgical procedure, this recurrence rate relative to other common surgical procedures is glaringly high and a significant contributor to patient dissatisfaction.

2D Osteotomy

In a 2D Osteotomy, the bunion "bump" is shaved off and the metatarsal bone of the great toe is cut in half and shifted over to reduce the appearance of the bunion. However, by failing to address the root cause of the disorder and not correcting the deformity in all three dimensions, there is an increased likelihood that the metatarsal bone will continue to drift out of position over time and for the bunion to return. Additionally, the recovery time has been reported to include up to 6 weeks of non-weight bearing.

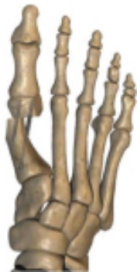
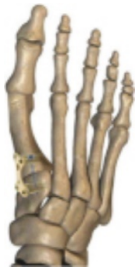


Lapidus Fusion

In contrast to 2D Osteotomy, the other common traditional surgical procedure, known as Lapidus Fusion, does address the root cause of the bunion and is routinely referenced in medical literature as a surgical option for bunions since the 1930s. However, even a Lapidus Fusion, as it is conventionally described and performed, still does not address the three dimensional rotational aspect known to contribute to bunion recurrences.

A conventional Lapidus Fusion surgery fuses the unstable first TMT joint but requires a technically challenging correction through a "freehand" technique and has been reported to involve a protracted period of recovery, including approximately 6 to 8 weeks of non-weight-bearing. The freehand technique is highly dependent on the surgeon's skill and requires the physician to perform complex corrections without the benefits of assistive instrumentation that are standard in most other orthopaedic joint procedures, and, consequently, this surgery often results in inconsistent outcomes. Thus, its use has been traditionally reserved for the most advanced and severe bunion pathology.

The table below provides a summary overview of traditional bunion surgical treatment approaches:

	2D Osteotomy	Lapidus Fusion
% of cases	Approximately 75%	Approximately 25%
Procedure overview	 Targets cosmetic bump by cutting and shifting metatarsal bone in two dimensions	 Fusion of the first TMT joint to realign the entire metatarsal and the toe joint and prevent the bunion from coming back
Procedure time	25 to 75 minutes	40 to 120 minutes
Recurrence rate	1.8% to 78%, depending on procedure type and follow-up duration	0% to 46%
Reported recovery time	1 day to 6 weeks non-weight bearing (post-operative shoe or boot, some cast)	Long recovery: 6 to 8 weeks non-weight bearing (often in a cast)
Patient dissatisfaction rate	30%	7% to 13%
Limitations	•Does not address all 3 dimensions of the deformity reliably and leaves the unstable foundation untreated	•Technically challenging “freehand” procedure increases inconsistency and variability of result •Primarily 2-plane procedure; does not address the frontal plane rotation problem consistently

While bunions have traditionally been viewed as a 2D deformity, recent scientific literature has indicated that 87% of bunions have a 3D, rotational component in addition to the horizontal and vertical misalignments of the metatarsal bone. Failure to correct this third “rotational” dimension of the bunion deformity has been reported to result in a 10 to 12 times increase in the chance of bunion recurrence as compared to 3D surgeries. We believe there is a rapidly increasing awareness among surgeons of the need for 3D bunion correction based on the frequency of lectures and medical journal publications on this topic, particularly in recent years.

Our Solution

We have pioneered our proprietary Lapiplasty 3D Bunion Correction System—a combination of innovative instruments, implants and surgical methods designed to improve the inconsistent clinical outcomes of traditional approaches to bunion surgery.

Our Lapiplasty System

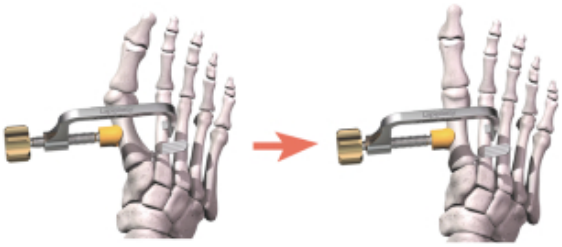
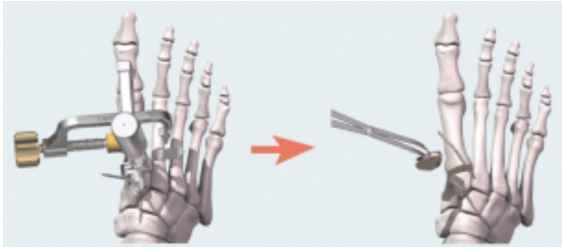
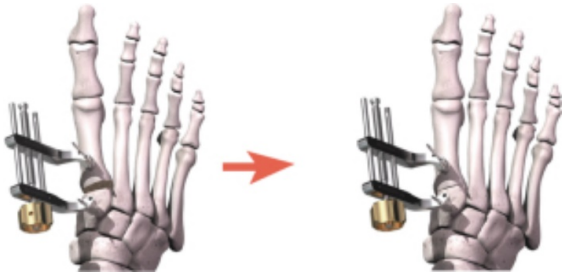
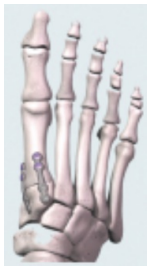
We believe our Lapiplasty System was the first and remains the leading system designed to consistently and reliably correct all three dimensions of the bunion deformity, address the root cause and allow rapid return to weight-bearing in a post-operative boot. In a Lapiplasty Procedure, the entire metatarsal bone is rotated and brought back into position in all three dimensions, eliminating the unsightly bump and restoring normal anatomy. The unstable foundation in the foot is secured with titanium plating technology allowing patients to get back on their feet quickly in a post-operative boot. The Lapiplasty Procedure can be performed on a wide range of patients with bunion deformities in the hospital outpatient or ambulatory surgery center setting, and utilizes existing, well-established reimbursement codes.

The Lapiplasty System includes both procedural instrumentation and single-use, sterile-packed implant kits. Our procedural instrumentation includes innovative surgical tools that enable surgeons to correct all three dimensions of the bunion deformity and the root cause of bunions with accuracy and consistency. Our single-use, sterile-packed implant kits feature biplanar plating, which are two low-profile titanium fixation plates designed to stabilize the TMT joint and to allow early weight-bearing in a post-operative boot during the critical healing period.

The following table illustrates key components of the Lapiplasty System:

Reusable Procedural instrumentation		Sterile-packed implant kits
Lapiplasty Positioner	**Lapiplasty Compressor**	**Sterile Implants and Instruments**
		
Engineered to quickly and reproducibly correct metatarsal alignment in all three dimensions	*Delivers controlled compression to the precision-cut joint surfaces, while maintaining the three-dimensional correction*	*Single-use implants and instruments used in the Lapiplasty Procedure and ancillary procedures*
Lapiplasty Cut Guide and Fulcrum	**Lapiplasty Light-Weight Tray**	**Biplanar Plating**
		
Delivers precise cuts with the metatarsal held in the corrected position, ensuring optimal cut trajectory	*Includes the Positioner, Compressor and Cut Guide and Fulcrum*	*Provides biomechanically-tested biplanar stability, which are designed to allow rapid return to weight-bearing in a walking boot*

The following table illustrates our patented Lapiplasty System, with procedural instrumentation and implants used in each step of our proprietary Lapiplasty Procedure:

Lapiplasty System	
Correct. Make the correction *before* the cut Using the **Lapiplasty Positioner**, the entire metatarsal bone is returned to normal 3D alignment.	
Cut. Perform precision cuts with confidence Using the **Lapiplasty Cut Guide**, the unstable joint surfaces are cut in the corrected position.	
Compress. Achieve controlled compression of joint surfaces Using the **Lapiplasty Compressor**, the two bone surfaces are brought together while 3D correction is maintained.	
Fixate. Apply biplanar fixation for robust stability Using **Biplanar Plating**, two titanium plates fastened at ninety degree angles, the joint is secured and stabilized, designed to allow for early return to weight-bearing in a post-operative boot while the bones fuse together.	

Our Lapiplasty Mini-Incision System

Expanding our Lapiplasty offerings, we launched the Lapiplasty Mini-Incision System, which is designed to allow the Lapiplasty Procedure to be performed through a miniature, 3.5cm incision as compared to the current 6cm to 8cm incision. Some patients prefer smaller incisions that may leave less visible scars. The Lapiplasty Mini-Incision System includes a new fixation plate known as the PlantarPower Plate. This innovative plate is contoured to span across the bottom half of the joint where the loads are the highest, while still providing easy access for insertion of the plate fixation screws through a small incision. We believe the Lapiplasty Mini-Incision System offers an attractive option for patients and surgeons.

Our New Adductoplasty System

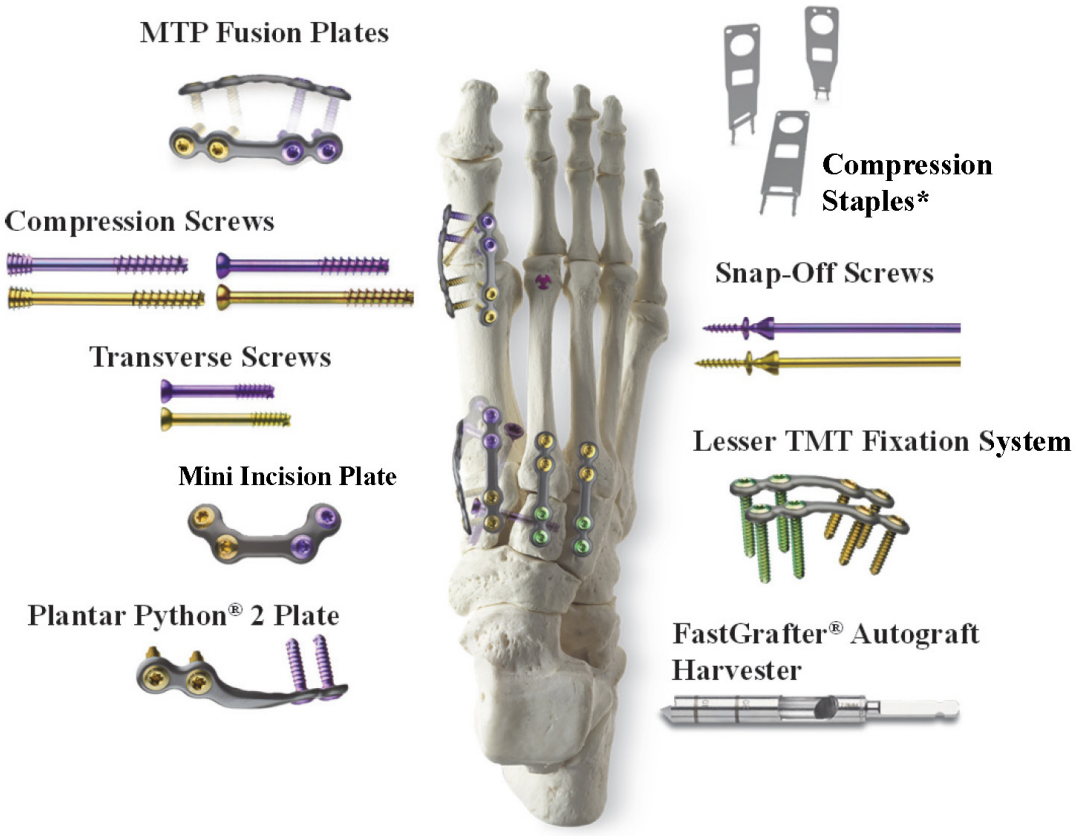
In the third quarter of 2021, we launched the Adductoplasty System, which brings together our implants and precision instrumentation for a comprehensive system designed for reproducible realignment, stabilization, and fusion of the midfoot. Midfoot deformities may occur in up to 30% of bunion patients. The Adductoplasty System includes instruments and fixation plates to be used for fusion of the second and third TMT joints, which may often be necessary in conjunction with bunion surgery.

Complementary Ancillary Products

We have also commercialized products to address ancillary surgical procedures performed routinely within a Lapiplasty surgical case, including Akin osteotomies (procedures to straighten the great toe), Weil osteotomies (procedures to shorten the lesser toes/metatarsals), intercuneiform stabilization (stabilization between the 1st & 2nd cuneiforms and 1st and 1st metatarsal & 2nd cuneiform), lesser TMT joint fusions and autograft bone harvesting, as well as for MTP (big toe joint) fusion. Providing these

ancillary products allows us to capture a higher percentage of the overall product revenue from the surgical case while providing greater efficiency and synergies to the facility and operating room staff by reducing the number of vendors needed to support the case.

These ancillary products are provided in convenient, sterile-packaged kits to allow convenient use when needed during the surgery. The following diagram depicts the ancillary products we currently offer as part of our broader portfolio:



*Distributed by Treace Medical Concepts, Inc.

Key Clinical Advantages of the Lapiplasty System

We believe that the differentiated clinical advantages of Lapiplasty will support its continued clinical adoption and help establish our Lapiplasty System as the standard of care for bunion surgery. We are committed to advancing the understanding of the Lapiplasty Procedure and its benefits to patients, surgeons, facilities and payors through clinical studies and publications in peer-reviewed literature. The Lapiplasty Procedure had been cited in 16 peer-reviewed journal publications as of December 2021.

The table below includes published results of outcomes of the two traditional bunion surgical approaches, 2D Osteotomy and Lapidus Fusion:

Key outcomes	2D Osteotomy	Lapidus Fusion
Recurrence rate	1.8% – 78%	0 – 46%
Reported time to start weight-bearing	1 – 6 weeks (post-operative boot)	6 weeks – 8 weeks (cast)
Non-union rate*	0 – 4%	2 – 12%
Hardware removal rate	0 – 12%	2 – 17%

** Non-union rate is a measure of the incidence of the bones not healing together.*

The table below includes published results of our outcomes, demonstrating the effectiveness and consistency of the Lapiplasty Procedure:

Key outcomes	Lapiplasty Procedure
Recurrence rate	0.9 – 3.2%
Reported time to start weight-bearing	1 – 11 days (post-operative boot)
Non-union rate*	0 – 2.6%
Hardware removal rate	0 – 3.1%

* *Non-union rate is a measure of the incidence of the bones not healing together.*

Based on the outcomes from multiple studies, further discussed below, and our deep experience in the field of bunion surgery, we believe the key advantages of the Lapiplasty System include:

- consistent 3D deformity correction;
- addressing root cause of the deformity;
- ease and reproducibility of the procedure;
- faster return to weight-bearing post-surgery in a post-operative boot;
- consistently slimmer foot; and
- low rate of recurrence.

Our differentiated Lapiplasty System is designed to consistently and reliably correct all three dimensions of the bunion deformity and address its root cause, key clinical advantages that have been demonstrated in multiple peer-reviewed publications. A traditional 2D Osteotomy performs an incomplete correction addressing the cosmetic appearance of the bunion rather than the root cause of the deformity. Alternatively, while Lapidus Fusion does seek to address the root cause of the deformity, it does not address the 3D rotational aspect known to contribute to bunion recurrence, and involves a technically challenging “freehand” technique, which is highly dependent on the surgeon’s skill and requires the physician to perform complex corrections without the benefits of assistive instrumentation. The Lapiplasty System includes specifically engineered procedural instrumentation and implants that enable the physician to correct the bunion deformity with accuracy and consistency.

Multiple peer-reviewed publications demonstrate the clinical benefits of the Lapiplasty System. These publications demonstrate that the Lapiplasty Procedure allows patients to quickly and safely return to weight-bearing in a post-operative boot within 1 to 11 days and experience meaningfully low rates of recurrence (0.9% to 3.2% measured at 17 and 13 months, respectively). In addition, these studies indicate a low-rate in incidence of the bones not healing together (i.e., non-union rate) as well as a low rate of hardware removal. Finally, research also suggests that Lapiplasty may result in a significant decrease in post-operative bony and soft tissue width (i.e., a slimmer foot)—although not an indication for surgery, foot width reduction is often a desirable cosmetic and functional outcome and commonly associated with postoperative patient satisfaction. Given its demonstrated clinical benefits, we believe the Lapiplasty System provides a positive physician and patient experience, and through continued clinical adoption, is poised to become the standard of care for bunion surgery.

Commercial Strategy

We currently market and sell the Lapiplasty System through a combination of a direct employee sales force and independent sales agencies across 118 territories in the United States. As of December 31, 2021, we had 81 direct sales representatives and 37 independent sales agencies. In 2021, employee sales representatives generated approximately 52% of total revenue while approximately 48% came through independent sales agencies. In 2020, employee sales representatives generated approximately 35% of total revenue while approximately 65% of revenue came through independent sales agencies.

We are dedicating meaningful resources to expand our sales force and management team in the United States. We are hiring additional direct sales representatives and employee field sales management to strategically access more regions with high densities of prospective patients. We also have initiatives that are designed to further focus our independent sales channel on our products. We believe this strategy will:

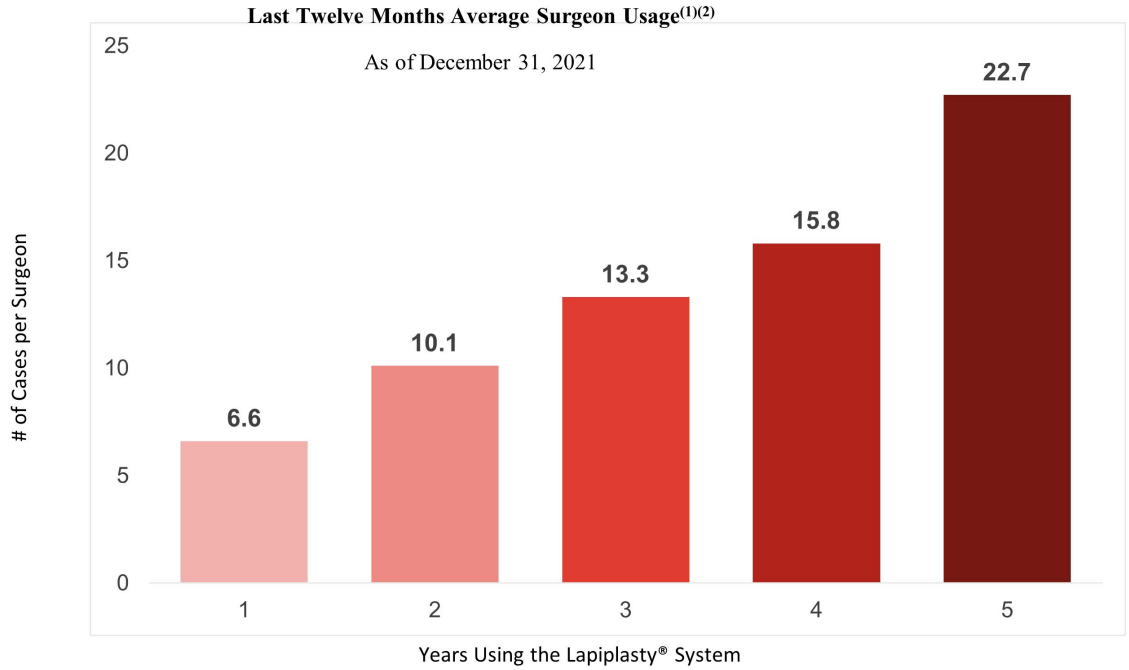
- accelerate growth and better penetrate the market with our products;
- further align incentives and allow for improved coordination of our sales team; and
- improve profitability with better operating leverage in the longer term.

We believe our surgeon education and training programs differentiate us from our competitors. We devote significant resources to training and educating physicians on the safe and effective use of the Lapiplasty System. Our comprehensive education programs include cadaveric workshops, technical assistance in the operating room and advanced training for both new and existing surgeon customers. Our multiple post-market clinical outcome studies are also unique in the bunion correction field and are a key element of our medical education program.

Our practice is to require surgeons to complete a simulated surgical training program before performing the Lapiplasty Procedure. To facilitate this training, we have developed a robust curriculum including clinical and procedural details as well as hands-on surgical workshops designed to simulate a live surgical procedure. These training events incorporate highly-skilled training personnel including experienced surgeon faculty and clinical specialists. Additionally, we host ongoing peer-to-peer advanced educational training programs to continue to develop the expertise of our surgeon customers, which include monthly online "Mastery Webinar" series and hands-on workshops with experienced faculty surgeons that cover more advanced Lapiplasty techniques and training on our newly developed products and procedures. Our training programs are complemented by 10 clinical specialists that assist with surgeon training and live surgery support with new surgeon users. We believe that our surgeon education programs are effective and they are intended to result in surgeon users improving their skill and familiarity with the Lapiplasty Procedure and improved clinical outcomes for their patients.

If our products have been approved by the surgical facility, surgeons generally can perform their first case as soon as the first day of their training. Obtaining facility approval may delay surgeon access to our products for 30 to 120 days depending on the nature of the facility (or integrated delivery network's) approval process.

Surgeon users typically increase usage of the Lapiplasty Procedure over time as they see improved clinical outcomes for their patients relative to traditional bunion surgery approaches. The bar chart below shows as of December 31, 2021 the average number of procedures performed over the trailing twelve months by surgeons based on the number of years that the surgeons have used the Lapiplasty System.



(1) Surgeons may discontinue performing cases over time. Usage shown excludes our Surgeon Advisory members.

(2) The usage in this chart represents the average surgeon utilization rate for the last twelve months. Usage information previously provided in the Registration Statement on Form S-1 provided usage in calendar years and included our Surgeon Advisory Board members. For the chart above, more than twelve months must have elapsed from the date of the surgeon's first use for the surgeon to be included in the year 1 column.

We believe our offering is differentiated by supporting surgeons with knowledgeable clinical specialists and direct sales employees who are experts in the Lapiplasty Procedure. These employees receive in-depth training to develop a thorough understanding of bunions, patient selection, procedure planning and regulatory policies to meaningfully support continued clinical adoption and existing surgeon customers. Our clinical specialists and direct sales employees participate in continuous education

programs that consist of in-person foundational training, procedure observation and sales skills development. These employees are a key resource for our surgeon customers and their expertise enables them to provide meaningful clinical and technical support in the operating room and to develop strong relationships with surgeons. We believe that our approach to supporting surgeons leads to better clinical outcomes for patients.

Our direct-to-patient outreach program is a key aspect of our commercial strategy. This program is focused on educating patients on the clinical advantages of the Lapiplasty Procedure and generating brand awareness. We are working to further establish brand recognition for Lapiplasty as the leading procedure for improving bunion treatment outcomes in an industry that has traditionally not conducted significant direct-to-patient programs. We have built a sophisticated marketing infrastructure to deliver our message in a targeted manner utilizing digital and traditional marketing channels. These programs direct potential bunion surgical candidates to our educational website that further explains the Lapiplasty Procedure and its related benefits. Our "Find a Doctor" tool allows them to search for experienced Lapiplasty Procedure surgeons in their local markets.

The following diagram illustrates our patient outreach program.

Research and Development

We devote significant resources to research and development of our products. We use internal employee engineering personnel and our Surgeon Advisory Board to generate ideas and develop product innovations. Our Surgeon Advisory Board is comprised of both podiatrists and orthopaedic foot and ankle surgeons who provide us with holistic insights for developing products that fully meet the needs of each group. Our development team is focused on improving clinical outcomes by designing new procedure-specific products and by developing enhanced surgical techniques in attractive subspecialties within the foot and ankle market.

Our initial product development and commercial efforts have been solely focused on the bunion market, and our Lapiplasty System specifically. We intend to continue iterating our core Lapiplasty System instrumentation and implants to improve surgical efficiency, enhance reproducibility of outcomes and speed up surgical recovery for patients. We are also pursuing the development and potential commercialization, if cleared, of new products that we believe would leverage and expand our position in the market to treat other concomitant pathologies that occur in a high percentage of bunion surgeries. Products provided by other companies are currently utilized in some of our Lapiplasty Procedure cases to treat these concomitant conditions. Providing these ancillary products allows us to capture a higher percentage of the overall product revenue from the surgical case while providing greater efficiency and synergies to the facility and operating room staff by reducing the number of vendors needed to support the case.

For the fiscal years ended December 31, 2021, 2020 and 2019, our research, development and clinical expenses were $10.2 million, $5.8 million and $5.1 million, respectively.

Coverage and Reimbursement

The Lapiplasty Procedure is performed by foot and ankle surgeons in both hospital outpatient facilities and ambulatory surgery centers. Hospitals, ambulatory surgery center and surgeons that purchase or use our products generally rely on third-party payors to reimburse for all or part of the costs and fees associated with procedures using our products. As a result, sales of our products depend, in part, on the extent to which the procedures using our products are covered by third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Based on historical claims data from 2017, approximately 63% of Lapidus cases and 60% of all bunion surgical cases were paid by private payors.

Medicare publishes national average rates for each procedure in the hospital outpatient and ambulatory surgery center settings. Medicare rates for procedures involving our products may vary from national averages due to geographic location, the nature of facility in which the procedure is performed (i.e., teaching or community hospital) and other factors. While private payors vary in their coverage and payment policies, many use coverage and payment by Medicare as a benchmark to make their own decisions.

Coding and Reimbursement

When procedures using our products are performed in hospital outpatient or ambulatory surgery center settings, both the surgeon and the health care facility submit claims (bills) for payment to the third-party payor using established medical codes (e.g., CPT codes, diagnosis codes and HCPCS codes) that describe the patient history and medical and surgical treatments. Obtaining appropriate payment for services is dependent in part on the physician and health care facility reporting or billing the CPT code that accurately describes the procedures performed in the case.

The table below sets forth the established CPT Codes that are commonly used for Lapidus-type and midfoot fusion surgeries, including the Lapiplasty and Adductoplasty Procedures.

Established CPT Codes	
CPT 28297	Correction, bunionectomy, with sesamoidectomy, when performed; with first metatarsal and medial cuneiform joint arthrodesis, any method
CPT 28730	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse
CPT 28740	Arthrodesis, midtarsal or tarsometatarsal, single joint
CPT 28735	Arthrodesis, midtarsal or tarsometatarsal, multiple or transverse; with osteotomy (e.g., flatfoot correction)

Bunion surgery also often involves multiple concomitant procedures, including Akin osteotomy, Weil osteotomy and hammertoe correction, for example. Each concomitant procedure has an applicable CPT code used for billing third-party payors, which is submitted on the same claim with the Lapiplasty Procedure for reimbursement.

Intellectual Property

We actively seek to protect the technology, inventions and improvements that we consider important to our business using patents, trade secrets, trademarks and copyrights in the United States and foreign markets.

As of December 31, 2021, our patent portfolio included 31 owned U.S. patents and one licensed patent. All of these patents are U.S. utility patents. The owned patents cover core Lapiplasty-related hardware and surgical techniques as well as other associated innovations, including the main surgical techniques used by the Lapiplasty Procedure as well as associated tools, techniques and/or implants used during the procedure. We have not been involved in any contested proceedings regarding our granted patents nor have we received any third-party claims related to the patents.

As of December 31, 2021, we had 56 pending patent applications globally, including 31 in the United States. Outside of the United States we have patent applications pending in Australia, Canada, Europe (before the European Patent Office) and Japan as well as through the Patent Cooperation Treaty ("PCT"). Our owned patents expire in 2035 or later. We have also obtained an exclusive license with respect to a third-party United States patent application that has now matured into a granted patent. This licensed patent expires in 2034. The pending patent applications are intended to exclude competitors from practicing the innovations of our currently marketed product offering and to protect potential future commercialization opportunities and to strategically block potential workarounds by competitors.

We have U.S. trademark registrations for several of our most important marks, including “Treace Medical Concepts®”, the “Treace Medical Concepts®” logo, “Lapiplasty®”, “Fast Grafter®” and “Plantar Python®”. We also have pending U.S. trademark registrations on other valuable marks, including “Align My Toe™”, “The Future of Hallux Valgus™”, “The Leader in Hallux Valgus Surgery™” and “Fix It Right The First Time™”.

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 is generally 20 years from the earliest claimed filing date of a nonprovisional patent application in the applicable country. We cannot assure that patents will be issued from any of our pending applications or that,

if patents are issued, they 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 treatment methods or devices that are not covered by our patents. Furthermore, numerous U.S. and foreign-issued patents and patent applications owned by third parties exist in the fields in which we have commercialized and are developing products. Because patent applications can take many years to issue, there may be applications unknown to us, which applications may later result in issued patents that our existing or future products or technologies may be alleged to infringe.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. In the future, we may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. Litigation could be costly and could divert our attention from other functions and responsibilities. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market.

Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties and could prevent us from manufacturing, selling or using our product or techniques, any of which could severely harm our business.

Our knowledge and experience, creative product development, marketing staff and trade secret information, with respect to manufacturing processes, materials and product design, are as important as our patents in maintaining our proprietary product lines. As a condition of employment, we require all employees and key contractors to execute an agreement obligating them to maintain the confidentiality of our proprietary information and assign to us inventions and other intellectual property created during their employment. For more information, refer to Item 1A, "Risk Factors—Risks Related to Intellectual Property".

Royalty and License Agreements

We have entered into product development and fee for service agreements with members of our Surgeon Advisory Board that specify the terms under which the member is compensated for his or her consulting services and grants us rights to the intellectual property created by the member in the course of such services. As products are commercialized with the assistance of members of the Surgeon Advisory Board, we may agree to enter into a royalty agreement if the member's contributions to the product are novel, significant and innovative.

We have entered royalty agreements with certain members of our Surgeon Advisory Board providing for royalties based on each individual's level of contribution. Each royalty agreement: (i) confirms the irrevocable transfer to us of all pertinent intellectual property rights; (ii) sets the applicable royalty rate; (iii) sets the period of time during which royalties are payable; (iv) is for a term of three years, renewable by the parties, and may be terminated by either party on 90 days' notice for convenience (provided that if terminated by the Company for convenience the obligation to pay royalties is not affected); and (v) prohibits the payment of royalties on products sold to entities and/or individuals with whom the surgeon advisor or any other surgeon advisor entitled to royalties is affiliated. Each of the royalty agreements may be subsequently amended to add the license of additional intellectual property covering new products, and as a result, multiple royalty rates and duration of royalty payments may be included in one royalty agreement.

As of December 31, 2021, our royalty agreements provide for (i) royalty payments for 10 years from first commercial sale of the relevant product and (ii) a royalty rate for each such agreement ranging from 0.5% to 3% of net sales for the particular product to which the surgeon contributed.

We paid royalties of $4.3 million, $2.4 million and $1.4 million for the years ended December 31, 2021, 2020 and 2019, respectively, resulting in an aggregate royalty rate of 4.6%, 4.1% and 4.3% for the years ended December 31, 2021, 2020 and 2019, respectively.

Manufacturing and Supply

We currently leverage third-party manufacturing relationships to ensure low cost production while maintaining a capital efficient business model. We have no long-term supply contracts and multiple sources of supply for critical components of the Lapiplasty System. Our supply agreements do not have minimum manufacturing or purchase obligations. As such, we have no obligations to buy any given quantity of products, and our suppliers have no obligation to sell us or to manufacture for us any given quantity of our products or components for our products. In most cases, we have redundant manufacturing capabilities for each of our products. To date, we have not experienced any significant difficulty obtaining our products or components for our products necessary to meet demand, and we have only experienced limited instances where our suppliers had difficulty supplying products by the

requested delivery date. We believe manufacturing capacity is sufficient to meet market demand for our products for the foreseeable future.

The suppliers for the Lapiplasty System and our other products are evaluated, qualified and approved through our supplier management program, which includes various evaluations, assessments, qualifications, validations, testing and inspection to ensure the supplier can meet acceptable quality requirements. We implement a robust change control policy with our key suppliers to ensure that no component or process changes are made without our prior approval.

Order quantities and lead times for components purchased from suppliers are based on our forecasts derived from both historical demand and anticipated future demand. Lead times for components may vary depending on the size of the order, time required to fabricate, specific supplier requirements and current market demand for the components, sub-assemblies and materials.

Competition

Our industry is competitive, subject to technological change and significantly affected by new product introductions and market activities of other industry participants. Our existing products are, and any future products we commercialize will be, subject to competition. We believe the principal competitive factors in our markets include:

- The quality of outcomes and adverse event rates.
- Patient experience, including patient recovery time and level of discomfort.
- Acceptance by surgeons, hospitals and other health care providers.
- Physician learning curves and willingness to adopt new techniques.
- Ease of use and reliability.
- Strength of clinical evidence.
- Economic benefits and cost savings.
- Strength and scope of intellectual property protections.
- Effective distribution and marketing to surgeons and potential patients.
- Product price and qualification for coverage and reimbursement.
- A highly specialized and focused sales force.
- Speed to market.
- Surgeon training and medical education programs.

Our competition includes medical device manufacturers in the orthopaedic foot and ankle market. Stryker Corporation is currently the leader in the orthopaedic foot and ankle market and has significant market share following its acquisition of Wright Medical in November 2020. Additional companies operating in the orthopaedic foot and ankle market specifically focused on 3D Lapidus surgery include CrossRoads Extremity Systems, Nextremity Solutions, Inc., Zimmer Biomet Holdings, Inc., Paragon 28, Inc. and Fusion Orthopedics, LLC. We also compete with companies in the orthopaedic foot and ankle market that manufacture ancillary products, including DePuy Synthes Products, Inc., a Johnson & Johnson subsidiary, Arthrex, Inc., Smith & Nephew, In2Bones Global, Inc. and Exactech, Inc. While foot and ankle product sales represent a relatively small percentage of our larger competitors' overall sales, many recognize the growth opportunities in this market and have been active in product additions through both internal development efforts and acquisitions.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified research & development, sales, marketing and management personnel, establishing clinical sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors. In addition to competing for market share for the Lapiplasty Procedure, we also compete against these companies for personnel, including qualified personnel that are necessary to grow our business.

Finally, we may compete with medical device manufacturers outside the United States if and when we pursue plans to market our products internationally. Among other competitive advantages, such companies may have more established sales and marketing programs and networks, established relationships with health care professionals and greater name recognition in such markets.

Government Regulation

Our products and our operations are subject to extensive regulation by the U.S. Food and Drug Administration (FDA) and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. Our products are subject to regulation as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act ("FDCA") as implemented and enforced by the FDA.

United States Regulation

The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, or FDA approval of a premarket approval application ("PMA"). Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation ("QSR"), facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified but are subject to FDA's premarket notification and clearance process in order to be commercially distributed. Our currently marketed products are Class I exempt devices and Class II devices subject to 510(k) clearance.

510(k) Clearance Marketing Pathway

Certain of our current products are subject to premarket notification and clearance under section 510(k) of the FDCA. To obtain 510(k) clearance, we must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed before May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months, but may take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees for medical device establishments. For fiscal year 2022, the standard user fee for a 510(k) premarket notification application is $12,745.

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.

After a device receives 510(k) 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) clearance or, depending on the modification, PMA approval or *de novo* classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), *de novo* classification or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance,

approval of a PMA, or issuance of a *de novo* classification. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. These proposals have not yet been finalized or adopted, although the FDA may work with Congress to implement such proposals through legislation.

More recently, in September 2019, the FDA issued revised final guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list of device types appropriate for the "safety and performance based" pathway and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

PMA Approval Pathway

Class III devices require PMA approval before they can be marketed, although some pre-amendment Class III devices for which FDA has not yet required approval of a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR. PMA applications are also subject to the payment of user fees, which for fiscal year 2022 includes a standard application fee of $374,858.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness. None of our products are currently marketed pursuant to a PMA.

Clinical Trials

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption ("IDE") regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective before commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials, but must still comply with abbreviated IDE requirements when conducting such trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board ("IRB") for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, the sponsor, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-Market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;

- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Manufacturing processes for medical devices are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. Failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of marketed products. The discovery of previously unknown problems with any marketed products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

Coverage and Reimbursement

In the United States, our currently approved products are commonly treated as general supplies utilized in orthopaedic surgery and if covered by third-party payors, are paid for as part of the surgical procedure. Outside of the United States, there are many reimbursement programs through private payors as well as government programs. In some countries, government reimbursement is the predominant program available to patients and hospitals. Our commercial success depends in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for the procedures during which our products are used. Failure by physicians, hospitals, ambulatory surgery centers and other users of our products to obtain sufficient coverage and reimbursement from third-party payors for procedures in which our products are used, or adverse changes in government and private third-party payors' coverage and reimbursement policies could materially adversely affect our business, financial condition, results of operations and prospects.

Based on our experience to date, third-party payors generally reimburse for the surgical procedures in which our products are used only if the patient meets the established medical necessity criteria for surgery. Some payors are moving toward a managed care system and control their health care costs by limiting authorizations for surgical procedures, including elective procedures using our devices. Although no uniform policy of coverage and reimbursement among payors in the United States exists and coverage and reimbursement for procedures can differ significantly from payor to payor, reimbursement decisions by particular third-party payors may depend upon a number of factors, including the payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific indication;
- cost effective; and
- neither experimental nor investigational.

Third-party payors are increasingly auditing and challenging the prices charged for medical products and services with concern for upcoding, miscoding, using inappropriate modifiers, or billing for inappropriate care settings. Some third-party payors must approve coverage for new or innovative devices or procedures before they will reimburse health care providers who use the products or therapies. Even though a new product may have been cleared for commercial distribution by the FDA, we may find limited demand for the product unless and until reimbursement approval has been obtained from governmental and private third-party payors.

A key component in ensuring whether the appropriate payment amount is received for physician and other services, including those procedures using our products, is the existence of a Current Procedural Terminology ("CPT"), code, to describe the procedure in which the product is used. To receive payment, health care practitioners must submit claims to insurers using these codes for payment for medical services. CPT codes are assigned, maintained and annually updated by the American Medical Association and its CPT Editorial Board. If the CPT codes that apply to the procedures performed using our products are changed or deleted, reimbursement for performances of these procedures may be adversely affected.

In the United States, some insured individuals enroll in managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs pay their providers on a per capita (patient) basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month and, consequently, may limit the willingness of these providers to use our products.

We believe the overall escalating cost of medical products and services being paid for by the government and private health insurance has led to, and will continue to lead to, increased pressures on the health care and medical device industry to reduce the costs of products and services. All third-party reimbursement programs are developing increasingly sophisticated methods of controlling health care costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, requiring second opinions before major surgery, careful review of bills, encouragement of healthier lifestyles and other preventative services and exploration of more cost-effective methods of delivering health care.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement levels. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our products are used. These updates could directly impact the demand for our products.

Health Care Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality or expanding access. Current and future legislative proposals to further reform health care or reduce health care costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any health care reform initiative implemented in the future could impact our revenue from the sale of our products.

In the United States, the implementation of the Affordable Care Act ("ACA") for example, has changed health care financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The ACA, among other things, provided incentives to programs that increase the federal government’s comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain health care services through bundled payment models. Additionally, the ACA expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court’s decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to health care, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other health care reform measures of the Biden administration will impact our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013

and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, unless additional Congressional action is taken. However, due to COVID-19 relief legislation, the 2% reduction has been temporarily suspended from May 1, 2020 through March 31, 2022, and from April 2022 through June 2022, a 1% sequester cut will be in effect, with the full 2% reduction resuming thereafter. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models, such as accountable care organizations.

We expect additional state and federal health care reform measures to be adopted in the future, particularly in light of the new presidential administration, some of which could limit the amounts that federal and state governments will pay for health care products and services, which could result in reduced demand for our products or additional pricing pressure.

Federal, State and Foreign Fraud and Abuse and Physician Payment Transparency Laws

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal and state laws restrict our business practices. These laws include, without limitation, foreign, federal, and state anti-kickback and false claims laws, as well as transparency laws regarding payments or other items of value provided to health care providers.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal health care programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered business, the federal Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The majority of states also have anti-kickback laws which establish similar prohibitions and, in some cases, may apply more broadly to items or services covered by any third-party payor, including commercial insurers and self-pay patients.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, 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 federal civil False Claims Act. Private parties may initiate "qui tam" whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit.

In addition, the civil monetary penalties statute, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program.

HIPAA also created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care 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 health care benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Additionally, there has been a recent trend of increased foreign, federal, and state regulation of payments and transfers of value provided to health care professionals or entities. The federal Physician Payments Sunshine Act imposes annual reporting requirements on certain drug, biologics, medical supplies and device manufacturers for which payment is available under Medicare, Medicaid or

CHIP for payments and other transfers of value provided by them, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Certain foreign countries and U.S. states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to health care professionals and entities.

Penalties for violation of any of the health care laws described above or any other governmental regulations that apply to us include, without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of an entity's operations.

Data Privacy & Security

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Employees and Human Capital Resources

As of December 31, 2021, we had 248 full-time employees. We believe that the success of our business will depend, in part, on our ability to attract and retain qualified personnel. None of our employees are represented by a labor union or are a party to a collective bargaining agreement and we believe that our employee relations are good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Facilities

We currently lease approximately 23,060 square feet for our corporate headquarters located in Ponte Vedra, Florida under a lease agreement which terminates in August 2026. We believe that this facility is sufficient to meet our current and anticipated needs in the near term and that additional space can be obtained on commercially reasonable terms as needed. Refer to Note 13, "Subsequent Events", for more information on plans related to our headquarters building.

Item 1A. Risk Factors.

Our business involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including our audited consolidated financial statements and the related notes, Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Special Notes Regarding Forward-Looking Statements." The risks described below are not the only ones facing us. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations, future prospects and stock price.

Risk Factors Summary

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. The below summary is qualified in its entirety by the more complete discussion of such risks and uncertainties that follows this summary.

- We have incurred losses in the past and may be unable to achieve or sustain profitability in the future.
- We operate in a very competitive business environment, and if we are unable to compete successfully against our existing or potential competitors, our business, financial condition and results of operations may be adversely affected.

- The ongoing global COVID-19 pandemic has adversely affected, and may continue to adversely affect, our business, financial condition and results of operations.
- If hospitals, ambulatory surgery centers and other health care facilities do not approve the use of our products, our sales may not increase.
- If adequate levels of reimbursement from third-party payors for procedures using our products are not obtained or maintained, surgeons and patients may be reluctant to use our products and our business will suffer.
- We may be unable to continue to successfully demonstrate to surgeons or key opinion leaders the merits of our products and technologies compared to those of our competitors, which may make it difficult to establish our products and technologies as a standard of care and achieve market acceptance.
- If we are unable to obtain significant patent protection for our products, or if our patents and other intellectual property rights do not adequately protect our products, our competitors could develop and commercialize products similar or identical to ours and we may be unable to gain significant market share and be unable to operate our business profitably.
- Although we are not presently a party to lawsuits or administrative proceedings involving patents or other intellectual property, the possibility exists that we may be in the future. If we were to lose any future intellectual property lawsuits, a court could require us to pay significant damages and/or prevent us from selling our products.
- We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties or other strategic alliances, and the failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.
- Our relationships with customers, physicians and third-party payors are subject to federal and state health care fraud and abuse laws, false claims laws, physician payment transparency laws and other health care laws and regulations. If we or our employees, independent contractors, consultants, commercial partners, or vendors violate these laws we could face substantial penalties.
- If we fail to develop and retain an effective direct sales force, or if we are unable to successfully expand our sales management and sales specialist teams, it could negatively impact our sales, and we may not generate sufficient revenue to sustain profitability.
- If surgeons fail to safely and appropriately use our products, or if we are unable to train podiatrists and orthopaedic surgeons on the safe and appropriate use of our products, we may be unable to achieve our expected sales, growth or profitability.
- If we do raise additional capital, stockholders may be subject to dilution.
- A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.
- Our products must be manufactured in accordance with federal and state quality regulations and are subject to FDA inspection, and our failure to comply with these regulations could result in fines, product recalls, product liability claims, limits on future product clearances, reputational damage and other adverse impacts.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred losses in the past and may be unable to achieve or sustain profitability in the future.

We incurred net losses in each period since we commenced operations. For 2021 and 2020, we incurred net losses of $20.6 million and $4.3 million, respectively. As of December 31, 2021, we had an accumulated deficit of $41.9 million and $30.0 million of principal outstanding under our term loan agreement. We expect to continue to incur significant product development, clinical and regulatory, sales and marketing, medical education and other expenses. In addition, we expect that our general and administrative expenses will continue to increase due to the additional costs associated with being a public company. These efforts and additional expenses may be more costly than we expect, and we cannot guarantee that we will be able to increase our revenue to offset such expenses. Our revenue may decline or our revenue growth may be constrained for a number of reasons, including reduced demand for our products and services, increased competition or if we cannot capitalize on growth opportunities. We will need to generate significant additional revenue to achieve and sustain profitability and, even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our failure to achieve or sustain profitability could negatively impact the value of our common stock.

We have a limited operating history and have grown significantly in a short period of time. If we fail to manage our growth effectively, our business could be materially and adversely affected.

We formed as a medical device consulting business in July 2013, and began focusing on the foot and ankle market in January 2014. Accordingly, we have a limited operating history, which makes it difficult to evaluate our future prospects. Our operating results have fluctuated in the past, and we expect our future quarterly and annual operating results to continue to fluctuate as we focus on increasing the demand for our products and continue to develop clinical evidence to support the safety and efficacy of our Lapiplasty and Adductoplasty Systems, as well as develop new product innovations. We may need to make business decisions that could adversely affect our operating results, such as modifications to our pricing strategy, business structure or operations.

In addition, we have experienced recent rapid growth and anticipate further growth. For example, the number of our full-time employees increased from 32 as of December 31, 2017 to 248 as of December 31, 2021. This growth has placed significant demands on our management, financial, operational, technological and other resources, and we expect that our growth will continue to place significant demands on our management and other resources and will require us to continue developing and improving our operational, financial and other internal controls. In particular, continued growth increases the challenges involved in a number of areas, including recruiting and retaining sufficient skilled personnel for our direct sales force, providing adequate training and supervision to maintain our high-quality standards and preserving our culture and values. We may not be able to address these challenges in a cost-effective manner, or at all. To achieve our revenue goals, we must also successfully increase our supply of products from third party manufacturers to meet expected customer demand. In the future, we may experience difficulties with quality control, component supply and shortages of qualified personnel, among other problems. These problems could result in delays in product availability and increases in expenses. Any such delay or increased expense could adversely affect our ability to generate revenue. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure. In order to manage our operations and growth, we will need to continue to improve our operational and management controls, hiring process, reporting and information technology systems and financial internal control procedures. If we do not effectively manage our growth, we may not be able to execute on our business plan, respond to competitive pressures, take advantage of market opportunities, satisfy customer requirements or maintain high-quality product offerings, which could have a material adverse effect on our business, financial condition and results of operations.

Additional capital, if needed, may not be available on acceptable terms, if at all.

We may require additional capital to maintain and expand our operations. Our operations are capital-intensive and are expected to increase as we expand our sales force, research and development efforts, direct to consumer education programs and product offerings. If we raise additional funds through the issuance of equity, equity-linked or debt securities, those securities may have rights, preferences or privileges senior to those of our common stock, and our existing stockholders may experience dilution. Any debt financing secured by us in the future could require that a substantial portion of our operating cash flow be devoted to the payment of interest and principal on such indebtedness, which may decrease available funds for other business activities, and could involve restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities. We cannot be certain that we will be able to obtain additional financing on favorable terms, if at all. If we cannot raise funds on acceptable terms, if and when needed, we may not be able to grow our business or respond to competitive pressures or unanticipated requirements, which could seriously harm our business.

The terms of our credit agreements require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

Under the terms of our loan agreements discussed in more detail under section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Short-Term and Long-Term Debt Obligations,” we are subject to certain affirmative and negative covenants, including (but not limited to), financial covenants related to minimum revenue and minimum liquidity, covenants limiting our ability to incur certain additional indebtedness, create certain liens, enter into a change of control transaction and make certain distributions and investments without our lenders’ consent. Our lenders may also declare us in default for certain types of events such as non-payment of debts, inaccurate representations and warranties, failure to comply with terms of material indebtedness and material agreements, bankruptcy and insolvency, a change of control and/or a material adverse change. Upon such events, our lenders could declare an event of default, which would give them the right to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, our lenders would have the right to proceed against the assets we provided as collateral under the loan agreements. For example, under our loan with Silicon Valley Bank (“SVB”), SVB would have the right to enforce liens and security interests over substantially all of our assets (excluding intellectual property) in the event of certain specified defaults under the loan with SVB. In addition, for our loan with CR Group LP (“CRG”), CRG would have the right to enforce liens and security interests in substantially all of our assets (including intellectual property) in the event of certain specified defaults under the loan with CRG, provided that the priority of such liens are subject to an intercreditor agreement between CRG and SVB. If the debt under any of our loan agreements is accelerated, we

may not have sufficient cash or be able to sell sufficient assets to repay this debt or may have to curtail our growth plans, which would harm our business and financial condition.

Risks Related to Our Business and Industry

We operate in a very competitive business environment, and if we are unable to compete successfully against our existing or potential competitors, our business, financial condition and results of operations may be adversely affected.

Our existing products and procedures are, and any new products or procedures we develop and commercialize will be, subject to intense competition. The industry in which we operate is competitive, subject to change and sensitive to the introduction of new products, procedures or other market activities of industry participants. Increasingly competitors are entering into the tri-planar bunion correction market with new instruments and implants to compete with the Lapiplasty System. Our ability to compete successfully will depend on our ability to continue to train surgeons on the Lapiplasty Procedure and gain their acceptance of the procedure, develop additional products and procedures to improve Lapiplasty and expand our product offerings that reach the market in a timely manner, receive adequate coverage and reimbursement from third-party payors and provide products that are easier to use, safer, less invasive and more effective than the products and procedures of our competitors. In addition, our ability to increase our customer base and achieve broader market acceptance of our products will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. It will negatively affect our business, financial condition and results of operations if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our products in a cost-effective manner is critical to achieving broad acceptance of our products and expanding domestically and internationally. Promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our products.

We compete with large, diversified orthopaedic companies, including Stryker Corporation, DePuy Synthes Products, Inc., a Johnson & Johnson subsidiary, Arthrex, Inc. and Smith & Nephew. Other large, diversified orthopaedic companies that may compete with us include Zimmer Biomet Holdings, Inc. and Integra LifeSciences Holdings Corporation. We also compete with smaller orthopaedic companies. We also face potential competition from many different sources, including academic institutions, governmental agencies and public and private research institutions.

At any time, these competitors and other potential market entrants may develop new products, procedures or treatment alternatives that could render our products obsolete or uncompetitive. In addition, one or more of such competitors may gain a market advantage by developing and patenting competitive products, procedures or treatment alternatives earlier than we can, obtaining regulatory clearances or approvals more rapidly than we can or selling competitive products at prices lower than ours. If medical research were to lead to the discovery of alternative therapies or technologies that improve or cure bunions as an alternative to surgery, such as by natural correction of the unstable joint in the middle of the foot, the use of pharmaceuticals or breakthrough bio-technological innovations or therapies, our profitability could suffer through a reduction in sales or a loss in market share to a competitor. The discovery of methods of prevention or the development of other alternatives to the Lapiplasty Procedure could result in decreased demand for our products and, accordingly, could have a material adverse effect on our business, financial condition and results of operations. Many of our current and potential competitors have substantially greater sales and financial resources than we do. These competitors may also have more established distribution networks, a broader offering of products, entrenched relationships with surgeons and distributors or greater experience in launching, marketing, distributing and selling products or treatment alternatives.

We also compete with our competitors to engage the services of independent sales agencies, both those presently working with us and those with whom we hope to work with as we expand. In addition, we compete with our competitors in acquiring technologies and technology licenses complementary to our products or procedures or advantageous to our business. If we are unable to compete successfully against our existing or potential competitors, our business, financial condition and results of operations may be adversely affected, and we may not be able to grow at our expected rate, if at all.

If we fail to develop and retain an effective direct sales force, or if we are unable to successfully expand our sales management and sales specialist teams, it could negatively impact our sales, and we may not generate sufficient revenue to sustain profitability.

Our revenue and profitability is directly dependent upon the sales and marketing efforts of our sales management and sales specialist teams. In order to expand our business, we are building a substantial direct sales force. We believe it is necessary to utilize sales management and sales specialist teams that have strong sales leadership and technical background specializing in sales and marketing of products for foot and ankle surgery procedures. As we increase our marketing efforts, we will need to retain, develop and

grow the number of direct sales personnel that we employ. We intend to make a significant investment in recruiting and training sales representatives and clinical representatives as we expand our business. There is significant competition for sales personnel experienced in relevant medical device sales. Once hired, the training process is lengthy because it requires significant education for new sales representatives and clinical specialists to achieve the level of clinical competency with our products expected by surgeons. Upon completion of the training, our sales representatives typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our products often requires or benefits from direct support from us, including through our experienced sales representatives that provide assistance in the operating room. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled members of our sales management and sales specialist teams with significant technical knowledge in various areas. If we are unable to attract, motivate, develop and retain a sufficient number of qualified sales personnel, and if our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect and our financial performance will suffer. Also, to the extent we hire personnel from our competitors, we may have to wait until applicable non-competition provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories, and we have been in the past, and may be subject to future allegations that these new hires have been improperly solicited, and that they have divulged to us proprietary or other confidential information of their former employers. Additionally, because the market for experienced sales personnel is competitive, our competitors may try to hire our sales personnel away from us. If successful, we would be required to dedicate resources to recruiting, filling and training those vacant positions. We may also be vulnerable to poaching of our sales personnel from our competitors. Any of these risks may adversely affect our business.

The ongoing global COVID-19 pandemic has adversely affected, and may continue to adversely affect, our business, financial condition and results of operations.

Our operations have been impacted by the novel coronavirus (“COVID-19”) pandemic beginning in 2020. In response to COVID-19 in March 2020, certain states within the United States implemented shelter-in-place rules requiring certain businesses not deemed “essential” to close and requiring elective procedures to be delayed. Our revenue growth was adversely impacted, particularly by the government-mandated restrictions on elective procedures, from March 2020 through May 2020. Even after government-mandated restrictions on elective surgeries have ended, patients continue to delay or forego bunion surgery procedures to avoid hospitals and ambulatory surgical centers and comply with quarantine and/or similar directives from local and national health and government officials. Despite some recovery, this reduction in sales, as compared to original expectations, has continued. In the third quarter of 2021, we experienced a softening in the demand for procedures as hospital capacity was constrained as a result of hospital staffing shortages and increased hospitalizations caused by the COVID-19 Delta variant, particular in Florida, Texas and other areas significantly impacted by COVID-19. In the 2021 fourth quarter and into the 2022 first quarter, we have continued to observe elective surgery delays and cancellations and hospital staffing and capacity constraints, primarily related to the surge of infections and hospitalizations from the Omicron variant of COVID-19.

In addition to reductions in our revenue growth, we have and may continue to experience further business disruptions from the pandemic, including disruptions to our supply chain, independent sales agencies, customers, study enrollment timelines and regulatory processes. There is still uncertainty around the breadth and duration of business disruptions related to COVID-19, as well as its impact on the United States and international economies, especially as more potentially contagious and virulent variants, like Omicron, of the virus are spreading. Our business, revenue growth, financial condition and results of operations have been and could be materially adversely affected by these disruptions related to the COVID pandemic. Moreover, the COVID-19 pandemic has contributed to significant volatility in global financial markets, potentially reducing our ability to access capital, which could in the future negatively affect our liquidity.

For additional information regarding the impact of the COVID-19 pandemic on our company, refer to Item 7, "Management’s Discussion and Analysis of Financial Conditions and Results of Operations—Factors Affecting Our Business—Impact of COVID-19 Pandemic".

Our business plan relies on certain assumptions about the market for our products, however, the size and expected growth of our addressable market has not been established with precision and may be smaller than we estimate, and even if the addressable market is as large as we have estimated, we may not be able to capture additional market share.

Our estimates of the addressable market for our current products and future products are based on a number of internal and third-party estimates and assumptions, including the prevalence of bunion sufferers and the difficulty of persuading bunion suffers to undergo bunion surgery and specifically the Lapiplasty Procedure. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and our estimates may not be correct. For example, we believe that the aging of the general population and increasingly active lifestyles will continue and that these trends will increase the need for our products. However, the projected demand for our products could materially differ from actual demand if our assumptions regarding these trends and acceptance of our products by the medical community prove to be incorrect or do not materialize, or if non-surgical treatments or other surgical techniques gain more widespread acceptance as a viable alternative to the Lapiplasty Procedure. In addition, even if the

number of bunion sufferers who elect to undergo bunion surgery, and the Lapiplasty Procedure in particular, increases as we expect, technological or medical advances could provide alternatives to address bunion deformities and reduce demand for bunion surgery. As a result, our estimates of the addressable market for our current or future products and procedures may prove to be incorrect. Further, one component of our growth strategy is our direct to patient education program, which we expect will help us educate additional bunion patients about our products and procedures; however, these patient engagements may not be as successful at educating potential surgical candidates as we expect. Thus, even if the total addressable market for our current and future products and procedures is as large as we have estimated, we may not be able to penetrate the existing market to capture additional market share for the reasons discussed in this "Risk Factors" section. If the actual number of bunion sufferers who would benefit from our products, the price at which we can sell future products or the addressable market for our products is smaller than we estimate, or if the total addressable market is as large as we have estimated but we are unable to capture additional market share, it could have a material adverse effect on our business, financial condition and results of operations.

If we cannot innovate at the pace of our competitors, we may not be able to develop or exploit new products or procedures in time to remain competitive.

For us to remain competitive, it is essential to develop and bring to market new products and procedures at an increasing speed. If we are unable to meet customer demands for new products and procedures, or if the products and procedures we introduce are viewed less favorably than our competitors' products or procedures, our results of operations and future prospects may be negatively affected. To meet our customers' needs in these areas, we must continuously design new products, update existing products and invest in and develop and enhance our procedures. Our operating results depend to a significant extent on our ability to anticipate and adapt to technological changes in the bunion and midfoot surgery markets, keep pace with developments and innovations by our competitors and maintain a strong product pipeline. Any inability to do so could have a material adverse effect on our business, financial condition and results of operations.

We rely in part on independent sales agencies to sell our products to our customers, and if we are unable to maintain and expand our network of independent sales agencies, we may be unable to generate anticipated sales.

We utilize a hybrid sales team with a mix of employee sales personnel and independent sales agencies to sell our products to surgeons, hospitals, clinics and other end users and to assist us in promoting market acceptance of, and creating demand for, our products. If we are unable to come to commercially reasonable terms with a sales agent or agencies, we may not generate the expected level of sales and may need to spend more of our capital resources to hire sales personnel as employees. In addition, there is a risk that a sales agent that we contract with will give higher priority to the products of other medical device companies, including products directly competitive with our products or may be required by larger medical devices companies to stop offering our products. Though we have established initiatives to further focus our independent sales channel on our products, these initiatives may not translate to the increase sales or penetration which we expect. There can be no assurance that a sales agent will devote the resources necessary to provide effective sales and promotional support to our products. In addition, if an independent sales agency terminates its relationship with us and is retained by one of our competitors, we may be unable to prevent them from helping competitors solicit business from our existing customers, which could adversely affect our sales. Until we establish a direct sales force sufficient to serve our customers, we will continue to rely on an independent sales force.

Product liability lawsuits and quality system problems could harm our business.

The manufacture and sale of medical devices exposes us to risk of product liability claims. If any of our products become the subject of a product liability claim, legal defenses are costly, regardless of the outcome. Thus, we may experience increased legal expenses as we defend any such matter, and we could incur liabilities associated with adverse outcomes that exceed our insurance coverage.

Additionally, we could experience a material design or manufacturing failure in our products, a quality system failure, other safety issues or heightened regulatory scrutiny that would warrant a recall of some of our products. Product liability lawsuits and claims, safety alerts and product recalls, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation and on our ability to attract and retain customers.

Although we have product liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. Further, such product liability matters may negatively impact our ability to obtain insurance coverage or cost-effective insurance coverage in future periods.

The seasonality of our business creates variance in our quarterly revenue, which makes it difficult to compare or forecast our financial results.

Our revenue fluctuates on a seasonal basis, which affects the comparability of our results between periods. In particular, we have experienced and expect to continue to experience seasonality in our business, with higher sales volumes in the fourth calendar quarter and lower sales volumes in the first calendar quarter. Our sales volumes in the fourth calendar quarter tend to be higher as many patients elect to have surgery after meeting their annual deductible and having time to recover over the winter holidays. Our sales volumes in the first calendar quarter tend to be lower as a result of adverse weather and by resetting annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. The orthopaedic industry traditionally experiences lower sales volumes in the third quarter than throughout the rest of the year as elective procedures generally decline during the summer months. Although we follow orthopaedic industry trends generally, to date our third quarter sales volumes have not been lower than other quarters but we may experience relatively lower sales volumes during third quarters in the future. Medical device companies historically experience a decline in the number of orthopaedic implant surgeries in the summer months, and we may experience similar seasonality in the future. These seasonal variations are difficult to predict accurately, may vary amongst different markets and at times may be entirely unpredictable, which introduce additional risk into our business as we rely upon forecasts of customer demand to build inventory in advance of anticipated sales. In addition, we believe our limited history commercializing our products has, in part, made our seasonal patterns more difficult to discern, making it more difficult to predict future seasonal patterns.

Industry trends have resulted in increased downward pricing pressure on medical services and products, which may affect our ability to sell our products at prices necessary to support our current business strategy.

The trend toward health care cost containment through aggregating purchasing decisions and industry consolidation, along with the growth of managed care organizations, is placing increased emphasis on the delivery of more cost-effective medical therapies. For example:

- There has been consolidation among health care facilities and purchasers of medical devices, particularly in the United States. One of the results of such consolidation is that group purchasing organizations ("GPOs"), integrated delivery networks and large single accounts use their market power to consolidate purchasing decisions, which intensifies competition to provide products and services to health care providers and other industry participants, resulting in greater pricing pressures and the exclusion of certain suppliers from important market segments. For example, some GPOs negotiate pricing for their member hospitals and require us to discount, or limit our ability to increase, prices for certain of our products. GPOs contracts may also require member hospitals to buy a significant percentage of their products from large, diversified medical device suppliers that offer significant discounts. This means that member hospitals may be obligated to use bunion and midfoot surgery systems from our larger competitors in order to meet the commitment to purchase a certain percentage of the GPO’s suppliers from the larger competitor.
- Surgeons increasingly have moved from independent, outpatient practice settings toward employment by hospitals and other larger health care organizations, which aligns surgeons’ product choices with their employers’ price sensitivities and adds to pricing pressures. Hospitals and health care facilities have introduced and may continue to introduce new pricing structures into their contracts to contain health care costs, including fixed price formulas and capitated and construct pricing.
- Certain hospitals provide financial incentives to doctors for reducing hospital costs (known as gainsharing), rewarding physician efficiency (known as physician profiling) and encouraging partnerships with health care service and goods providers to reduce prices.
- Existing and proposed laws, regulations and industry policies, in both domestic and international markets, regulate or seek to increase regulation of sales and marketing practices and the pricing and profitability of companies in the health care industry.

More broadly, provisions of the ACA could meaningfully change the way health care is developed and delivered in the United States, and may adversely affect our business and results of operations. For further discussion of these challenges, refer to “Risks Related to Regulatory Matters—Changes in health care policy and regulation may have a material adverse effect on us". We cannot predict accurately what health care programs and regulations will ultimately be implemented at the federal or state level, or the effect of any future legislation or regulation in the United States or elsewhere. However, any changes that have the effect of reducing reimbursement for procedures using our products or reducing medical procedure volumes could have a material and adverse effect on our business, financial condition and results of operations. Any decline in the amount that payors reimburse our customers for our products could make it difficult for customers to either adopt or continue to use our products, and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, or if we add more components to our systems, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode.

In addition, the largest medical device companies with multiple product franchises have increased their effort to leverage and contract broadly with customers across franchises by providing volume discounts and multi-year arrangements that could prevent our access to these customers or make it difficult, or impossible, to compete on price.

Our employees and independent contractors, including independent sales representatives and any other consultants, any future service providers and other vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including independent sales agencies and any other consultants, any future commercial collaborators, and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate federal, state or local laws and regulations, as well as the laws, regulations and rules of regulatory bodies such as the FDA; manufacturing standards; U.S. federal and state health care fraud and abuse, data privacy laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or data. It is not always possible to identify and deter misconduct by employees and other third parties, 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 comply with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. health care programs, other sanctions, imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Administrative, Organizational and Commercial Operations and Growth

If hospitals, ambulatory surgery centers and other health care facilities do not approve the use of our products, our sales may not increase.

In order for surgeons to use our products at hospitals, ambulatory surgery centers and other health care facilities, we are often required to obtain approval from those hospitals, ambulatory surgery centers and health care facilities. Typically, hospitals, ambulatory surgery centers and health care facilities review the comparative effectiveness and cost of products used in the facility. The makeup and evaluation processes for health care facilities vary considerably, and it can be a lengthy, costly and time-consuming effort to obtain approval by the relevant health care facilities. Additionally, hospitals, ambulatory surgery centers, other health care facilities and GPOs, which manage purchasing for multiple facilities, may also require us to enter into a purchase agreement and satisfy numerous elements of their administrative procurement process, which can also be a lengthy, costly and time-consuming effort. If we do not obtain access to hospitals, ambulatory surgery centers and other health care facilities in a timely manner, or at all, via their approvals or purchase contract processes, or otherwise, or if we are unable to obtain approvals or secure contracts in a timely manner, or at all, our operating costs will increase, our sales may decrease, and our operating results may be adversely affected. Furthermore, we may expend significant efforts on these costly and time-consuming processes but may not be able to obtain necessary approvals or secure a purchase contract from such hospitals, ambulatory surgery centers, health care facilities or GPOs.

If adequate levels of reimbursement from third-party payors for procedures using our products are not obtained or maintained, surgeons and patients may be reluctant to use our products and our business will suffer.

In the United States, health care providers who purchase our products generally rely on third-party payors, principally federally-funded Medicare, state-funded Medicaid and private health insurance plans, to pay for all or a portion of the cost of bunion correction procedures and products utilized in those procedures. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of reimbursement for procedures using products of the type we intend to offer. Our sales depend largely on governmental health care programs and private health insurers reimbursing patients' medical expenses. Surgeons, hospitals and other health care providers may not purchase our products if they do not receive appropriate reimbursement from third-party payors for procedures using our products. Payors continue to review their coverage policies for existing and new therapies and may deny coverage for treatments that include the use of our products.

In addition, some health care providers in the United States have adopted or are considering bundled payment methodologies and/or managed care systems in which the providers contract to provide comprehensive health care for a fixed cost per person. Health care providers may attempt to control costs by authorizing fewer elective surgical procedures, including bunion correction surgeries, or by requiring the use of the least expensive procedure available. In addition, third-party payors increasingly are requiring evidence that medical devices are cost-effective, and if we are unable to meet this requirement, the third-party payor may not reimburse the use of our products, which could reduce sales of our products to health care providers who depend upon reimbursement for payment.

Changes in reimbursement policies or health care cost containment initiatives that limit or restrict reimbursement for procedures using our products may have an adverse effect on our business.

If we experience problems with, or are required to change, our suppliers or manufacturers, we may be unable to meet customer orders for our products in a timely manner or within our budget.

For us to be successful, our suppliers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these components, and if we cannot then obtain an acceptable substitute. We rely on a limited number of suppliers for the components used in our products. Our suppliers may encounter manufacturing problems for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our supply requirements. Our suppliers may also not prioritize the production of our products compared to the suppliers' larger customers so we may experience longer delays in receiving our requested orders.

If we are required to transition to new third-party suppliers for certain components of our products, the use of components or materials furnished by these alternative suppliers could require us to alter our operations. Any such interruption or alteration could harm our reputation, business, financial condition and results of operations.

Furthermore, if we are required to change the manufacturer of a critical component of our Lapiplasty System or other products, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products or could require that we modify the design of those products. A change in manufacturer could trigger the requirement to submit and obtain a new 510(k) clearance from the U.S. Food and Drug Administration ("FDA"), or similar international regulatory authorization before we implement the change, which could cause substantial delays. The occurrence of any of these events could harm our ability to meet the demand for our products in a timely manner or cost-effectively.

We cannot assure you that any need to change suppliers or manufacturers will not cause interruptions in our workflow. For example, if we should encounter delays or difficulties in securing, reconfiguring or revalidating the equipment and components we require for our Lapiplasty Systems and other products, our reputation, business, financial condition and results of operations could be negatively impacted.

We may be unable to continue to successfully demonstrate to surgeons or key opinion leaders the merits of our products and technologies compared to those of our competitors, which may make it difficult to establish our products and technologies as a standard of care and achieve market acceptance.

Surgeons play the primary role in determining the course of treatment and, ultimately, the type of products that will be used to treat a patient. As a result, our success depends, in large part, on our ability to effectively market and demonstrate to foot and ankle surgeons the merits of our products and methodologies compared to those of our competitors. Acceptance of our products and methodologies depends on educating surgeons as to the distinctive characteristics, clinical benefits, safety and cost-effectiveness of the Lapiplasty Procedure, including the Mini-Incision and Adductoplasty procedures, and our other products and technologies as compared to those of our competitors, and on training surgeons in the proper use of our products. If we are not successful in convincing surgeons of the merits of our products and methodologies or educating them on the use of our products, they may not use our products or may not use them effectively and we may be unable to increase our sales, sustain our growth or achieve and sustain profitability.

Also, since the Lapiplasty Procedure, including the Mini-Incision variation and the Adductoplasty Procedure, are new procedures, some surgeons may be reluctant to change their surgical treatment practices for the following reasons, among others:

- lack of experience with our products and procedures;
- existing relationships with competitors and distributors that sell competitive products;
- lack or perceived lack of evidence supporting additional patient benefits;
- perceived liability risks generally associated with the use of new products and procedures;
- less attractive availability of coverage and reimbursement by third-party payors compared to procedures using competitive products and other techniques;

- costs associated with the purchase of new products and equipment; and
- the time commitment that may be required for training.

These reasons may affect the pace of adoption of the Lapiplasty Procedure, including the Mini-Incision and Adductoplasty procedures, and future products and techniques that we may offer.

In addition, we believe recommendations and support of our products and technologies by influential surgeons and key opinion leaders in our industry are essential for market acceptance and establishment of our products and procedures as a standard of care. If we do not receive support from such surgeons and key opinion leaders, if long-term data does not show the benefits of using our products and procedures or if the benefits offered by our products and procedures are not sufficient to justify their cost, surgeons, hospitals and other health care facilities may not use our products and we might be unable to establish our products and procedures as a standard of care and continue to achieve market acceptance.

We may not be able to establish or strengthen our brand.

We believe that establishing and strengthening the Treace, Lapiplasty and Adductoplasty brands are important to achieving widespread acceptance of the Lapiplasty and Adductoplasty Procedures, particularly because of the highly competitive nature of the market for similar products. Promoting and positioning our brand will depend largely on the success of our medical education efforts and our ability to educate surgeons and patients. Additionally, we believe the quality and reliability of our product is critical to building physician support of this new surgical technique in the United States, and any negative publicity regarding the quality or reliability of the Lapiplasty System or other products could significantly damage our reputation in the market. These brand promotion activities may not yield increased sales and, even if they do, any sales increases may not offset the expenses we incur to promote our brand. If we fail to successfully promote and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, our Lapiplasty solution and other products may not be accepted by physicians or patients, which would adversely affect our business, results of operations and financial condition.

Our inability to maintain contractual relationships with health care professionals could have a negative impact on our research and development and medical education programs.

We maintain contractual relationships with respected physicians and medical personnel in hospitals, private practice and universities who assist in clinical studies, product research and development and in the training of surgeons on the safe and effective use of our products (refer to “Business — Product Development and our Surgeon Advisory Board”). We continue to place emphasis on the validation of the benefits of the Lapiplasty Procedure, the Lapiplasty Mini-Incision System and Adductoplasty system, through clinical studies, the development of proprietary products and product improvements to develop our product lines as well as providing high quality training on those products. If we are unable to maintain these relationships, our ability to develop and market new and improved products and train on the use of those products could decrease, and future operating results could be unfavorably affected. At the same time, the medical device industry’s relationship with physicians is under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General ("OIG"), the U.S. Department of Justice ("DOJ"), the state attorneys general and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry’s relationships with physicians or an investigation into our compliance by the OIG, the DOJ, state attorneys general and other government agencies, could negatively affect our business, financial condition and results of operations. Refer to “Risk Factors—Risks Related to Regulatory Matters— Our relationships with customers, physicians and third-party payors are subject to federal and state health care fraud and abuse laws, false claims laws, physician payment transparency laws and other health care laws and regulations. If we or our employees, independent contractors, consultants, commercial partners, or vendors violate these laws we could face substantial penalties.”

If surgeons fail to safely and appropriately use our products, or if we are unable to train podiatrists and orthopaedic surgeons on the safe and appropriate use of our products, we may be unable to achieve our expected sales, growth or profitability.

An important part of our sales process includes our ability to screen for and identify podiatrists and orthopaedic surgeons who have the requisite training and experience to safely and appropriately use our products and to train a sufficient number of these surgeons and to provide them with adequate instruction in use of our products. There is a training process involved for surgeons to become proficient in the safe and appropriate use of our products. This training process may take longer or be more expensive than expected and may therefore affect our ability to increase sales. Convincing surgeons to dedicate the time and energy necessary for adequate training is challenging, and we may not be successful in these efforts. Recent changes to federal guidance regarding medical education programs under the federal Anti-Kickback Statute also could limit our ability to train podiatrists and orthopaedic surgeons, and such programs could be subject to challenge under the federal Anti-Kickback Statute. Refer to “Risk Factors—Risks Related to Regulatory Matters—Our relationships with customers, physicians and third-party payors are subject to federal and state health care fraud and abuse laws, false claims laws, physician payment transparency laws and other health care laws and regulations. If we or our

employees, independent contractors, consultants, commercial partners, or vendors violate these laws we could face substantial penalties." Furthermore, if clinicians are not properly trained, they may misuse or ineffectively use our products. Any improper use of our products may result in unsatisfactory outcomes, patient injury, negative publicity or lawsuits against us, any of which could harm our reputation and affect future product sales. Accordingly, if surgeons fail to safely and appropriately use our products or if we are unable to train surgeons on the safe and appropriate use of our products, we may be unable to achieve our expected sales, growth or profitability.

The loss of any member on our executive management team or our inability to attract and retain highly skilled members of our sales management and marketing teams and engineers could have a material adverse effect on our business, financial condition and results of operations.

Our success depends on the skills, experience and performance of the members of our executive management team and John T. Treace, our founder and chief executive officer, in particular. The individual and collective efforts of these executives will be important as we continue to commercialize our existing products, develop new products and technologies and expand our commercial activities. The loss or incapacity of existing members of our executive management team could have a material adverse effect on our business, financial condition and results of operations if we experience difficulties in hiring qualified successors. We do not maintain "key person" insurance for any of our executives or key employees.

Our commercial, quality and research and development programs and operations depend on our ability to attract and retain highly skilled team members. We may be unable to attract or retain qualified team members. All of our employees are at-will, which means that either we or the employee may terminate his or her employment at any time. The loss of key employees, failure of any key employee to perform, our inability to attract and retain skilled employees, as needed, or our inability to effectively plan for and implement a succession plan for key employees could have a material adverse effect on our business, financial condition and results of operations.

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

Expedited, reliable shipping of our kits is important to our operations. We rely on providers of transport services for reliable and secure point-to-point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of our products, it would be costly to replace our products in a timely manner, could cause surgeries using our products to be delayed or canceled and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis.

Any future international expansion will subject us to additional costs and risks that may have a material adverse effect on our business, financial condition and results of operations.

Historically, all of our sales have been to customers in the United States. To the extent we enter into international markets in the future, there are significant costs and risks inherent in conducting business in international markets. If we expand, or attempt to expand, into foreign markets, we will be subject to new business risks, in addition to regulatory risks. In addition, expansion into foreign markets imposes additional burdens on our executive and administrative personnel, finance and legal teams, research and marketing teams and general managerial resources.

We have limited experience with regulatory environments and market practices internationally, and we may not be able to penetrate or successfully operate in new markets. We may also encounter difficulty expanding into international markets because of limited brand recognition in certain parts of the world, leading to delayed acceptance of our products by surgeons and their patients, hospitals, ambulatory surgery centers and payors in these international markets. If we are unable to expand internationally and manage the complexity of international operations successfully, it could have a material adverse effect on our business, financial condition and results of operations. If our efforts to introduce our products into foreign markets are not successful, we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for expansion into foreign markets could exceed the results of operations generated from this expansion.

Risks Related to Our Intellectual Property

If we are unable to obtain significant patent protection for our products, or if our patents and other intellectual property rights do not adequately protect our products, our competitors could develop and commercialize products similar or identical to ours and we may be unable to gain significant market share and be unable to operate our business profitably.

Our success depends in large part on our ability to obtain, maintain and solidify a proprietary position for our products, which will depend on our success in obtaining effective intellectual property protection, including through patents, trade secrets, copyrights, know-how, trademarks, license agreements and contractual provisions to establish our intellectual property rights and protect our products. These legal means, however, afford only limited protection and may not completely protect our rights. Any failure to obtain or maintain patent and other intellectual property protection with respect to our products could harm our business, financial condition and results of operations.

As of December 31, 2021, our patent portfolio included 31 owned U.S. patents, one licensed U.S. patent, 31 pending U.S. patent applications, eight granted foreign patents, three pending international PCT patent applications, and 25 pending foreign patent applications. We cannot assure you that our intellectual property position will not be challenged or that all patents for which we have applied will be granted. The validity and breadth of claims in patents involve complex legal and factual questions and, therefore, may be highly uncertain. Uncertainties and risks that we face include the following:

- our pending or future patent applications may not result in the issuance of patents;
- the scope of any existing or future patent protection may not exclude competitors or provide competitive advantages to us;
- our patents may not be held valid or enforceable if subsequently challenged;
- other parties may claim that our products and designs infringe the proprietary rights of others—even if we are successful in defending our patents and proprietary rights, the cost of such litigation may adversely affect our business; and
- other parties may develop similar products, duplicate our products, or design around our patents.

The patent prosecution process is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner, or in all jurisdictions. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek and obtain patent protection. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our developments before it is too late to obtain patent protection. Furthermore, our ability to obtain and maintain valid and enforceable patents depends in part on whether the differences between our inventions and the prior art allow our inventions to be patented over the prior art. Furthermore, the publication of discoveries in scientific literature often lags behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until eighteen (18) months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to file for patent protection of such inventions.

In addition, the laws of foreign jurisdictions may not protect our rights to the same extent as the laws of the United States. For example, most countries outside of the United States do not allow patents for methods of treating the human body. This may preclude us from obtaining method patents outside of the United States having similar scope to those we have obtained or may obtain in the future in the United States. This includes certain key method patents covering the Lapiplasty Procedure. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office ("USPTO") or patent offices in foreign jurisdictions, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology and compete directly with us, without payment to us.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and techniques, or limit the duration of the patent protection of our technology.

While we are aware of several third-party patents of interest, we do not believe that any of our products infringe any valid claims of patents or other proprietary rights held by others. However, there can be no assurances that we do not infringe any patents or other proprietary rights held by third parties. If our products were found to infringe any proprietary right of another party, we could be required to pay significant damages or license fees to such party and/or cease production, marketing and distribution of those products. Litigation may also be necessary to defend infringement claims of third parties or to enforce patent rights we hold or to protect trade secrets or techniques we own. Moreover, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe.

We also rely on trade secrets and other unpatented proprietary technology. There can be no assurances that we can meaningfully protect our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our proprietary technology. We seek to protect our trade secrets and proprietary know-how, in part, with confidentiality agreements with employees and consultants that include customary intellectual property assignment obligations. There can be no assurances, however, that the agreements will not be breached, adequate remedies for any breach would be available or competitors will not discover our trade secrets or independently develop comparable intellectual property.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent and/or applications and any patent rights we may obtain in the future. While an unintentional lapse of a patent or patent application can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

Although we are not presently a party to lawsuits or administrative proceedings involving patents or other intellectual property, the possibility exists that we may be in the future. If we were to lose any future intellectual property lawsuits, a court could require us to pay significant damages and/or prevent us from selling our products.

The medical device industry is litigious with respect to patents and other intellectual property rights. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage.

Although we are not presently a party to lawsuits or administrative proceedings involving patents or other intellectual property, including interference proceedings, post grant review and inter partes review before the USPTO or the equivalent foreign patent authority, the possibility exists that we may be in the future. A legal proceeding, regardless of the outcome, could drain our financial resources and divert the time and effort of our management. Protracted litigation to defend or prosecute our intellectual property rights could result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation.

If we are found to infringe a third party’s intellectual property rights, we could be required to obtain a license from such third party to continue selling, developing and marketing our products and techniques. However, we may not be able to obtain any required license on commercially reasonable terms or at all. The acquisition or licensing of third-party intellectual property rights is a competitive area, and our competitors may pursue strategies to acquire or license third party intellectual property rights that we may consider attractive or necessary. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant products or redesign those products that contain the allegedly infringing intellectual property, which could harm our business, financial condition and results of operations. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys’ fees if we are found to have willfully infringed a patent. A finding of infringement could force us to cease some of our business operations, which could

materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming, and could distract our technical and management personnel from their normal responsibilities. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims or file administrative actions against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding or administrative action could put one or more of our patents at risk of being invalidated or interpreted narrowly. Our competitors may assert invalidity on various grounds, including lack of novelty, obviousness or that we were not the first applicant to file a patent application related to our product. We may elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes before litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure.

Our competitors, many of which have made substantial investments in patent portfolios, trade secrets, trademarks and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that may prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use our technologies or product names. Moreover, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," purchase patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments.

If we fail to execute invention assignment agreements with our employees and contractors involved in the development of intellectual property or are unable to protect the confidentiality of our trade secrets, the value of our products and our business and competitive position could be harmed.

In addition to patent protection, we also rely on protection of copyright, trade secrets, know-how and confidential and proprietary information. We generally enter into confidentiality and invention assignment agreements with our employees, consultants and third parties upon their commencement of a relationship with us. However, we may not enter into such agreements with all employees, consultants and third parties who have been involved in the development of our intellectual property. In addition, these agreements may not provide meaningful protection against the unauthorized use or disclosure of our trade secrets or other confidential information, and adequate remedies may not exist if unauthorized use or disclosure were to occur. The exposure of our trade secrets and other proprietary information would impair our competitive advantages and could have a material adverse effect on our business, financial condition and results of operations. In particular, a failure to protect our proprietary rights may allow competitors to copy our products and procedures, which could adversely affect our pricing and market share. Further, other parties may independently develop substantially equivalent know-how and technology.

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 products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome 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. While we have agreements with our employees, consultants and third parties that obligate them to assign their inventions to us, these agreements may not be self-executing, not all employees or consultants may enter into such agreements, or employees or consultants may breach or violate the terms of these agreements, and we may not have adequate remedies for any such breach or violation. If any of our intellectual property or 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, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

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

We rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. There can be no assurance 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 products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, there can be no assurance that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. We also license third parties to use our trademarks. In an effort to preserve our trademark rights, we enter into license agreements with these third parties, which govern the use of our trademarks and require our licensees to abide by quality control standards with respect to the goods and services that they provide under our trademarks. Although we make efforts to monitor the use of our trademarks by our licensees, there can be no assurance that these efforts will be sufficient to ensure that our licensees abide by the terms of their licenses. In the event that our licensees fail to do so, our trademark rights could be diluted. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Patent terms may not be sufficient to effectively protect our products and business for an adequate period of time.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the term of a patent, and the protection it affords, is limited. Even if patents covering our proprietary technologies and their uses are obtained, once the patent has expired, we may be open to competition. In addition, although upon issuance in the United States a patent’s term can be extended based on certain delays caused by the USPTO, this extension can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. If we do not have sufficient patent terms to protect our products, proprietary technologies and their uses, our business would be seriously harmed.

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

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act ("Leahy-Smith Act") includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, which became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business.

However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the Leahy-Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board ("PTAB"), provides a venue for challenging the validity of patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long-term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them.

The America Invents Act also includes a number of significant changes that affect the way U.S. patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by the USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U.S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could harm our business, financial condition and results of operations.

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

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents or trademarks on our products and any future products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions or utilizing our trademarks in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and any future products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing in these jurisdictions.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.

Many of our employees and consultants were previously employed at or engaged by other medical device companies, including our competitors or potential competitors. Some of these employees, consultants and contractors may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers, competitors or other third parties. Additionally, we may be subject to claims from third parties challenging our ownership interest in or inventorship of intellectual property we regard as our own, for example, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages or a settlement payment, a court could prohibit us from using technologies, features or other intellectual property that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies, features or other intellectual property that are important or essential to our products could have a material adverse effect on our business and competitive position, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Risks Related to Regulatory Matters

We are subject to substantial government regulation that could have a material adverse effect on our business.

Our products are regulated as medical devices. The production and marketing of our products and its ongoing research and development, pre-clinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. U.S. and foreign regulations govern the design, development, testing, clinical trials, premarket clearance and approval, safety, marketing and registration of new medical devices, in addition to regulating manufacturing

practices, reporting, labeling, relationships with health care professionals and recordkeeping procedures. The regulatory process requires significant time, effort and expenditures to bring our products to market, and we cannot be assured that any of our products will be approved. The regulations to which we are subject are complex and have tended to become more stringent over time. Our failure to comply with applicable regulatory requirements could result in these governmental authorities:

- issuing warning letters or untitled letters;
- imposing fines and penalties on us;
- preventing us from manufacturing or selling our products;
- bringing civil or criminal charges against us;
- delaying the introduction of our new products into the market;
- recalling or seizing our products; or
- withdrawing, suspending or denying approvals or clearances for our products.

Our relationships with customers, physicians and third-party payors are subject to federal and state health care fraud and abuse laws, false claims laws, physician payment transparency laws and other health care laws and regulations. If we or our employees, independent contractors, consultants, commercial partners, or vendors violate these laws we could face substantial penalties.

Our relationships with customers, physicians and third-party payors are subject to federal and state health care fraud and abuse laws, false claims laws, physician payment transparency laws and other health care laws and regulations. In particular, the promotion, sales and marketing of health care items and services is subject to extensive laws and regulations designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive and other business arrangements. The U.S. health care laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully, offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchasing, leasing, ordering or arranging for the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal health care programs. The term “remuneration” has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that may be alleged to be intended to induce the purchases or recommendations, include any payments of more than fair market value, may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal government programs that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government, including federal health care programs. In addition, the government may assert that 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 federal civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which created new federal civil and criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, health care benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other transfers of value

made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- state and foreign equivalents of each of the health care laws described above, among others, some of which may be broader in scope including, without limitation, state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third party payors, including private insurers, or that apply regardless of payor; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other health care providers, marketing expenditures; and state and local laws requiring the registration of device sales and medical representatives. Greater scrutiny of marketing practices in the medical device industry has resulted in numerous government investigations by various government authorities, and this industry-wide enforcement activity is expected to continue. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different and difficult compliance and reporting requirements, increases the possibility that we may run afoul of one or more laws. The costs to comply with these regulatory requirements are becoming more expensive and will also impact our profitability.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, patient outreach programs or our arrangements with physicians, independent sales agencies and customers could be subject to challenge under one or more of such laws. It is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct 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. Efforts to ensure that our business arrangements will comply with applicable health care laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations.

If we or our employees, agents, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and/or significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may not receive, or may be delayed in receiving, the necessary clearances or approvals for our future products or modifications to our current products, and failure to timely obtain necessary clearances or approvals for our future products or modifications to our current products would adversely affect our ability to grow our business.

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDCA") or approval of a premarket approval ("PMA"), from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed before May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. To date, our Class II devices have received marketing authorization pursuant to the 510(k) clearance process.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes

from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

In the United States, we have obtained clearance of our Lapiplasty System and other products through the 510(k) clearance process. Any modification to these systems that has not been previously cleared may require us to submit a new 510(k) premarket notification and obtain clearance, or submit a PMA and obtain FDA approval before implementing the change. Specifically, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to 510(k)-cleared products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances or PMA approvals were not required. We may make modifications or add additional features in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMA applications 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 regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business. The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials or the interpretation of data from pre-clinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

Even though we have obtained clearance for our Lapiplasty and other products in the United States, we are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration and listing of devices. For example, we must submit periodic reports to the FDA as a condition of 510(k) clearance. These reports include information about failures and certain adverse events associated with the device after its clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation. In addition, any marketing authorizations we are granted are limited to the cleared indications for use. Further, the manufacturing facilities for a product are subject to periodic review and inspection. Subsequent discovery of problems with a product, manufacturer, or manufacturing facility may result in restrictions on the product, manufacturer or manufacturing facility, withdrawal of the product from the market or other enforcement actions.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Plus regulation such as the FDA and other state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention or seizure of our products;

- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future clearances or approvals or foreign marketing authorizations of new products, new intended uses or modifications to existing products;
- withdrawals or suspensions of our current 510(k) clearances, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations. In addition, the FDA may change its clearance policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay clearance or approval of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new clearances or approvals, increase the costs of compliance or restrict our ability to maintain our clearances of our current products.

Legislative or regulatory reforms may have a material adverse effect on us.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the 510(k) premarket notification pathway. Among other things, the FDA announced that it plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old.

In September 2019, the FDA also issued revised final guidance establishing a “Safety and Performance Based Pathway” for “manufacturers of certain well-understood device types” allowing manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list of device types appropriate for the “safety and performance based” pathway and will continue to develop product-specific guidance documents that identify the performance criteria and recommended testing methodologies for each such device type, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require additional testing before obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

The FDA’s and other regulatory authorities’ policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, and we may not achieve or sustain profitability.

In addition, in response to perceived increases in health care costs in recent years there have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control these costs and, more generally, to reform the U.S. health care system. Certain of these proposals could limit the prices we will be able to charge for our products or the amount of reimbursement available for our products and could limit the acceptance and availability of our products.

In March 2010, the federal government enacted the ACA. Among other provisions, the ACA established new value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the ACA included a reduction in the annual rate of inflation for Medicare payments to hospitals that began in 2011.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, a President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to health care, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other health care reform measures of the Biden administration will impact our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, effective on April 1, 2013 and, will remain in effect through 2030 unless additional Congressional action is taken. However, due to COVID-19 relief legislation, the 2% reduction has been temporarily suspended from May 1, 2020 through March 31, 2022, and from April 2022 through June 2022, a 1% sequester cut will be in effect, with the full 2% reduction resuming thereafter.

Our products must be manufactured in accordance with federal and state quality regulations and are subject to FDA inspection, and our failure to comply with these regulations could result in fines, product recalls, product liability claims, limits on future product clearances, reputational damage and other adverse impacts.

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

We or our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: (i) warning letters or untitled letters; (ii) fines, injunctions or civil penalties; (iii) suspension or withdrawal of approvals or clearances; (iv) customer notifications or repair, replacement, refunds, detention, seizures or recalls of our products; (v) total or partial suspension of production or distribution; (vi) administrative or judicially imposed sanctions; (vii) the FDA's refusal to grant pending or future clearances or approvals for our products; (viii) clinical holds; (ix) refusal to permit the import or export of our products; and (x) criminal prosecution of us or our employees. Any of these actions could significantly and negatively impact supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and suffer reduced revenue and increased costs.

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

Our currently marketed products are either Class II medical devices cleared by the FDA for specific indications or they are Class I exempt for general orthopaedic use. For example, our Lapiplasty plating system has been cleared by the FDA for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet. We train our marketing personnel and direct sales force to not promote our devices for uses outside of the FDA-authorized indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our devices off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our devices off-label. Furthermore, the use of our devices for indications other than those cleared by the FDA or approved by any foreign

regulatory body (to the extent our products are cleared for use outside the United States in the future) may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. We could face similar consequences from action by foreign regulatory bodies if we should offer our products outside the United States. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government health care programs and the curtailment of our operations.

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

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

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

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

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

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

The clinical trial process is lengthy and expensive with uncertain outcomes. We have limited data and experience regarding the safety and efficacy of our products. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products.

Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. We cannot guarantee our ALIGN3D or our Mini3D post-market clinical studies, or any other clinical study we may conduct or sponsor in the future, will be successful or will otherwise generate data that support the performance of our products. Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and institutional review board at the medical institutions where the clinical trials are conducted. Furthermore, we rely, and in the future may continue to rely upon, on contract research organizations ("CROs"), and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to required good clinical practice standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both.

The initiation and completion of any of clinical studies may be prevented, delayed or halted for numerous reasons, which could adversely affect the costs, timing or successful completion of our clinical trials.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Any of these occurrences may significantly harm our business, financial condition and prospects.

Furthermore, patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations and financial condition.

We and our partners may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address data privacy and security). In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our partners. We may also be subject to U.S. federal rules, regulations and guidance concerning data security for medical devices, including guidance from the FDA. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity or business associate in a manner that is not authorized or permitted by HIPAA. The regulatory framework for data privacy and security worldwide is continuously evolving and developing and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In addition, California enacted the California Consumer Privacy Act ("CCPA") on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act ("CPRA"), recently passed in California. The CPRA significantly amends the CCPA and will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and

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

Furthermore, the Federal Trade Commission (FTC) and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. 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.

In Europe, the GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area (EEA). Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Relatedly, from January 1, 2021, companies have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how the United Kingdom data protection laws and regulations will develop in the medium to longer term. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from European Union member states to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision. If we do not comply with our obligations under the GDPR and the United Kingdom data protection laws, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations and financial condition.

Further, in July 2020, the Court of Justice of the European Union ("CJEU") limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the EU-US Privacy Shield Framework for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses ("SCCs"). The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the UK; the UK's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021 and laid its proposal before Parliament, with the UK SCCs expected to come into force in March 2022, with a two-year grace period. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, future developments may necessitate further expenditures on local infrastructure, changes to internal business processes, or may otherwise affect or restrict sales and operations.

In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation and application of laws, regulations, standards and other obligations relating to data privacy and security are still uncertain, it is possible that these laws, regulations, standards and other obligations may be interpreted and applied in a manner that is inconsistent with our data processing practices and policies or the features of our products. If so, in addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business, financial condition and results of operations. We may be unable to make such changes and modifications in a commercially reasonable manner, or at all. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with consumers and harm our business, financial condition and results of operations.

We make public statements about our use and disclosure of personal information through our privacy policies, information provided on our website and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are

found to be deceptive, unfair or misrepresentative of our actual practices. Any concerns about our data privacy and security practices, even if unfounded, could damage the reputation of our business and harm our business, financial condition and results of operations.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation and adversely affect our business and results of operations. In addition, if our practices are not consistent, or viewed as not consistent, with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may also become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, criminal or civil sanctions, all of which may harm our business, financial condition and results of operations.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be volatile and fluctuate substantially.

The market price of our common stock may be highly volatile and could fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control or are related in complex ways, including:

- the impact of COVID-19 or other pandemics on the performance of elective procedures;
- delays or setbacks in the ongoing commercialization of our Lapiplasty System and other products;
- the success of existing or new competitive products or technologies;
- actual or anticipated fluctuations in our financial condition and results of operations;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the commencement of litigation;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders as well as the anticipation of expiration of market standoff or lock-up releases;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of health care payment systems;
- market conditions in the medical device sectors;
- the seasonality of our business;
- an increase in the rate of returns of our Lapiplasty System Kits or an increase in warranty claims;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In recent years, the stock market in general, and the market for medical device companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Further, the stock market in general has been highly volatile due to the COVID-19 pandemic and political uncertainty in the United States. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our stock in the early years after our initial public offering. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management’s attention and resources from our business.

If our operating and financial performance in any given period does not meet any guidance that we provide to the public, the market price of our common stock may decline.

We may, but are not obligated to, provide public guidance on our expected operating and financial results for future periods. Any such guidance will be comprised of forward-looking statements subject to the risks and uncertainties described in this Annual Report and in our other public filings and public statements. Our actual results may not always be in line with or exceed any guidance we have provided, especially in times of economic uncertainty. If, in the future, our operating or financial results for a particular period do not meet any guidance we provide or the expectations of investment analysts, or if we reduce our guidance for future periods, the market price of our common stock may decline. Even if we do issue public guidance, there can be no assurance that we will continue to do so in the future.

If we do raise additional capital, stockholders may be subject to dilution.

If we issue additional shares of our common stock or other equity securities convertible into common stock to fund operations, develop new products, accelerate other strategies, make acquisitions or support other activities, the ownership interests of our stockholders will be diluted. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future offerings. To the extent that we raise additional capital through the sale of equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. As of December 31, 2021, we had outstanding 54,181,082 shares of common stock. Sale of these shares, or the perception in the market that the holders of a large number of shares of our common stock intend to sell shares, could reduce the market price of our common stock.

Furthermore, we have registered all shares of our common stock that we may issue under our equity compensation plans. Shares issued upon the exercise of stock options outstanding under our equity incentive plans, or pursuant to future awards granted under those plans, have and will continue to become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, and Rule 144 and Rule 701 under the Securities Act of 1933, as amended (the Securities Act). Refer to Note 10, "Stockholders' Equity", of the Notes to the Financial Statements for information about outstanding options. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties or other strategic alliances, and the failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing clinician and patients' needs, competitive technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our existing products and technologies or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products, employees or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management's attention from our core business and disruption of ongoing operations;

- adverse effects on existing business relationships with suppliers, sales agents, health care facilities, surgeons and other health care providers;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms, if 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, sales agent, health care facilities, surgeons or other health care providers. Our ability to successfully grow through strategic transactions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses, technologies or products 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 pursue any foreign acquisitions, they typically involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures, languages and legal and regulatory environments, currency risks and the particular economic, political and regulatory risks associated with specific countries.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our common stock as consideration. Additional funds may not be available on terms that are favorable to us, or at all.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We have a limited number of analysts who cover us. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

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

We have never paid cash dividends and do not anticipate paying cash dividends on our common stock in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects for future earnings and other factors our board of directors may deem relevant. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it. In addition, our term loan agreement limits our ability to, among other things, pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates and you then sell our common stock. In addition, our loan agreements limit our ability to pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions.

Insiders will continue to have substantial influence over us, which could limit your ability to affect the outcome of key transactions, including a change of control.

As of December 31, 2021, our directors, officers, holders of more than 5% of our outstanding stock and their respective affiliates will beneficially own shares representing approximately 42.3% of our outstanding common stock. Further, while there is no voting agreement or other similar arrangements between them, our CEO and two other directors are family members. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws, and Delaware law, could discourage a change in control of our company or a change in our management.

Our amended and restated certificate of incorporation and bylaws as currently in effect contain provisions that might enable our management to resist a takeover. These provisions include:

- a classified board of directors;
- advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholders' notice;
- a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws;
- the right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;
- allowing a supermajority of stockholders to remove directors only for cause;
- a requirement that the authorized number of directors may be changed only by resolution of the board of directors;
- allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law;
- eliminate cumulative voting in elections of directors;
- a requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent;
- limiting the forum to Delaware for certain litigation against us; and
- limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president, in the absence of a chief executive officer.

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' abilities to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against any defendant arising under the Securities Act. Such provision is intended to benefit and may be enforced by us, our officers and directors, employees and agents, including the underwriters and any other professional or entity who has prepared or certified any prospectus, including the prospectus for our initial public offering.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, 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. 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 or make such lawsuits more costly for stockholders, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, 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 a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could seriously harm our business.

General Risk Factors

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from the current COVID-19 pandemic, wars, invasions or political disruption could result in a variety of risks to our business, including weakened demand for our procedures or products and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including those resulting from pandemics, wars, invasions, energy supply interruptions or international trade disputes, staffing shortages, or similar events, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

We, along with our suppliers, are dependent on various information technology systems, and failures of, interruptions to, or unauthorized tampering of those systems could have a material adverse effect on our business.

We and our suppliers rely extensively on information technology systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security system and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided or used by third-parties or their vendors, to conduct business. These systems include, but are not limited to, ordering and managing materials from suppliers, converting materials to finished products (suppliers), shipping products to customers, processing transactions, summarizing and reporting results of operations, complying with regulatory, legal or tax requirements, providing data security and other processes necessary to manage our business.

Despite the implementation of security measures, our internal computer systems and those of our contractors, consultants and collaborators are vulnerable to damage from cyberattacks, "phishing" attacks, intentional or accidental actions or omissions to act that cause vulnerabilities, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. We and certain of our service providers are from time to time, subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our or our critical third parties' operations, it could result in material disruptions of our operations and ultimately, our financial results. Further, if our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security breaches, and our business continuity plans do not effectively compensate timely, we may suffer interruptions in our ability to manage operations, and would also be exposed to a risk of loss, including financial assets or litigation and potential liability, which could materially adversely affect our business, financial condition, results of operations and prospects.

We cannot assure you that any limitations of liability provisions in our contracts would be enforceable or adequate or would otherwise protect us from any liabilities or damages with respect to any particular claim relating to a security lapse or breach. While we maintain certain insurance coverage, our insurance may be insufficient or may not cover all liabilities incurred by such attacks. We also cannot be certain that our insurance coverage will be adequate for data handling or data security liabilities actually incurred, that insurance will continue to be available to us on economically reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceeds available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, including our financial condition, operating results and reputation.

Our operations are vulnerable to interruption or loss due to natural or other disasters, power loss, strikes and other events beyond our control.

A major hurricane, fire or other disaster (such as a major flood, earthquake or terrorist attack) affecting our headquarters or our other facilities, or facilities of our suppliers and manufacturers, could significantly disrupt our operations, and delay or prevent product shipment or installation during the time required to repair, rebuild or replace our suppliers' and manufacturers' damaged facilities, which delays could be lengthy and costly. If any of our customers' facilities are negatively impacted by a disaster, shipments of our products could be delayed. Additionally, customers may delay purchases of our products until operations return to normal. Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our business. Concerns about terrorism, the effects of a terrorist attack or political turmoil could have a negative effect on our operations, those of our suppliers and manufacturers and our customers.

We will incur significant costs as a result of operating as a public company and our executive management team expects to devote substantial time to public company compliance programs.

As a public company, we have and will continue to incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act, as well as rules implemented by the SEC and the Nasdaq Stock Market. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our executive management team and other personnel has and will continue to devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and as a result of the corporate governance and executive compensation related rules, regulations and guidelines prompted by the Dodd-Frank Wall Street Reform and Consumer Protection Act, and further regulations and disclosure obligations expected in the future, we must devote additional time and costs to comply with such compliance programs and rules. These rules and regulations cause us to incur significant legal and financial compliance costs and make some activities more time-consuming and costly.

We are an "emerging growth company" and a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we intend to 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, 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 stockholder approval of any golden parachute payments not previously approved. In addition, as an "emerging growth company" the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

We cannot predict if investors will find our common stock less attractive because we will 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. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (i) December 31, 2026, (ii) the last day of the year in which we have total annual gross revenue of at least $1.07 billion, (iii) the last day of the year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Even after we no longer qualify as an "emerging growth company," we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including, among other things, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, presenting only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Failure to establish and maintain an effective system of internal controls could result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud in which case, our stockholders could lose confidence in our financial reporting and the market price of our common stock could decline.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq Stock Market. Under Section 404 of the Sarbanes-Oxley Act, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second annual report on Form 10-K. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. However, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an EGC. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. During our evaluation of our internal control, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective.

We may in the future discover material weaknesses in our system of internal financial and accounting controls and procedures that could result in a misstatement of our financial statements. If we are unable to remediate future material weaknesses, or otherwise maintain effective internal control over financial reporting, we may not be able to report our financial results accurately, prevent fraud or file our periodic reports in a timely manner, which may adversely affect investor confidence in us and, as a result, our stock price and ability to access the capital markets in the future.

In addition, our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system’s objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

Furthermore, in connection with the future attestation process by our independent registered public accounting firm, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation. If we cannot favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls, our stockholders could lose confidence in our reporting and the market price of our common stock could decline. In addition, we could be subject to sanctions or investigations by the Nasdaq Stock Market, the SEC or other regulatory authorities.

We are subject to U.S. anti-corruption, export control, sanctions and other trade laws and regulations (collectively, the "Trade Laws"). We can face serious consequences for violations.

We are subject to anti-corruption laws, including the U.S. domestic bribery statute contained in 18 U.S.C. 201, the U.S. Travel Act, and the U.S. Foreign Corrupt Practices Act of 1977, as amended. These anti-corruption laws generally prohibit companies and their employees, agents and intermediaries from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to recipients in the public or private sector. We can be held liable for the corrupt or illegal activities of our agents and intermediaries, even if we do not explicitly authorize or have actual knowledge of such activities. We are also subject to other U.S. laws and regulations governing export controls, as well as economic sanctions and embargoes on certain countries and persons.

Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. Likewise, any investigation of potential violations of Trade Laws could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Changes in tax laws or regulations that are applied adversely to us or our customers may seriously harm our business.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of any of our future domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ("Code"), if a corporation undergoes an “ownership change,” generally defined as a cumulative change of more than 50 percentage points (by value) in its equity ownership by certain stockholders over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. Based upon our analysis as of December 31, 2021, we have determined that we do not expect these limitations to impair our ability to use our NOLs prior to expiration. However, if changes in our ownership occur in the future, our ability to use our NOLs may be further limited. For these reasons, we may not be able to utilize a material portion of the NOLs, even if we achieve profitability.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

As of December 31, 2021, we leased approximately 23,060 square feet for our corporate headquarters located in Ponte Vedra, Florida under a lease agreement which terminates in August 2026. We believe that this facility is sufficient to meet our current and anticipated needs in the near term and that additional space can be obtained on commercially reasonable terms as needed. Refer to Note 13, "Subsequent Events", for more information on plans related to our headquarters building.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings. We may, however, in the ordinary course of business face various claims brought by third parties and we may, from time to time, make claims or take legal actions to assert our rights, including intellectual property rights as well as claims relating to employment matters and the safety or efficacy of our products. Any of these claims could subject us to costly litigation and, while we generally believe that we have adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock began trading on the NASDAQ Global Select Market under the symbol "TMCI" on April 23, 2021. Prior to that time, there was no public market for our common stock.

Holders of Record

At February 23, 2022, there were approximately 26 stockholders of record of our common stock. Since many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividends

We have never declared or paid, and do not anticipate declaring or paying, any cash dividends on any of our capital stock. We do not anticipate paying any dividends in the foreseeable future, and we currently intend to retain all available funds and any future earnings for use in the operation of our business, to finance the growth and development of our business and for future repayment of debt. Future determinations as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then-existing conditions, including our operating results, financial condition, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. In addition, our term loan agreement limits our ability to pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by this Item 5 regarding equity compensation plans is incorporated by reference from the information under the captions "Equity Compensation Plan Information" set forth under Item 10 of this Annual Report and the "Security Ownership of Certain Beneficial Owners and Management" information will be contained in the Proxy Statement.

Use of Proceeds

The registration statement on Form S-1 (File Nos. 333-254863 and 333- 255451) filed pursuant to Rule 462(b) relating thereto (the "Prospectus"), each relating to the IPO of shares of our common stock, became effective on April 22, 2021. On April 27, 2021, we completed our IPO of 12,937,500 shares of common stock, which included the exercise in full of the underwriters' option to purchase additional shares. As part of the IPO, 6,953,125 shares of common stock issued and sold by us (inclusive of 703,125 shares pursuant to the exercise of the underwriters' option) and 5,984,375 shares of common stock sold by the selling stockholders named in the Prospectus (inclusive of 984,375 shares pursuant to the exercise of the underwriters' option), at a price to the public of $17.00 per share. We received net proceeds of approximately $107.6 million, after deducting underwriting discounts of $8.3 million and commissions and offering expenses payable by us of $2.3 million. Upon the completion of the IPO, all 6,687,475 shares of Series A convertible preferred stock then outstanding were converted into shares of common stock on a one-to-one basis plus 158,447 shares of common stock were issued to pay accrued cumulative dividends on Series A convertible preferred stock of $2.5 million.

No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

We maintain the funds received from our IPO in an investment account, pending their use. There has been no material change in the planned use of proceeds from our IPO from that described in the Prospectus dated April 22, 2021 filed with the SEC pursuant to Rule 424(b)(4).

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes thereto included elsewhere in this Annual Report. This discussion and other parts of this Annual Report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors." Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a medical technology company driving a paradigm shift in the surgical treatment of *Hallux Valgus* (commonly known as bunions). We have pioneered our proprietary Lapiplasty 3D Bunion Correction System—a combination of innovative instruments, implants and surgical methods designed to improve the inconsistent clinical outcomes of traditional approaches to bunion surgery. Although bunions are deformities typically caused by an unstable joint in the middle of the foot that leads to a three-dimensional ("3D") misalignment in the foot's anatomical structure, the majority of traditional surgical approaches focus on correcting the deformity from a two-dimensional ("2D") perspective and therefore fail to address the root cause of the disorder. To effectively restore the normal anatomy of bunion patients and improve clinical outcomes, we believe addressing the root cause of the bunion is critical and have developed the Lapiplasty System to correct the deformity across all three anatomic dimensions. Our mission is to be the leader in the surgical treatment of bunions by establishing the Lapiplasty System as the standard of care. We recently expanded our offerings with the Adductoplasty™ Midfoot Correction System, designed for reproducible correction of the midfoot to provide further support to hallux valgus patients.

We were formed in 2013 and since receiving 510(k) clearance for the Lapiplasty System in March 2015, we have sold more than 42,000 Lapiplasty Procedure Kits in the United States. We market and sell our Lapiplasty Systems to physicians, surgeons, ambulatory surgery centers and hospitals. The Lapiplasty Procedure can be performed in either hospital outpatient or ambulatory surgery centers settings, and utilizes existing, well-established reimbursement codes. We currently market and sell the Lapiplasty System through a combination of a direct employee sales force and independent sales agencies across 118 territories in the United States. As of December 31, 2021, we had 81 direct sales representatives and 37 independent sales agencies. In 2021, employee sales representatives generated approximately 52% of revenues while approximately 48% of revenues came through independent sales agencies.

On April 27, 2021, we completed our initial public offering ("IPO") of 12,937,500 shares of common stock, which included the exercise in full of the underwriters' option to purchase additional shares. Before our IPO, our primary sources of capital have been private placements of common stock and convertible preferred stock, debt financing agreements and revenue from the sale of our products. As part of the IPO, we received net proceeds of approximately $107.6 million. Upon the completion of the IPO, all 6,687,475 shares of Series A convertible preferred stock then outstanding were converted into shares of common stock on a one-to-one basis plus 158,447 shares of common stock were issued to pay accrued cumulative dividends on Series A convertible preferred stock of $2.5 million. As of December 31, 2021, we had cash and cash equivalents of $105.8 million, an accumulated deficit of $41.9 million and $30.0 million of principal outstanding under our term loan agreement.

COVID-19 Impact

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus (COVID-19) as a pandemic, and in response to COVID-19 at that time, certain states within the United States implemented shelter-in-place rules requiring certain businesses not deemed "essential" to close and requiring elective procedures to be delayed. These restrictions began to adversely affect our revenue growth and operating results during the three months ended March 31, 2020. While we are encouraged by our results since restrictions were eased at the end of the second quarter of 2020 and with the introduction of vaccines in early 2021, we are aware that the actual and perceived impact of COVID-19 is changing and cannot be predicted, particularly due to potentially more contagious and virulent variants of the virus becoming prevalent and vaccination rates in the United States slowing. For example, during the three months ended September 30, 2021, the volume of procedures utilizing our product were adversely impacted by elective surgery delays and cancellations, and hospital capacity constraints due to increased hospitalizations caused by the COVID-19 Delta variant, particularly in Florida, Georgia, Texas and other areas significantly impacted by COVID-19. In the 2021 fourth quarter and into the 2022 first quarter, we have continued to observe elective surgery delays and cancellations and hospital staffing and capacity constraints, primarily related to the surge of infections and hospitalizations from the Omicron variant of COVID-19. We cannot assure you that we will not experience additional negative impacts associated with COVID-19, which could be significant. The COVID-19 pandemic has negatively impacted our business, financial condition and results of operations by significantly decreasing and delaying the number of procedures performed using our products, and we expect the pandemic could continue to negatively impact our business, financial condition and results of operations.

Key Business Metrics

We regularly review a number of operating and financial metrics, including the number of Lapiplasty Procedure Kits sold, the number of active surgeons using the Lapiplasty System and utilization rate, to evaluate our business, measure our performance, identify trends affecting our business, formulate our business plans and make strategic decisions. The number of Lapiplasty Procedure Kits sold during the twelve months ended December 31, 2021 increased by 6,377 or 57.4% over the twelve months ended December 31, 2020, and the number of active surgeons as of December 31, 2021 was 1,783, an increase of 39.8% from the prior year. The utilization rate for the twelve months ended December 31, 2021 increased 12.6% over the twelve months ended December 31, 2020 to an average of 9.8 Lapiplasty Procedure Kits per active surgeon.

We believe that the number of Lapiplasty Procedure Kits sold, number of active surgeons using the Lapiplasty System and utilization rate are useful indicators of our ability to drive adoption of the Lapiplasty System and generate revenue and are helpful in tracking the progress of our business. While we believe these metrics are representative of our current business, we anticipate these metrics may be substituted for additional or different metrics as our business grows.

Factors Affecting Our Business

We believe that our financial performance has been and in the foreseeable future, will continue to depend on many factors, including COVID-19 as described above, those described below, those noted in the section titled “Special Note Regarding Forward-Looking Statements” and in the section titled “Risk Factors”.

Adoption of the Lapiplasty System

The growth of our business depends on our ability to gain broader acceptance of the Lapiplasty System by successfully marketing and distributing the Lapiplasty System and ancillary products. We currently have approval at over 1,500 facilities across the United States and plan to continue to increase access by convincing even more surgeons and facility administrators that our products are alternatives to traditional products used in bunion surgical procedures. While surgeon adoption of the Lapiplasty Procedure remains critical to driving procedure growth, hospital and ambulatory surgery center facility approvals are necessary for both existing and future surgeon customers to access our products. To facilitate greater access to our products and drive future sales growth, we intend to continue educating hospitals and facility administrators on the differentiated benefits associated with the Lapiplasty System, supported by our robust portfolio of clinical data. If we are unable to successfully commercialize our Lapiplasty System, we may not be able to generate sufficient revenue to achieve or sustain profitability. In the near term, we expect we will continue to operate at a loss, and we anticipate we will finance our operations principally through offerings of our capital stock and by incurring debt.

Investments in Innovation and Growth

We expect to continue to focus on long-term revenue growth through investments in our business. In sales and marketing, we are dedicating meaningful resources to expand our sales force and management team in the United States, as well as our patient focused outreach and education campaigns. We are hiring additional direct sales representatives and employee field sales management to strategically access more regions with high densities of prospective patients and by focusing the efforts of our independent sales channel on our products. In research and development, our team and our Surgeon Advisory Board are continually working on next-generation innovations of the Lapiplasty System and related products. In addition to expanding our Lapiplasty offerings with products like the Lapiplasty Mini-Incision System, we are continually exploring opportunities to advance our core Lapiplasty System instrumentation and implants to further improve surgical efficiency, enhance reproducibility of outcomes and speed surgical recovery for patients.

We are also pursuing the development and potential commercialization, if cleared, of new products to address ancillary surgical procedures performed routinely in connection with the Lapiplasty Procedure. For example, to help address midfoot deformities that can occur in up to 30% of bunion patients, we developed and, in September 2021, announced the commercial launch of the Adductoplasty™ System. The Adductoplasty™ System brings together our implants and instrumentation to provide a comprehensive system designed for reproducible realignment, stabilization, and fusion of the midfoot and thus, provides surgeons with a precision, instrumented approach to treat both the bunion and coexisting midfoot deformities.

Moreover, in our general and administrative functions, we expect to continue to hire personnel and expand our infrastructure to both drive and support our anticipated growth and operations as a public company. Accordingly, in the near term, we expect these activities to increase our net losses, but in the longer term we anticipate they will positively impact our business and results of operations.

Seasonality

We have experienced and expect to continue to experience seasonality in our business, with higher sales volumes in the fourth calendar quarter, historically accounting for approximately 40% of full year revenues, and lower sales volumes in the first calendar quarter. Our sales volumes in the fourth calendar quarter tend to be higher as many patients elect to have surgery after meeting their annual deductible and having time to recover over the winter holidays. Our sales volumes in the first calendar quarter also tend to be lower as a result of adverse weather and by resetting annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. The orthopaedic industry traditionally experiences lower sales volumes in the third quarter than throughout the rest of the year as elective procedures generally decline during the summer months. Although we follow orthopaedic industry trends generally, to date our third quarter sales volumes have not been lower than other quarters, but we may experience relatively lower sales volumes during third quarters in the future.

Coverage and Reimbursement

Hospitals, ambulatory surgery centers and surgeons that purchase or use our products generally rely on third-party payors to reimburse for all or part of the costs and fees associated with procedures using our products. As a result, sales of our products depend, in part, on the extent to which the procedures using our products are covered by third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Based on historical claims data from 2017, approximately 63% of Lapidus cases and 60% of all bunion surgical cases were paid by private payors.

Medicare payment rates to hospital outpatient departments are set under the Medicare hospital outpatient prospective payment system, which groups clinically similar hospital outpatient procedures and services with similar costs to ambulatory payment classifications ("APCs"). Each APC is assigned a single lump sum payment rate, which includes payment for the primary procedure as well as any integral, ancillary, and adjunctive services. The primary CPT codes for the Lapiplasty Procedure, CPT 28297 and CPT 28740, are grouped together under APC 5114. For Lapiplasty Procedures in which fusion is performed on multiple TMT joints, CPT 28730 applies and is classified under APC 5115.

Components of Our Results of Operations

Revenue

We currently derive nearly all of our revenue from the sale of our proprietary Lapiplasty System, and to a lesser extent from the Adductoplasty System, which we introduced in the third quarter of 2021, and ancillary products. The Lapiplasty and Adductoplasty Systems are comprised of single-use implant kits and reusable instrument trays. We sell the Lapiplasty and Adductoplasty Systems to physicians, surgeons, hospitals and ambulatory surgery centers in the United States through a network of independent agencies and employee sales representatives. Our primary product is the Lapiplasty System, which is an instrumented, reproducible approach to 3D bunion correction that helps patients rapidly return to weight-bearing in a post-operative boot. We also offer other advanced instrumentation and implants for use in the Lapiplasty and Adductoplasty Procedures or other ancillary procedures performed in high frequency with bunion surgery. No single customer accounted for 10% or more of our revenue during 2021. We expect our revenue to increase in absolute dollars in the foreseeable future as we expand our sales territories, new accounts and trained physician base and as existing physician customers perform more Lapiplasty Procedures, though it may fluctuate from quarter to quarter due to a variety of factors, including seasonality.

Cost of Goods Sold

Cost of goods sold consists primarily of manufacturing costs for the purchase of our Lapiplasty and Adductoplasty Systems and other products from third-party manufacturers. Direct costs from our third-party manufacturers includes costs for raw materials plus the markup for the assembly of the components. Cost of goods sold also includes royalties, allocated overhead for indirect labor, depreciation, certain direct costs such as those incurred for shipping our products and personnel costs. We expense all provisions for excess and obsolete inventories as cost of goods sold. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. We expect our cost of goods sold to increase in absolute dollars in the foreseeable future to the extent more of our products are sold, though it may fluctuate from quarter to quarter.

Gross Profit and Gross Margin

We calculate gross profit as revenue less cost of goods sold, and gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily average selling prices, production and ordering volumes, change in mix of customers, third-party manufacturing costs and cost-reduction strategies. We expect our gross profit to increase in the foreseeable future as our revenue grows, though our gross margin may fluctuate from quarter to quarter due to changes in average selling prices as we introduce new products, and as we adopt new manufacturing processes and technologies.

Operating Expenses

Sales and Marketing

Sales and marketing expenses consist primarily of compensation for personnel, including salaries, bonuses, benefits, sales commissions and share-based compensation, related to selling and marketing functions, physician education programs, training, travel expenses, marketing initiatives including our direct-to-patient outreach program and advertising, market research and analysis and conferences and trade shows. We expect sales and marketing expenses to continue to increase in absolute dollars in the foreseeable future as we continue to invest in our direct sales force and expand our marketing efforts, and as we continue to expand our sales and marketing infrastructure to both drive and support anticipated sales growth, though it may fluctuate from quarter to quarter.

Research and Development

Research and development ("R&D") expenses consist primarily of engineering, product development, clinical studies to develop and support our products, regulatory expenses, and other costs associated with products and technologies that are in development. These expenses include compensation for personnel, including salaries, bonuses, benefits and share-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses, depreciation and an allocation of facility overhead expenses. We expect R&D expenses to continue to increase in absolute dollars in the foreseeable future as we continue to hire personnel and invest in next-generation innovations of the Lapiplasty System and related products, though it may fluctuate from quarter to quarter due to a variety of factors, including the level and timing of our new product development efforts, as well as our clinical development, clinical trial and other related activities.

General and Administrative

General and administrative expenses consist primarily of compensation for personnel, including salaries, bonuses, benefits and share-based compensation, related to finance, information technology, legal and human resource functions, as well as professional services fees (including legal, audit and tax fees), insurance costs, general corporate expenses and allocated facilities-related expenses. We expect general and administrative expenses to continue to increase in absolute dollars in the foreseeable future as we hire personnel and expand our infrastructure to drive and support the anticipated growth in our organization. Moreover, we have incurred, and expect to continue to incur, additional general and administrative expenses associated with operating as a public company, including legal, accounting, insurance, compliance with the rules and regulations of the SEC and those of any stock exchange on which our securities are traded, investor relations, and other administrative and professional services expenses.

Interest and other income (expense), net

Interest income and other income (expense), net consists of interest received on our money market funds and a loss and penalties from the extinguishment of term loans under the SVB Credit Facility.

Interest Expense

Interest expense consists of interest incurred and amortization of debt discount related to outstanding borrowings during the reported periods.

Results of Operations

Comparison of the years ended December 31, 2021 and 2020

The following table summarizes our results of operations for the periods indicated ($ in thousands):

	Year Ended December 31,		Change	
	2021	2020	Amount	%
Revenue	$ 94,419	$ 57,365	$ 37,054	64.6%
Cost of goods sold	17,826	12,470	5,356	43.0%
Gross profit	76,593	44,895	31,698	70.6%
Operating expenses				
Sales and marketing	64,467	31,654	32,813	103.7%
Research and development	10,204	5,847	4,357	74.5%
General and administrative	18,432	6,539	11,893	181.9%
Total operating expenses	93,103	44,040	49,063	111.4%
Loss from operations	(16,510)	855	(17,365)	*
Interest and other income (expense), net	18	(1,746)	1,764	(101.0)%
Interest expense	(4,060)	(2,777)	(1,283)	46.2%
Other expense, net	(4,042)	(4,523)	481	(10.6)%
Net loss and comprehensive loss	$ (20,552)	$ (3,668)	$ (16,884)	460.3%

* Not meaningful

Revenue. Revenue increased by $37.1 million, or 64.6%, from the year ended December 31, 2021 as compared to 2020. The increase was primarily due to a 57.4% increase in the number of Lapiplasty Procedure Kits sold in 2021 compared to 2020 as the result of an expanded customer base and a slight increase in average sales prices. In addition, revenues in 2020 were adversely impacted by government-mandated restrictions on elective procedures in response to the COVID-19 pandemic that lasted from March 2020 through May 2020 when such restrictions began to ease. Although the restrictions were eased at the end of the second quarter of 2020 and vaccines were introduced in early 2021, the volume of procedures utilizing our product in 2021 were adversely impacted by elective surgery delays or cancellations and hospital staffing and capacity constraints, primarily related to the surge of infections and hospitalizations from the Delta and Omicron variants of COVID-19.

Cost of Goods Sold, Gross Profit and Gross Margin. Cost of goods sold increased by $5.4 million, or 43.0%, in the year ended December 31, 2021 as compared to 2020. The increase in cost of goods sold was primarily due to $4.0 million increase in direct costs of goods sold resulting from increased sales, $1.9 million increase in royalty expense resulting from our increased sales, and $0.5 million increase in overhead expenses resulting from expansion of our headquarters and headcount and the normalization of operations compared to the year ended December 31, 2020, which was adversely impacted by pandemic-related restrictions on elective surgeries. The increases were partially offset by a decrease in provision for inventory obsolescence of $0.9 million and $0.3 million decrease in depreciation expense of our surgical instruments due to a prospective adjustment that was made on January 1, 2021 to the useful life of our capitalized instruments to align with the expected life of the instruments. Gross profit and gross margin increased to $76.6 million and 81.1%, respectively, from the year ended December 31, 2021 as compared to 2020, primarily due to the decreased per unit direct costs of goods sold and depreciation expense of our surgical instruments, which were partially offset by an increase in royalty expense as a percent of sales.

Sales and Marketing Expenses. Sales and marketing expenses increased by $32.8 million, or 103.7%, from the year ended December 31, 2021 as compared to 2020. The increase in sales and marketing expenses was primarily due to growth in our overall business. Sales and marketing expenses increased as a result of an increase of $9.7 million in professional services primarily for higher commissions from increased sales by our independent sales agencies, an increase of $11.4 million in advertising and marketing-related expenses primarily due to higher advertising fees and a new television commercial campaign, an increase of $9.5 million in payroll and payroll-related expenses resulting from increased headcount of sales personnel, and $2.2 million in other marketing-related expenses resulting from increased sales efforts. Additionally, we experienced delayed expenditures for surgeon education events, patient outreach campaigns and other planned sales and marketing expenses in connection with the pandemic in 2020.

Research and Development Expenses. Research and development expenses increased by $4.4 million, or 74.5%, from the year ended December 31, 2021 as compared to 2020. The increase in research and development expenses was due to an increase of $3.1 million in payroll and payroll-related costs resulting from increased headcount of research and development personnel, an increase of $1.1 million in professional services from higher consulting fees, and an increase of $0.4 million due to increased purchases of prototypes.

General and Administrative Expenses. General and administrative expenses increased by $11.9 million, or 181.9%, from the year ended December 31, 2021 as compared to 2020. The increase in general and administrative expenses was primarily due to an increase of $5.8 million in payroll and payroll-related costs due to increased headcount in our business, an increase of $3.0 million in business-related expenses primarily resulting from increased insurance costs and fees, an increase of $2.6 million in professional services primarily related to legal and audit expenses, and an increase of $0.3 million in rent expense resulting from the expansion of our headquarters.

Interest and Other Income (Expense), Net. Interest and other income (expense), net increased by $1.8 million, or 101%, in 2021 as compared to 2020. The increase was primarily due to the recognition of a $0.6 million loss from the extinguishment of term loans under the SVB Credit Facility and $1.2 million prepayment penalty paid upon termination of the loans under the SVB Credit Facility in 2020.

Interest Expense. Interest expense increased by $1.3 million, or 46.2%, during 2021 as compared to 2020. The increase in interest expense was primarily due to higher interest due under our CRG loan of $30.0 million, which is outstanding from July 2020.

For the comparison of the results of operations for the years ended December 31, 2020 and 2019, refer to our Registration Statement on Form S-1 as filed with the U.S Securities and Exchange Commission on April 19, 2021.

Liquidity and Capital Resources

Overview

Before our IPO, our primary sources of capital were private placements of common stock and convertible preferred stock, debt financing agreements and revenue from the sale of our products. In April 2021, we received net proceeds of $107.6 million from our IPO. As of December 31, 2021, we had cash and cash equivalents of $105.8 million, an accumulated deficit of $41.9 million and $30.0 million of principal outstanding under our term loan agreement with CRG. We repaid $1.8 million in borrowings outstanding from the Paycheck Protection Program loan program (the "PPP Loan") under the Coronavirus Aid Relief and Economic Recovery Act in 2021. We have an existing credit facility with SVB that provides a revolving line of credit of $10.0 million. We believe that our existing cash and cash equivalents, available debt borrowings and expected revenues will be sufficient to meet our capital requirements and fund our operations for at least twelve months from the issuance of our financial statements as of and for the year ended December 31, 2021. We may be required or decide to raise additional financing to support further growth of our operations.

Short-Term and Long-Term Obligations

Silicon Valley Bank Loan

On August 3, 2020, we entered into the Third Amendment to the Loan and Security Agreement (the "Third Amendment"), with SVB which terminated the third tranche term loan and increased the revolving line of credit to $10.0 million. The Loan and Security Agreement ("LSA"), as amended by the First Amendment, Second Amendment, and Third Amendment (collectively, the "SVB Credit Facility") matures August 3, 2024. The SVB Credit Facility incurs interest at the greater of (i) 1.00% above the Prime Rate or (ii) 5.00% and is subject to a termination fee of 1.00%.

As of December 31, 2021, we had $10 million of availability to borrow under the revolving line of credit and no borrowings outstanding related to our revolving line of credit.

Under the terms of the SVB Credit Facility, we granted SVB first-priority liens and security interests in substantially all of our assets (excluding our intellectual property but including any proceeds and rights to payments associated with our intellectual property) as collateral. The SVB Credit Facility also contains certain representations and warranties, indemnification provisions in favor of SVB, affirmative and negative covenants (including, among other things, requirements that we maintain a minimum amount of liquidity and achieve minimum revenue targets, limitations on other indebtedness, liens, acquisitions, investments and dividends and requirements relating to financial reporting, sales and leasebacks, insurance and protection of our intellectual property rights) and events of default (including payment defaults, breaches of covenants following any applicable cure period, investor abandonment, a material impairment in the perfection or priority of the lender's security interest or in the collateral), and events relating to bankruptcy or insolvency). As of December 31, 2021, we were in compliance with all covenants under the SVB Credit Facility.

CRG Term Loan Facility

On July 31, 2020, we entered into a non-revolving term loan facility with CRG (the "CRG Term Loan Facility") to obtain up to $50.0 million in financing over three tranches to be advanced no later than December 31, 2021. Principal borrowings outstanding excluding discount and issuance costs as of December 31, 2021, totaled $30.0 million.

The CRG Term Loan Facility matures on June 30, 2025, and we can elect to make quarterly interest-only payments, to pay 7.50% interest in cash and 5.5% interest in-kind. We are not required to make any principal payments until the maturity of the CRG Term Loan Facility and all outstanding principal and accrued interest are due upon the maturity of the CRG Term Loan Facility. Interest under the CRG Term Loan Facility is applied to outstanding principal and accrued interest at a rate of 13.00% per annum. If an event of default occurs, interest under the CRG Term Loan Facility will increase by 4.00%. If we repay the CRG Term Loan Facility within one year of the applicable borrowing date, we are required to pay a premium of 20.00% of the aggregated outstanding principal amount of the loans that is repaid. If we repay the CRG Term Loan Facility between one and two years from the applicable borrowing date, we are required to pay a premium of 11.00% of the aggregated outstanding principal amount of the loans that is repaid. The CRG Term Loan Facility does not require a prepayment premium for loans being prepaid on the prepayment date that is after two years from the applicable borrowing date.

Under the terms of the CRG Term Loan Facility, we granted CRG first priority liens and security interests in substantially all of our assets as collateral (including our intellectual property), provided that the priority of such liens are subject to an intercreditor agreement between CRG and SVB. The CRG Term Loan Facility also contains certain representations and warranties, indemnification provisions in favor of CRG, affirmative and negative covenants (including, among other things, requirements that we maintain a minimum amount of liquidity and achieve minimum revenue targets, limitations on other indebtedness, liens, acquisitions, investments and dividends and requirements relating to financial reporting, sales and leasebacks, insurance and protection of our intellectual property rights) and events of default (including payment defaults, breaches of covenants following any applicable cure period, investor abandonment, a material impairment in the perfection or priority of the lender's security interest or in the collateral, and events relating to bankruptcy or insolvency). As of December 31, 2021, we were in compliance with all covenants under the CRG Term Loan Facility.

Funding Requirements

We use our cash to fund our operations, which primarily include the costs of manufacturing our Lapiplasty and Adductoplasty Systems and ancillary products, as well as our sales and marketing and research and development expenses and related personnel costs. We expect our sales and marketing expenses to increase for the foreseeable future as we continue to invest in our direct sales force and expand our marketing efforts, and as we continue to expand our sales and marketing infrastructure to both drive and support anticipated sales growth. We also expect R&D expenses to increase for the foreseeable future as we continue to hire personnel and invest in next-generation innovations of the Lapiplasty System and related products. In addition, we expect our general and administrative expenses to increase for the foreseeable future as we hire personnel and expand our infrastructure to both drive and support the anticipated growth in our organization. We will also incur additional expenses as a result of operating as a public company and also expect to increase the size of our administrative function to support the growth of our business. From time to time, we may also consider additional investments in technologies, assets and businesses to expand or enhance our product offerings. The timing and amount of our operating expenditures will depend on many factors, including:

- the scope and timing of our investment in our commercial infrastructure and sales force;
- the costs of our ongoing commercialization activities including product sales, marketing, manufacturing and distribution;
- the scope of our marketing efforts, including the degree to which we utilize direct to consumer campaigns;
- the degree and rate of market acceptance of the Lapiplasty System;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including enforcing our intellectual property rights against infringing products or technologies;
- our need to implement additional infrastructure and internal systems;
- the research and development activities we intend to undertake in order to improve the Lapiplasty System and to develop or acquire additional products;
- the investments we make in acquiring other technologies, assets or businesses to expand our product portfolio;
- the success or emergence of new competing technologies or other adverse market developments;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company; and
- the impact of the COVID-19 pandemic, hospital staffing shortages, and general economic conditions on our operations and business.

Based upon our current operating plan, we believe that our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. We have based this estimate on assumptions that may prove to be wrong or that may change in the future, and we could utilize our available capital resources sooner than we expect. We may seek to raise any necessary additional capital through public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these or other funding sources. Additional funds may not be available to us on acceptable terms or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, we could be forced to delay, limit, reduce or terminate our product development programs, commercialization efforts, sales and marketing initiatives, or other operations. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for the periods presented below (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Net cash (used in) provided by:			
Operating activities	$ (17,193)	$ (4,494)	$ (7,673)
Investing activities	(2,705)	(1,069)	(1,211)
Financing activities	107,652	11,503	19,739
Net increase in cash and cash equivalents	$ 87,754	$ 5,940	$ 10,855

Net Cash Used in Operating Activities

Net cash used in operating activities for 2021 was $17.2 million, consisting primarily of a net loss of $20.6 million and an increase in net operating assets of $1.3 million, which were partially offset by non-cash charges of $4.6 million. The increase in net operating assets was primarily due to an increase in accounts receivable resulting from higher revenues in 2021, higher inventories resulting from higher purchases in anticipation of growing demand in 2022, and an increase in prepaid expenses and other assets due to timing of payments and growth of our operations, which were offset by increases in accounts payable and accrued liabilities due to timing of payments and growth of our operations. The non-cash charges primarily consisted of depreciation and amortization expense of $0.7 million, share-based compensation expense of $3.4 million, amortization of debt issuance costs of $0.2 million and the provision for inventory obsolescence of $0.3 million.

Net cash used in operating activities for 2020 was $4.5 million, consisting primarily of a net loss of $3.7 million and an increase in net operating assets of $5.3 million, which were partially offset by non-cash charges of $4.5 million. The increase in net operating assets was primarily due to an increase in accounts receivable resulting from higher revenues in 2020 and inventories resulting from higher purchases in anticipation of growing demand in 2021, which were offset by increases in accounts payable and accrued liabilities due to timing of payments and growth of our operations. The non-cash charges primarily consisted of depreciation and amortization expense of $1.2 million, provision for excess and obsolete inventories of $1.1 million, share-based compensation expense of $0.9 million, provision for allowance for doubtful accounts of $0.2 million, amortization of debt issuance costs of $0.2 million and impairment of surgical instruments of $0.1 million.

Net cash used in operating activities for 2019 was $7.7 million, consisting primarily of a net loss of $4.3 million and an increase in net operating assets of $5.3 million, partially offset by non-cash charges of $1.9 million. The increase in net operating assets was primarily due to an increase in accounts receivable resulting from higher revenues in 2019, inventories resulting from increased purchases in anticipation of growing demand in 2020 and prepaid expenses to support the growth of our operations, partially offset by increases in accrued liabilities and accounts payable, due to timing of payments and growth of our operations. The non-cash charges primarily consisted of depreciation and amortization expense of $0.8 million, stock-based compensation expense of $0.8 million, provision for doubtful accounts of $0.1 million and amortization of debt issuance costs and warrant discount of $0.1 million.

Net Cash Used in Investing Activities

Net cash used in investing activities was $2.7 million, $1.1 million and $1.2 million in 2021, 2020 and 2019, respectively, consisting of purchases of capitalized surgical instruments for our reusable instrument trays.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in 2021 was $107.7 million, consisting primarily of net proceeds from our IPO of $107.6 million and $1.8 million proceeds from exercise of stock options, partially offset by repayment of our PPP Loan from the SBA of $1.8 million.

Net cash provided by financing activities in 2020 was $11.5 million, consisting primarily of additional borrowings under the CRG Term Loan Facility of $29.5 million, net of debt discount, partially offset by repayment of the term loans under the SVB Credit Facility of $20.0 million, borrowing under SBA Loan of $1.8 million and cash received of $0.3 million from the exercise of stock options, partially offset by debt issuance costs of $0.2 million.

Net cash provided by financing activities in 2019 was $19.7 million, consisting primarily of additional borrowings under the term loan agreement of $20.0 million and cash received of $0.1 million from the exercise of stock options, partially offset by debt issuance costs of $0.3 million.

Surgeon Advisory Board Royalty Agreements

We recognized royalties' expense of $4.3 million and $2.4 million for the years ended December 31, 2021 and 2020, respectively. For the years ended December 31, 2021 and 2020, the aggregate royalty rate was 4.6% and 4.1%, respectively. Each of the SAB Royalty Agreements prohibits the payment of royalties on products sold to entities and/or individuals with whom any of the surgeon advisors is affiliated.

Operating Lease

We have commitments for future payments related to our office lease located in Ponte Vedra, Florida which expires in 2026. Lease payments comprise of the base rent stated in the lease plus operating costs which include taxes, insurance and common area maintenance. The remaining lease obligation was $2.3 million under this lease as of December 31, 2021.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. 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 value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in Note 2 of our financial statements included in this Annual Report on Form 10-K, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Stock-Based Compensation

We account for stock-based compensation arrangements with employees in accordance with ASC 718, Compensation—Stock Compensation, using a fair-value based method. We determine the fair value of stock options on the date of grant using the Black-Scholes option pricing model.

The fair value of time-based awards is recognized over the period during which an award holder is required to provide services in exchange for the award, known as the requisite service period, which is typically the vesting period using the straight-line method. Stock-based compensation expense is recorded net of estimated forfeitures in our statements of operations.

We estimate the fair value of our stock-based awards using the Black-Scholes option-pricing model, which requires the input of highly subjective assumptions regarding the expected volatility of our stock, the expected life of the stock award and our dividend ratio. We primarily use historical data to determine the assumptions to be used in the Black-Scholes model and have no reason to believe that future data is likely to differ materially from historical data. However, changes in the assumptions regarding future stock price volatility, future dividend payments and future stock award exercise could result in a change in the assumptions used to value awards in the future and may result in a material change to the fair value calculation of stock-based awards.

Fair Value of Common Stock

Prior to our IPO, the estimated fair value of the common stock underlying our stock options and stock awards was determined at each grant date by our board of directors, with assistance from management and external appraisers. All options to purchase shares of our common stock were intended 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. The approach to estimate the fair value of our common stock was consistent with the methods outlined in the American Institute of Certified Public Accountants' Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or Practice Aid. Subsequent to our IPO, the fair value of our common stock is determined based on its closing market price.

Recently Issued Accounting Pronouncements

Refer to Note 3, "Recent Accounting Pronouncements", to our audited financial statements included elsewhere in this Annual Report on Form 10-K for new accounting pronouncements as of the date of this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The primary objectives of our investment activities are to preserve principal and provide liquidity. The risk associated with fluctuating interest rates is primarily limited to our cash equivalents, which are carried at quoted market prices. Since our results of operations are not dependent on investments, the risk associated with fluctuating interest rates is limited to our investment portfolio, and we believe that a hypothetical 10% change in interest rates would not have a significant impact on our financial statements included elsewhere in this Annual Report. As of December 31, 2021, our investments consisted only of money market funds. We do not currently use or plan to use financial derivatives in our investment portfolio.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders
Treace Medical Concepts, Inc.

Opinion on the financial statements

We have audited the accompanying balance sheets of Treace Medical Concepts, Inc. (a Delaware corporation) (the "Company") as of December 31, 2021 and 2020, the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2018.

Jacksonville, FL
March 4, 2022

TREACE MEDICAL CONCEPTS, INC.
Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2021	2020
Assets		
Current assets		
Cash and cash equivalents	$ 105,833	$ 18,079
Accounts receivable, net of allowance for doubtful accounts of $414 and $446 as of December 31, 2021 and 2020, respectively	18,568	14,486
Inventories	10,561	7,820
Prepaid expenses and other current assets	3,010	593
Total current assets	137,972	40,978
Property and equipment, net	2,849	829
Total assets	$ 140,821	$ 41,807
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 4,056	$ 2,265
Accrued liabilities	4,518	1,848
Accrued commissions	5,181	3,513
Accrued compensation	4,455	2,183
Short-term debt	—	1,788
Total current liabilities	18,210	11,597
Derivative liability on term loan	173	245
Long-term debt, net of discount of $635 and $811 as of December 31, 2021 and 2020, respectively	29,365	29,189
Total liabilities	47,748	41,031
Commitments and contingencies (Note 7)		
Stockholders' equity		
Series A convertible preferred stock, $0.001 par value, 0 shares authorized and 0 shares issued and outstanding as of December 31, 2021; 6,687,500 shares authorized and 6,687,475 shares issued and outstanding as of December 31, 2020; liquidation value of $0 and $8,000 as of December 31, 2021 and 2020, respectively	—	7,935
Preferred stock, $0.001 par value, 5,000,000 shares authorized; 0 shares issued and outstanding as of December 31, 2021; 0 shares authorized, issued and outstanding as of December 31, 2020	—	—
Common stock, $0.001 par value, 300,000,000 shares authorized; 54,181,082 issued and outstanding as of December 31, 2021; 66,875,000 shares authorized, 37,366,865 issued and outstanding as of December 31, 2020	45	28
Common stock Class B, $0.001 par value, 0 shares authorized, issued and outstanding as of December 31, 2021; 1,000,000 shares authorized and 0 shares issued and outstanding as of December 31, 2020	—	—
Additional paid-in capital	134,933	14,166
Accumulated deficit	(41,905)	(21,353)
Total stockholders' equity	93,073	776
Total liabilities and stockholders' equity	$ 140,821	$ 41,807

The accompanying notes are an integral part of these financial statements

TREACE MEDICAL CONCEPTS, INC.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2021	2020	2019
Revenue	$ 94,419	$ 57,365	$ 39,416
Cost of goods sold	17,826	12,470	7,631
Gross profit	76,593	44,895	31,785
Operating expenses			
Sales and marketing	64,467	31,654	25,786
Research and development	10,204	5,847	5,070
General and administrative	18,432	6,539	4,464
Total operating expenses	93,103	44,040	35,320
Income (loss) from operations	(16,510)	855	(3,535)
Interest and other income (expense), net	18	(1,746)	111
Interest expense	(4,060)	(2,777)	(841)
Other expense, net	(4,042)	(4,523)	(730)
Net loss and comprehensive loss	(20,552)	(3,668)	(4,265)
Convertible preferred stock cumulative and undeclared dividends	(196)	(640)	(640)
Net loss attributable to common stockholders	$ (20,748)	$ (4,308)	$ (4,905)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.43)	$ (0.12)	$ (0.13)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	48,415,679	37,068,965	36,911,586

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

TREACE MEDICAL CONCEPTS, INC.
Statements of Stockholders' Equity
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balances at January 1, 2019	6,687,475	$ 7,935	36,771,697	$ 27	$ 11,407	$ (13,421)	$ 5,948
Issuance of warrants for Class A common stock in connection with Credit Facility (Note 9)	—	—	—	—	595	—	595
Common stock issued upon exercise of stock options	—	—	260,144	1	67	—	68
Share-based compensation expense	—	—	—	—	815	—	815
Net loss	—	—	—	—	—	(4,265)	(4,265)
Balances at December 31, 2019	6,687,475	$ 7,935	37,031,841	$ 28	$ 12,884	$ (17,686)	$ 3,161
Common stock issued upon exercise of stock options	—	—	335,025	—	364	—	364
Share-based compensation expense	—	—	—	—	919	—	919
Net loss	—	—	—	—	—	(3,668)	(3,668)
Balances at December 31, 2020	6,687,475	$ 7,935	37,366,865	$ 28	$ 14,167	$ (21,353)	$ 776
Issuance of common stock upon exercise of stock options	—	—	2,368,705	2	1,828	—	1,830
Issuance of restricted stock awards	—	—	24,895	—	—	—	—
Share-based compensation expense	—	—	—	—	3,409	—	3,409
Issuance of common stock from initial public offering, net of issuance costs and underwriting discount of $10.6 million	—	—	6,953,125	7	107,603	—	107,610
Issuance of common stock upon net exercise of warrants	—	—	621,570	1	(1)	—	—
Conversion of convertible preferred stock and accrued dividends on convertible preferred stock into common stock	(6,687,475)	(7,935)	6,845,922	7	7,928	—	—
Net loss	—	—	—	—	—	(20,552)	(20,552)
Balances at December 31, 2021	—	$ —	54,181,082	$ 45	$ 134,934	$ (41,905)	$ 93,073

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

TREACE MEDICAL CONCEPTS, INC.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities			
Net loss	$ (20,552)	$ (3,668)	$ (4,265)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation and amortization expense	685	1,210	793
Provision for allowance for doubtful accounts	144	216	145
Share-based compensation expense	3,409	919	815
Amortization of debt issuance costs	176	220	147
Impairment of capitalized surgical instruments	—	144	—
Gain on fair value adjustment to derivative liability	(72)	—	—
Provision for inventory obsolescence	347	1,144	—
Loss on early settlement of debt	—	639	—
Net changes in operating assets and liabilities:			
Accounts Receivable	(4,226)	(4,290)	(6,022)
Inventory	(3,088)	(3,402)	(2,813)
Prepaid expenses and other assets	(2,417)	(103)	(94)
Accounts payable	1,791	1,334	(236)
Accrued liabilities	6,610	1,143	3,857
Net cash used in operating activities	(17,193)	(4,494)	(7,673)
Cash flows from investing activities			
Purchases of property and equipment	(2,705)	(1,069)	(1,211)
Net cash used in investing activities	(2,705)	(1,069)	(1,211)
Cash flows from financing activities			
Proceeds from interest bearing debt	—	29,530	20,000
Payments on interest bearing debt	—	(20,000)	—
Proceeds from PPP Loan	—	1,788	—
Repayments on PPP Loan	(1,788)	—	—
Proceeds from issuance of common stock upon initial public offering, net of issuance costs and underwriting fees of $10.6 million	107,610	—	—
Debt issuance costs	—	(179)	(329)
Proceeds from exercise of employee stock options	1,830	364	68
Net cash provided by financing activities	107,652	11,503	19,739
Net increase in cash and cash equivalents	87,754	5,940	10,855
Cash and cash equivalents at beginning of period	18,079	12,139	1,284
Cash and cash equivalents at end of period	$ 105,833	$ 18,079	$ 12,139
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 3,900	$ 1,146	$ 739
Noncash financing activities:			
Issuance of warrants for Class A common stock in connection with the Company's Credit Facility	$ —	$ —	$ 595
Issuance of common stock upon exercise of warrants	$ 1	$ —	$ —
Conversion of convertible preferred stock and accrued dividends on convertible preferred stock into common stock	$ 7,935	$ —	$ —
Initial fair value of derivative liability	$ —	$ 245	$ —

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

1. Formation and Business of the Company

The Company

Treace Medical Concepts, LLC was formed on July 29, 2013 as a Florida limited liability company. Effective July 1, 2014, the entity converted to a Delaware corporation and changed its name to Treace Medical Concepts, Inc. (the "Company"). The Company is a medical technology company driving a paradigm shift in the surgical treatment of *Hallux Valgus* (commonly known as "bunions"). The Company received 510(k) clearance for the Lapiplasty System in March 2015 and began selling its surgical medical devices in September 2015. The Company has pioneered the proprietary Lapiplasty 3D Bunion Correction System – a combination of innovative instruments, implants and surgical methods designed to improve the inconsistent clinical outcomes of traditional approaches to bunion surgery. In addition, the Company offers other advanced instrumentation and implants for use in the Lapiplasty Procedure or other ancillary procedures performed in high frequency with bunion surgery. The Company recently expanded its offerings with the Adductoplasty™ Midfoot Correction System, designed for reproducible correction of the midfoot to provide further support to hallux valgus patients. The Company operates from its corporate headquarters located in Ponte Vedra, Florida.

Initial Public Offering

On April 27, 2021, the Company completed its initial public offering ("IPO") of 12,937,500 shares of its common stock, which included the exercise in full of the underwriters' option to purchase additional shares. As part of the IPO, 6,953,125 shares of common stock were issued and sold by the Company (inclusive of 703,125 shares pursuant to the exercise of the underwriters' option) and 5,984,375 shares of common stock that were sold by the selling stockholders named in the prospectus (inclusive of 984,375 shares pursuant to the exercise of the underwriters' option), at a price to the public of $17.00 per share. The Company received net proceeds of approximately $107.6 million, after deducting underwriting discounts and commissions of $8.3 million and offering expenses payable by the Company of $2.3 million. The Company did not receive any proceeds from the sale of the shares by the selling stockholders. Upon the completion of the IPO, all 6,687,475 shares of Series A convertible preferred stock then outstanding were converted into shares of common stock on a one-to-one basis plus 158,447 shares of common stock were issued to pay accrued cumulative dividends on Series A convertible preferred stock of $2.5 million.

Forward Stock Split

On April 16, 2021, in connection with the IPO, the Company filed an Amended and Restated Certificate of Incorporation with the Delaware Secretary of State to implement a 1.3375-for-1 forward stock split (the "Forward Stock Split"), effective on April 16, 2021, whereby each 1.0 share of Class A common stock issued and outstanding was reclassified as 1.3375 shares of Class A common stock and each 1.0 share of Series A convertible preferred stock (each a "Preferred Share") issued and outstanding was reclassified as 1.3375 Preferred Shares. In connection with the Forward Stock Split, the total number of shares of all classes of stock which the Company is authorized to issue was adjusted to 73,562,500, divided into 66,875,000 shares of Class A common stock and 6,687,500 Preferred Shares. There was no adjustment to the par value of $0.001 per share. All share and per share amounts in the accompanying financial statements for the prior periods have been retroactively adjusted to reflect the Forward Stock Split. In lieu of issuing fractional shares in connection with the Forward Stock Split, the Company is obligated to pay cash in an amount equal to the fair value of such fractional shares (as determined in good faith by the Company's Board of Directors).

Liquidity and Capital Resources

The Company has incurred operating losses to date and has an accumulated deficit of $41.9 million as of December 31, 2021. During the years ended December 31, 2021, 2020 and 2019, the Company used $17.2 million, $4.5 million and $7.7 million of cash in its operating activities, respectively. As of December 31, 2021, the Company had cash and cash equivalents of $105.8 million.

Management believes that the Company's existing cash and cash equivalents will allow the Company to continue its planned operations for at least the next 12 months from the date of the issuance of these financial statements.

Coronavirus Pandemic

The Company's operations have been impacted by the coronavirus ("COVID-19") pandemic beginning in 2020. In response to COVID-19, certain states within the United States implemented shelter-in-place rules requiring certain businesses not deemed "essential" to close and requiring elective procedures to be delayed. The Company's revenue growth was adversely impacted, particularly by the restrictions on elective procedures, from March 2020 through May 2020, when such restrictions were largely eased. In the third quarter of 2021, the Company experienced a softening in the demand for procedures as hospital capacity was constrained as a result of increased hospitalizations caused by the COVID-19 Delta variant, particularly in Florida, Texas and other areas significantly impacted by COVID-19. In addition to constraints in hospital capacity, the Company continues to observe disruption

from deferral of elective procedures and hospital staffing shortages. In the 2021 fourth quarter and into the 2022 first quarter, the Company continued to observe elective surgery delays and cancellations and hospital staffing and capacity constraints, primarily related to the surge of infections and hospitalizations from the Omicron variant of COVID-19. There is still uncertainty around the breadth and duration of business disruptions related to COVID-19, as well as its impact on the United States and international economies, especially as more potentially contagious and virulent variants of the virus are spreading. While the Company has experienced revenue growth during the pandemic, if states implement shelter-in-place rules again or medical facilities implement restrictions on elective surgeries, the Company may be required to adjust its forecasted revenues and operating results.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared using accounting principles generally accepted in the United States of America ("GAAP"), as defined by the Financial Accounting Standards Board, or the FASB.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the periods presented. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Significant estimates and assumptions include reserves and write-downs related to accounts receivable, inventories, the recoverability of long-term assets, valuation of equity instruments, valuation of common stock, stock-based compensation, deferred tax assets and related valuation allowances and impact of contingencies. The Company had no accrued contingent liabilities as of December 31, 2021 and 2020.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities, approximate their fair value due to the short-term nature of these assets and liabilities. The derivative liability is carried at fair value based on unobservable market inputs. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the term loans approximates their fair value (Note 4).

Segments

The Company operates and manages its business as one reportable and operating segment, which is the business of designing, manufacturing, and marketing medical devices for physicians, surgeons, ambulatory surgery centers and hospitals. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating and evaluating financial performance. All long-lived assets are maintained in the United States.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original or remaining maturity of three months or less at the time of purchase to be cash equivalents, which include money market funds.

Accounts Receivable and Allowances

Accounts receivable are generally from hospitals and ambulatory surgery centers and are stated at amounts billed less allowances for doubtful accounts. The Company continually monitors customer payments and maintains an allowance for losses resulting from a customer's inability to make required payments. The Company considers factors such as historical experience, credit quality, age of the accounts receivable balances, geographic related risks and economic conditions that may affect a customer's ability to pay. Accounts receivable are written off when individual balances are no longer collectible. As of December 31, 2021 and 2020, accounts receivable is presented net of an allowance for doubtful accounts of $0.4 million in both years. For the years ended December 31, 2021, 2020 and 2019, the Company recorded provision for bad debts of $0.1 million, $0.2 million and $0.1 million, respectively.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash, cash equivalents and accounts receivable. The Company maintains its cash and cash equivalents balances with established financial institutions and, at times, such balances with any one financial institution may be in excess of the Federal Deposit Insurance Corporation ("FDIC") insured limits.

The Company earns revenue from the sale of its products to customers such as hospitals and ambulatory surgery centers. The Company's accounts receivable is derived from revenue earned from customers. The Company performs ongoing credit evaluations of its customers' financial condition and generally requires no collateral from its customers and independent sales agencies. At December 31, 2021 and 2020, no customer accounted for more than 10% of accounts receivable. For the years ended December 31, 2021, 2020 and 2019, there were no customers that represented 10% or more of revenue.

Inventories

Inventories consist primarily of surgical kits and components as finished goods and are stated at the lower of cost or net realizable value. Cost is determined based on an average cost method which approximates the first-in, first-out basis and includes primarily outsourced manufacturing costs and direct manufacturing overhead costs. The Company reviews inventory for obsolescence and writes down inventory, as necessary. For the years ended December 31, 2021, 2020 and 2019, the Company recorded a provision of $0.3 million, $1.1 million and $0.1 million, respectively, for obsolete inventory to cost of goods sold.

Property and Equipment, Net

Property and equipment is recorded at cost. Depreciation of property and equipment is recorded using the straight-line method over the following estimated useful lives as follows:

	Years
Furniture, fixtures and equipment	7
Machinery and equipment	3
Capitalized surgical instruments	3
Computer equipment	3
Leasehold improvements	5 or lease term, whichever is shorter
Software	3

Long-lived assets are evaluated whenever a change in circumstances indicates that the carrying amount of an asset may not be recoverable. If assets are considered to be impaired, a charge is recorded for an amount that the carrying value exceeds the fair value. The Company recorded impairment charges for its property and equipment, net of $0 for the year ended December 31, 2021 and 2019, and $0.1 million for the year ended December 31, 2020.

Beginning January 1, 2021, the Company adjusted the useful life of its capitalized instruments from 18 months to 36 months to align with the expected life of the instruments. The change in useful life was made as a prospective adjustment and resulted in a decrease of depreciation expense of $0.3 million during the year ended December 31, 2021 and no material impact on earnings per share. The change in useful life is not expected to significantly impact annual depreciation expense.

Leases

The Company leases certain office spaces which are classified as operating leases under Accounting Standards Codification ("ASC") 840, *Leases.* Rent expense is recognized on a straight-line basis over the term of the lease and, accordingly, the difference between cash rent payments and the rent expense is recorded as deferred rent liability and is accrued within accrued expenses and other liabilities.

Revenue Recognition

The Company generates revenue through the sale of its primary product, the Lapiplasty System, the new Adductoplasty and Lapiplasty Mini-Incision Systems and ancillary products. The Lapiplasty and Adductoplasty Systems are comprised of single-use implant kits and reusable instrument trays. Implant kits and ancillary products are sold in the United States through a combination of a direct employee sales force and independent sales agencies. The Company invoices hospitals and ambulatory surgery centers for the

implant kits and ancillary products and pays commissions to the sales representatives and independent sales agencies. The Company has no international sales.

For shipments to customers, the Company offers the right to return the product within 30 days for a full refund, and for returns between 30 and 90 days, the Company offers a full refund less 15% restocking fee. The Company does not have a history of product returns for refund. Customer invoices are generally payable within 30 days. The Company's products are generally sold with a limited standard warranty to the original purchaser of the products against defects in workmanship and materials for 180 days. The Company's liability is limited to providing, at the Company's option, a full refund or credit of the purchase price, or repairing or replacing the product, provided that the customer returns the defective product within 180 days from the purchase date. To date, the Company has had negligible returns of any products alleged to be defective.

On January 1, 2019, the Company adopted ASC 606, *Revenue from Contracts with Customers*, using the modified retrospective method for all contracts not completed as of the date of adoption. In connection with the adoption of ASC 606, the Company also adopted the related amendments that impact the accounting for the incremental costs of obtaining a contract. Adoption of ASC 606 did not have any impact on the financial statements, except changes in the disclosures.

Under ASC 606, revenue is recognized when the customer obtains control of promised goods or services, in an amount that reflects consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps as prescribed by ASC 606:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies performance obligations.

A contract with a customer exists when (i) the Company enters into a legally enforceable contract with a customer that defines each party's rights regarding the products to be transferred and identifies the payment terms related to these products, (ii) the contract has commercial substance and, (iii) the Company determines that collection of substantially all consideration for its products that are transferred is probable based on the customer's intent and ability to pay the promised consideration. The Company considers signed agreements and purchase orders as a customer's contract.

The Company identifies performance obligations based on the terms of the contract and customary business practices, which include products that are distinct, or a series of distinct goods that are substantially the same and that have the same pattern of transfer to the customer. The Company's Lapiplasty System products are distinct performance obligations. The Company does not have any contracts with customers that contain multiple performance obligations.

The transaction price in the Company's customer contracts includes fixed consideration to be contractually billed to the customer while variable consideration includes the right of return. The Company does not allocate the transaction price or any variable consideration to the right of return. The Company did not recognize a refund liability as of December 31, 2021 and 2020 and there were no product returns during the years ended December 31, 2021, 2020 and 2019.

Revenue for products is recognized when a customer obtains control of the promised products, which is generally when the customer has the ability to (i) direct its use and (ii) obtain substantially all of the remaining benefits from it. The Company consigns products with its independent sales agencies but does not recognize revenue at the time the product is transferred on consignment. Revenue recognition occurs when control of the product transfers to the customer which is generally at the time the product is used in surgery. When a customer purchases products directly from us before the time of surgery, revenue is recognized upon shipment based on the contract terms.

Contract Costs

The Company applies the practical expedient to recognize the incremental costs of obtaining a contract as expense when incurred if the amortization period would be one year or less. These incremental costs include sales commissions paid to the Company's independent sales agencies or internal sales representatives.

Cost of Goods Sold

Cost of goods sold consists primarily of costs for the purchase of the Company's Lapiplasty and Adductoplasty Systems as well as ancillary products from third-party manufacturers. Direct costs from the Company's third-party manufacturers includes costs for raw materials plus the markup for the assembly of the components. Cost of goods sold also includes royalties, allocated overhead for indirect labor, depreciation, certain direct costs such as those incurred for shipping our products and personnel costs. The Company expenses all inventory provisions for excess and obsolete inventories as cost of goods sold. The Company records adjustments to its inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions.

Research and Development Expenses

Research and development ("R&D") expenses consist primarily of engineering, product development, clinical studies to develop and support the Company's products, regulatory expenses, and other costs associated with products and technologies that are in development. These expenses include compensation for personnel, including salaries, bonuses, benefits and stock-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses, depreciation and an allocation of facility overhead expenses.

Shipping and Handling

The Company bills customers for shipping and handling costs. Amounts billed for shipping and handling are included in revenue. Shipping and handling costs incurred by the Company are included in marketing and sales expenses.

Advertising Costs

Advertising costs are expensed as incurred and are included as a component of marketing and sales expenses. Advertising expense includes the cost of advertising across the various mediums we employ, including print, digital, radio and television. Advertising costs totaled approximately $13.02 million, $3.1 million and $1.9 million, for the years ended December 31, 2021, 2020 and 2019, respectively.

Income Taxes

The Company accounts for income taxes under the liability method, whereby deferred tax assets and liabilities are determined based on the difference between the financial statements 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. A valuation allowance is established when necessary to reduce deferred tax assets when management estimates, based on available objective evidence, that it is more likely than not that the benefit will not be realized for the deferred tax assets.

The Company also follows the provisions of ASC 740-10, *Accounting for Uncertainty in Income Taxes*. ASC 740-10, which prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or expected to be taken on a tax return. No liability related to uncertain tax positions is recorded on the financial statements. It is the Company's policy to include penalties and interest expense related to income taxes as part of the provision for income taxes.

Product Liability

The Company believes it carries adequate insurance for possible product liability claims. Accruals for product liability claims and legal defense costs in excess of insured amounts are recorded if it is probable that a liability has been incurred and the amount of any liability can be reasonably estimated. No accruals for product liability claims had been recorded as of December 31, 2021 and December 31, 2020.

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees in accordance with ASC 718, Compensation—Stock Compensation, using a fair-value based method. The Company determines the fair value of stock options on the date of grant using the Black-Scholes option pricing model. The fair value for RSAs and RSUs awards is the fair value at the grant date.

The fair value of time-based awards is recognized over the period during which an award holder is required to provide services in exchange for the award, known as the requisite service period, which is typically the vesting period using the straight-line method. The Company accrues for estimated forfeitures on share-based awards and, adjusts stock-based compensation cost to actual as forfeitures occur. The estimated forfeitures are based on a historical analysis of actual forfeitures of awards.

The Company estimates the fair value of the stock-based awards using the Black-Scholes option-pricing model, which requires the input of highly subjective assumptions. The assumptions are as follows:

- *Expected Term*. The expected term represents the period that the stock options are expected to remain outstanding. Prior to the closing of the IPO, the Company was using the probabilities of the anticipated timing of potential liquidity events to determine the expected term. After the closing of the IPO, the Company is using the "simplified" method, which is the simple average of the vesting period and the contractual term.
- *Expected Volatility*. The expected volatility is derived from the historical stock volatilities of comparable publicly listed peers over a period approximately equal to the expected term of the options as the Company does not have sufficient trading history to determine the volatility of its common stock.
- *Risk-Free Interest Rate*. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the stock-based awards' expected term.
- *Expected Dividend Yield*. The expected dividend yield is zero as the Company has not paid nor anticipates paying any dividends on the common stock in the foreseeable future.
- *Fair Market Value of Common Stock.* Prior to the IPO, the fair market value of the common stock was determined by the board of directors with assistance from management and external valuation experts. The Company's approach to estimating the fair market value of its common stock was consistent with the methods outlined in the American Institute of Certified Public Accountants' Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Following our IPO, the fair market value of the common stock is based on its closing price on NASDAQ as reported on the date of grant.

The Company continues to use judgment in evaluating the expected volatility and expected terms utilized for the stock-based compensation calculations on a prospective basis. As the Company continues to accumulate additional data, the Company may have refinements to the assumptions, which could materially impact the future stock-based compensation expense.

Comprehensive Loss

The Company is required to report all components of comprehensive loss, including net loss, in the financial statements in the period in which they are recognized. Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions and other events and circumstances from non-owner sources. Comprehensive loss equaled net loss for the years ended December 31, 2021, 2020 and 2019.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders, by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, common stock options, unvested restricted stock units and restricted stock awards are considered to be potentially dilutive securities. Because the Company has reported a net loss for the years ended December 31, 2021, 2020 and 2019, diluted net losses per common share were the same as basic net losses per common share for these periods.

Derivative Liability

The Company evaluates its financial instruments for embedded features and bifurcates embedded features from the host instrument that meet the definition of a derivative and if (a) the economic characteristics and risks of the embedded feature are not clearly and closely related to the host instrument, (b) the hybrid instrument that embodies both the embedded feature and the host contract is not remeasured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded feature would be considered a derivative instrument subject to the accounting requirements of derivative instruments.

The Company uses judgment in determining the fair value of embedded features that are bifurcated from the host instrument and accounted for as derivative instruments at the date of issuance and at every balance sheet date thereafter. The valuation method used in

the determination of fair value is based on the type of derivative instrument. At each balance sheet date, the Company remeasures its derivative instruments at fair value with adjustments to fair value recognized within other expense, net.

Deferred Issuance Costs

Issuance costs, consisting of legal, accounting, audit, and filing fees relating to in-process equity financings, including IPO, are capitalized. Deferred issuance costs are offset against offering proceeds upon the completion of an equity financing or an offering. In the event an equity financing or an offering is terminated or delayed, deferred issuance costs will be expensed immediately as a charge to general and administrative expenses in the consolidated statements of operations and comprehensive loss. As of December 31, 2020, $0.2 million was recorded on the balance sheet. The Company had no capitalized issuance costs recorded on the balance sheet as of December 31, 2021.

3. Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842) ("ASC 842")*, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e. lessees and lessors). In July 2018, the FASB issued ASU 2018-10, *Codification Improvements to Topic 842, Leases*, which provides clarification to ASU 2016-02. In March 2019, the FASB issued ASU 2019-01, which provides clarification on implementation issues associated with adopting ASU 2016-02. These ASUs (collectively the "new leasing standard") require lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. ASC 842 provides a lessee with an option to not account for leases with a term of 12 months or less as leases within the scope of the new standard. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which allows entities to elect an optional transition method where entities may continue to apply the existing lease guidance during the comparative periods and apply the new lease requirements through a cumulative effect adjustment in the period of adoption rather than in the earliest period presented. The new standard is effective for fiscal years beginning after December 15, 2021 and early application is permitted. The Company is currently evaluating the impact of the standard on the Company's financial statements based on the lease portfolio and anticipates that the adoption will result in recognition of an approximately $1.9 million right-of-use asset and corresponding lease liability. Refer to Note 7, "Commitment and Contingencies", for more information related to the Company's lease obligations, which are presented on an undiscounted basis therein.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses*. This new guidance will require financial instruments to be measured at amortized cost, and trade accounts receivable to be presented at the net amount expected to be collected. The new model requires an entity to estimate credit losses based on historical information, current information and reasonable and supportable forecasts, including estimates of prepayments. In November 2019, the FASB issued ASU 2019-10, according to which, the new standard is effective for fiscal years beginning after December 15, 2022, and interim periods within that fiscal year. The Company is currently evaluating the impact of the new standard on its financial statements and related disclosures.

4. Fair Value Measurements

Assets and liabilities recorded at fair value in the financial statements are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels which are directly related to the amount of subjectivity associated with the inputs to the valuation of these assets or liabilities are as follows:

Level 1—Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access as of the measurement date.

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.

Level 3—Unobservable inputs for the asset or liability only used when there is little, if any, market activity for the asset or liability at the measurement date. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

Assets and Liabilities Measured and Recorded at Fair Value on a Recurring Basis – The following assets and liabilities are measured at fair value on a recurring basis as of December 31, 2021 and December 31, 2020:

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds(1)	$ 105,220	$ —	$ —	$ 105,220
Total	$ 105,220	$ —	$ —	$ 105,220
Liabilities:				
Derivative liability	$ —	$ —	$ 173	$ 173
Total	$ —	$ —	$ 173	$ 173

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds(1)	$ 17,577	$ —	$ —	$ 17,577
Total	$ 17,577	$ —	$ —	$ 17,577
Liabilities:				
Derivative liability	$ —	$ —	$ 245	$ 245
Total	$ —	$ —	$ 245	$ 245

(1) Money market funds are included in cash and cash equivalents in the balance sheets as of December 31, 2021 and 2020.

As discussed in Note 6, in July 2020, the Company entered into the CRG Term Loan Facility and accounted for embedded features in the agreement as a derivative liability with an initial fair value of $0.2 million. The derivative liability was accounted for at fair value using the income approach and inputs consisting of (a) the probability of events occurring that trigger an event of default of the Company's term loans under the CRG Term Loan Facility, ranging from 1% to 2%, (b) the prepayment premium payable upon early redemption, and (c) additional interest payable upon an event of default. The change in fair value of the derivative liability was $0.1 million in the year ended December 31, 2021, and was recorded as a component of other expense, net in the statements of operations and comprehensive loss. There was no adjustment to the fair value of the derivative liability recognized in net loss for the year ended December 31, 2020.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments (in thousands):

	Derivative liability
Fair value as of January 1, 2020	$ —
Initial fair value of derivative liability	245
Fair value as of December 31, 2020	245
Change in fair value included in other expense, net	(72)
Fair value as of December 31, 2021	$ 173

There were no assets or liabilities measured at fair value on a nonrecurring basis as of December 31, 2021 and December 31, 2020.

5. Balance Sheet Components

Cash and Cash Equivalents

The Company's cash and cash equivalents consisted of the following (in thousands):

	December 31,	
	2021	2020
Cash	$ 613	$ 502
Cash equivalents:		
Money market funds	105,220	17,577
Total cash and cash equivalents	$ 105,833	$ 18,079

Property and equipment, net

The company's property and equipment, net consisted of the following (in thousands):

	December 31,	
	2021	2020
Furniture and fixtures, and equipment	$ 180	$ 131
Construction in progress	126	—
Machinery and equipment	274	226
Capitalized surgical equipment	4,442	2,652
Computer equipment	160	150
Leasehold improvements	268	168
Software	138	138
Total property and equipment	5,588	3,465
Less: accumulated depreciation and amortization	(2,739)	(2,636)
Property and equipment, net	$ 2,849	$ 829

Depreciation and amortization expense was $0.7 million, $1.2 million and $0.8 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2021	2020
Accrued royalties expense	$ 1,522	$ 1,032
Accrued interest	975	—
Accrued professional services	941	375
Other accrued expense	1,080	441
Total accrued liabilities	$ 4,518	$ 1,848

6. Long Term Debt

The Company's debt consisted of the following (in thousands):

	December 31,	
	2021	2020
Revolving line of credit		
SVB Credit Facility	$ —	$ —
Term loans		
CRG Term Loan Facility	30,000	30,000
PPP Loan	—	1,788
Total term loans	30,000	31,788
Less: debt discount and issuance costs	(635)	(811)
Total debt	29,365	30,977
Short-term debt	—	1,788
Long-term debt	$ 29,365	$ 29,189

As of December 31, 2021, future payments under term loan were as follows (in thousands):

Fiscal Year	
2022	$ —
2023	—
2024	—
2025	30,000
Total principal payments	30,000
Less: Unamortized debt discount and debt issuance costs	(635)
Total short-term and long-term debt	$ 29,365

Silicon Valley Bank

The Company entered into a Loan and Security Agreement dated April 18, 2018 (the “LSA”) with Silicon Valley Bank (“SVB”) as amended by a First Amendment to the Loan and Security (the “First Amendment”) dated February 14, 2019, a Second Amendment dated December 31, 2019 (the “Second Amendment”) and a Third Amendment dated August 3, 2020 (the “Third Amendment”). The LSA, as amended by the First Amendment, Second Amendment and Third Amendment (collectively the “SVB Credit Facility”) matures August 3, 2024.

The Company borrowed $10.0 million (the "Tranche 1") upon execution of the First Amendment and $10.0 million (the "Tranche 2") upon execution of the Second Amendment and repaid the term loans in August 2020 using the proceeds received from the CRG Term Loan Facility (described below). The term loans accrued interest, payable monthly in arrears, at a floating per annum rate equal to the greater of (i) prime rate plus 2.25% as published in the money rates section of the Wall Street Journal, or (ii) seven and one-half percent (7.5%) for Tranche 1 and Tranche 2.

Under the Third Amendment, the SVB Credit Facility provides for up to $10.0 million in a revolving line of credit. Availability under the revolving line of credit is subject to a formula based on, among other things, eligible accounts receivable. Borrowings on the line of credit bear interest at a floating rate per annum equal to the greater of (a) 1.00% above the prime rate as published from time to time in the money rates section of the Wall Street Journal and (b) 5.00%, and includes a termination fee of 1.00% of the revolving line of credit if the termination occurs before August 3, 2022.

Under the terms of the SVB Credit Facility, the Company granted SVB first priority liens and security interests in substantially all of the Company’s assets (excluding its intellectual property but including any proceeds and rights to payments associated with our intellectual property) as collateral. The SVB Credit Facility also contains certain representations and warranties, indemnification provisions in favor of SVB, affirmative and negative covenants (including, among other things, requirements that the Company maintain a minimum amount of liquidity and achieve minimum revenue targets, limitations on other indebtedness, liens, acquisitions, investments and dividends and requirements relating to financial reporting, sales and leasebacks, insurance and protection of the Company’s intellectual property rights) and events of default (including payment defaults, breaches of covenants following any applicable cure period, investor abandonment, a material impairment in the perfection or priority of the lender’s security interest or in the collateral, and events relating to bankruptcy or insolvency).

The Company issued warrants in connection with the SVB Credit Facility that gave the lender the right to purchase up to 713,330 shares of the Company’s Class A common stock (refer to Note 9, "Warrants for Class A Common Stock").

The Company paid issuance costs in connection with the SVB Credit Facility of $0.3 million which were recorded as a reduction of debt. The debt discount and debt issuance costs were amortized over the term of the debt using the effective interest method and included within interest expense on the statements of operations and comprehensive loss. Upon repayment of the term loans under the SVB Credit Facility in August 2020, the Company recognized a loss of $0.6 million for the year ended December 31, 2020 within interest and other income (expense), net, relating to unamortized balance of debt issuance costs and debt discount.

The Company did not have any balances outstanding under the revolving line of credit as of December 31, 2021 and 2020. As of December 31, 2021, the Company had $10.0 million in available borrowings on the line of credit and was in compliance with all covenants under the SVB Credit Facility.

CRG Term Loan Facility

On July 31, 2020, the Company entered into the CRG Term Loan Facility, to obtain up to $50.0 million in financing over three tranches to be advanced no later than December 31, 2021. Principal amounts totaling $30.0 million were borrowed through December 31, 2021 and are currently outstanding. The CRG Term Loan Facility matures on June 30, 2025, and the Company could elect to make quarterly interest-only payments or to pay interest in-kind through December 31, 2020. The Company is not required to make any principal payments until the maturity of the CRG Term Loan Facility and all outstanding principal and accrued interest are due upon the maturity of the CRG Term Loan Facility. Interest under the CRG Term Loan Facility is applied to outstanding principal and accrued interest at a rate of 13.00% per annum. If an event of default occurs, interest under the CRG Term Loan Facility will increase by 4.00%. If the Company repaid the CRG Term Loan Facility within one year of the borrowing date, the Company was required to pay a premium of 20.00% of the aggregated outstanding principal amount of the loans that was repaid. If the Company repays the CRG Term Loan Facility between one and two years from the borrowing date, it is required to pay a premium of 11.00% of the aggregated outstanding principal amount of the loans that is repaid. The CRG Term Loan Facility does not require a prepayment premium for loans being prepaid on the prepayment date that is longer than two years from the initial borrowing date.

Under the terms of the CRG Term Loan Facility, the Company granted first priority liens and security interests in substantially all of the Company’s assets as collateral (including the Company’s intellectual property), provided that the priority of such liens is

subject to an intercreditor agreement between CRG and SVB. The CRG Term Loan Facility also contains certain representations and warranties, indemnification provisions in favor of CRG, affirmative and negative covenants (including, among other things, requirements that the Company maintain a minimum amount of liquidity and achieve minimum revenue targets, comply with limitations on other indebtedness, liens, acquisitions, investments and dividends and requirements relating to financial reporting, sales and leasebacks, insurance and protection of the Company's intellectual property rights) and events of default (including payment defaults, breaches of covenants following any applicable cure period, investor abandonment, a material impairment in the perfection or priority of the lender's security interest or in the collateral, and events relating to bankruptcy or insolvency).

The Company paid $0.5 million in fees to CRG and $0.2 million in fees to third parties in connection with the CRG Term Loan Facility. The fees were recorded as debt issuance costs and classified as contra-debt. In addition, the Company recognized $0.2 million as debt discount on borrowings under the CRG Term Loan Facility due to embedded features contained in the agreement which resulted in a derivative liability (Note 4). Debt issuance costs and debt discount are amortized to interest expense using the effective interest method.

As of December 31, 2021 and 2020, the balance outstanding under the CRG Term Loan Facility, net of debt issuance costs and debt discount, was $29.4 million and $29.2 million, respectively.

PPP Loan

The Company applied for and received a $1.8 million loan (the "PPP Loan") under the Paycheck Protection Program (the "PPP") under the Coronavirus Aid Relief, and Economic Security Act ("CARES Act"). The PPP Loan, which was in the form of a promissory note, dated April 22, 2020, between the Company and SVB as the lender, was scheduled to mature on April 22, 2022, accrued interest at a fixed rate of 1% per annum, and was payable monthly. The Company repaid $1.8 million borrowed under the PPP Loan in March 2021.

During the years ended December 31, 2021, 2020, and 2019, the Company recorded, $4.1 million, $2.7 million and $0.8 million, respectively, in interest expense related to the borrowings under the SVB Credit Facility and CRG Credit Facility. During the years ended December 31, 2021 and 2020, amortization of the debt discount was $0.2 million and $0.1 million, respectively. During the year ended December 31, 2019 amortization of the debt discount was immaterial.

7. Commitments and Contingencies

Operating Lease

The Company has commitments for future payments related to its lease of office space located in Ponte Vedra, Florida. The Company leases its office space under an operating lease agreement expiring in 2026. Lease payments comprise of the base rent stated in the lease plus operating costs which include taxes, insurance and common area maintenance.

The future minimum rental obligations required under non-cancelable leases as of December 31, 2021 were as follows (in thousands):

Fiscal Year	
2022	$ 627
2023	444
2024	458
2025	472
2026	321
Total minimum lease payments	$ 2,322

Total rent expense was approximately $0.6 million, $0.2 million and less than $0.1 million for the years ended December 31, 2021, 2020 and 2019, respectively.

License and Royalty Commitments

The Company has entered into product development and fee for service agreements with members of its Surgeon Advisory Board that specify the terms under which the member is compensated for his or her consulting services and grants the Company rights to the intellectual property created by the member in the course of such services. As products are commercialized with the assistance of members of the Surgeon Advisory Board, the Company may agree to enter into a royalty agreement if the member's contributions to the product are novel, significant and innovative.

As of December 31, 2021 and 2020, the Company has royalty agreements with certain members of our Surgeon Advisory Board providing for royalties based on each individual's level of contribution. Each royalty agreement: (i) confirms the irrevocable transfer to the Company of all pertinent intellectual property rights; (ii) sets the applicable royalty rate; (iii) sets the period of time during which royalties are payable; (iv) is for a term of three years, renewable by the parties, and may be terminated by either party on 90 days' notice for convenience (provided that if terminated by the Company for convenience the obligation to pay royalties is not affected); and (v) prohibits the payment of royalties on products sold to entities and/or individuals with whom the surgeon advisor or any other surgeon advisor entitled to royalties is affiliated. Each of the royalty agreements may be subsequently amended to add the license of additional intellectual property covering new products, and as a result, multiple royalty rates and duration of royalty payments may be included in one royalty agreement.

As of December 31, 2021 and 2020, the Company's royalty agreements provide for (i) royalty payments for 10 years from first commercial sale of the relevant product and (ii) a royalty rate for each such agreement ranging from 0.5% to 3.0% of net sales for the particular product to which the surgeon contributed.

The Company recognized royalties' expense of $4.3 million, $2.4 million and $1.7 million for the years ended December 31, 2021, 2020 and 2019, respectively, resulting in an aggregate royalty rate of 4.6%, 4.1% and 4.3%, for the years ended December 31, 2021, 2020 and 2019, respectively.

Contingencies

From time to time, the Company may be a party to various litigation claims in the normal course of business. Legal fees and other costs associated with such actions are expensed as incurred. The Company assesses, in conjunction with legal counsel, the need to record a liability for litigation and contingencies. Accrual estimates are recorded when and if it is determinable that such a liability for litigation and contingencies are both probable and reasonably estimable. There were no accrued contingent liabilities as of December 31, 2021 and 2020.

8. Income Taxes

The Company has not recorded an income tax provision for years ended December 31, 2021, 2020 and 2019 due to its operating losses. All losses before income taxes were generated in the United States.

Reconciliation of the statutory federal income tax to the Company's effective tax is as follows:

	December 31,		
	2021	2020	2019
Income tax at the statutory rate	(21)%	(21)%	(21)%
Stock-based and other compensation	(8)%	0%	0%
State taxes, net of federal benefit	(6)%	(4)%	(4)%
Research and development credits	(1)%	(4)%	(3)%
Change in valuation allowance	32%	28%	27%
Other	4%	1%	1%
Effective tax rate	0%	0%	0%

The tax effects of temporary differences and carryforwards that give rise to significant portions of deferred tax assets were as follows (in thousands):

	December 31,	
	2021	2020
Components of the deferred tax assets		
Net operating loss carryforwards	$ 8,264	$ 3,703
Interest expense	1,025	—
Stock option compensation expense	456	672
Accrued bonus	726	244
Research and development credits	717	475
Other	753	407
Total deferred tax assets	11,941	5,501
Deferred tax asset valuation allowance	(11,941)	(5,501)
Net deferred tax assets	$ —	$ —

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax asset will not be realized. 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. Management considers the scheduled reversal of deferred tax assets, projected future taxable income, and tax planning strategies in making this assessment. Due to the Company's history of net losses, the deferred tax assets have been fully offset by full valuation allowance of $11.9 million and $5.5 million as of December 31, 2021 and December 31, 2020, respectively. The Company's change in the deferred tax asset valuation allowance for the years ended December 31, 2021 and 2020, were approximately $6.4 million and $0.9 million, respectively.

The Company had unused federal and state net operating loss carryforwards of approximately $35.4 million and $17.2 million, respectively as of December 31, 2021, and federal and state net operating loss carryforwards of approximately $14.6 million and $9.5 million, respectively, as of December 31, 2020. The net operating loss carryforwards begin to expire in 2034. The Company's research and development tax credit carryforwards were $0.7 million and $0.4 million as of December 31, 2021 and 2020, respectively, and begin to expire in 2037.

The federal and state net operating loss carryforwards and credits may be subject to significant limitations under Section 382 and Section 383 of the Internal Revenue Code and similar provisions under state law. The Tax Reform Act contains provisions that limit the federal net operating loss carryforwards that may be used in any given year in the event of special occurrences, including significant ownership changes. A Section 382 "ownership change" generally occurs if one or more stockholders or groups of stockholders, who own at least 5% of the Company's stock, increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. The Company may have previously experienced, and may in the future experience, one or more Section 382 "ownership changes," including in connection with the Company's initial public offering. If so, the Company may lose some or all of the tax benefits of its carryforwards and credits.

Management has reviewed and evaluated the relevant technical merits of each of its tax positions in accordance with accounting principles generally accepted in the United States of America for accounting for uncertainty in income taxes and determined that there are no uncertain tax positions that would have a material impact on the financial statements of the Company. The Company is not subject to U.S. Federal and state income tax examinations by tax authorities for tax years before 2017.

9. Warrants for Class A Common Stock

During 2019, the Company issued warrants in connection with the SVB Credit Facility that gave SVB the right to purchase up to 713,330 shares of the Company's Class A common stock. The warrants had a 10-year expiration period with a strike price equal to $4.0224. The estimated fair value of the warrants was $0.6 million on the date of issuance and was recorded to additional paid-in capital and debt discount. The Company determined the grant date fair value of the warrants using a Black-Scholes option pricing model, with the following assumptions:

Expected dividend yield	0.00%
Expected volatility	49.19%
Risk-free interest rate	2.30%
Expected term (in years)	3.0 years

Under the terms of the SVB Credit Facility, the Company was required to issue an additional 89,168 warrants for shares of common stock at the time of the closing of tranche 3. The additional warrants would have the same terms as the already-issued warrants and an exercise price equal to the fair value of common stock at the date when issued. These warrants were considered contingently issuable financial instruments and the estimated fair value was immaterial as of December 31, 2019. On August 3, 2020, the Company entered into the Third Amendment with SVB, which terminated tranche 3 of the term loans and the related obligation to issue the additional 89,168 common stock warrants.

On April 28, 2021, the holders of the warrants exercised their warrants in a cashless net exercise using the closing price of the Company's common stock on the prior business day of $31.27 as permitted by the warrant agreement. Accordingly, the transaction resulted in 621,570 shares of the Company's common stock being issued to the warrant holders.

10. Stockholders' Equity

Series A Convertible Preferred Stock

Immediately before the completion of the IPO, all outstanding shares of Series A convertible preferred stock were converted into shares of the Company's common stock. Accordingly, no shares of Series A convertible preferred stock were outstanding as of December 31, 2021.

Upon the closing of the IPO in April 2021, the Company issued 158,447 shares of common-stock, to settle accrued and unpaid Series A convertible preferred stock dividends of $2.5 million. At December 31, 2020, the Company had accrued and unpaid dividends of $2.3 million on the Series A convertible preferred stock outstanding.

Preferred Stock

Upon the closing of the IPO, the Company is authorized to issue 5,000,000 shares of preferred stock. As of December 31, 2021, no shares of preferred stock were outstanding.

Common Stock

On April 27, 2021, the Company amended and restated its Certificate of Incorporation, which became effective upon the closing of the IPO. The Company is authorized to issue 300,000,000 shares of common stock.

Shares Reserved for Future Issuance

The Company has reserved shares of common stock for future issuances as follows:

	December 31,	
	2021	2020
Series A convertible preferred stock outstanding	—	6,687,475
Warrants to purchase Class A common stock	—	713,330
Estimated preferred share conversion for dividends in kind	—	334,316
Common stock options issued and outstanding	7,464,580	8,081,828
Shares available for future awards granted under the 2021 Plan	3,766,337	—
Unvested restricted stock units under the 2021 Plan	10,000	—
Common stock available for Employee Stock Purchase Plan	504,627	—
Class A common stock available for future grants	—	13,691,186
Class B common stock available for future grants	—	1,000,000
Total	11,745,544	30,508,135

Stock Option Plans

In April 2021, prior to the IPO closing, the Company's Board of Directors and stockholders approved the 2021 Incentive Award Plan ("2021 Plan"), which became effective upon the IPO closing. The Company has initially reserved 5,046,278 shares of common stock for issuance share-based compensation awards, including stock options, restricted stock awards, restricted stock unit awards and other stock-based awards. The number of shares initially reserved for issuance or transfer pursuant to awards under the 2021 Plan will be increased by (i) the number of shares represented by awards outstanding under the Company's 2014 Stock Option Plan ("2014 Plan") that become available for issuance under the terms of the 2021 Plan and (ii) an annual increase on the first day of each fiscal year beginning in 2022 and ending in 2031, equal to the lesser of (i) 5.0% of the shares of stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such smaller number of shares of stock as determined by our board of directors; provided, however, that no more than 37,847,090 shares of stock may be issued upon the exercise of incentive stock options.

Prior to the IPO, the Company was authorized to issue stock purchase rights and to grant options to purchase Class A Common Stock to employees, directors and consultants under the 2014 Plan. Stock options under the 2014 Plan have a term of no more than ten years from the date of grant and vest in equal installments over a maximum of five years. No future awards can be granted under the 2014 Plan. The shares underlying outstanding and unexercised options granted to employees, directors and consultants under the 2014 Plan may become available for issuance under the 2021 Plan as follows: (i) to the extent that such an option award terminates, expires or lapses for any reason or is settled in cash without the delivery of shares, any shares subject to the award at such time will be available for future grants under the 2021 Plan; (ii) to the extent shares are tendered or withheld to satisfy the grant, exercise price or tax withholding obligation with respect to any award under the 2014 Plan, such tendered or withheld shares will be available for future grants under the 2021 Plan; and (iii) to the extent that the Company repurchases the shares prior to vesting so that shares are returned to the Company, such shares will be available for future grants under the 2021 Plan.

Options under the 2021 Plan may be granted for periods of up to 10 years at exercise prices no less than the fair market value of our common stock on the date of grant; provided, however, that the exercise price of an incentive stock option granted to a 10% stockholder may not be less than 110% of the fair market value of the shares on the date of grant and such option may not be exercisable after the expiration of five years from the date of grant. Options usually vest ratably annually over 4 years.

At December 31, 2021, 3,766,337 shares of common stock remain available for issuance as awards under the 2021 Plan. In January 2022, the number of shares of common stock available for issuance under the 2021 Plan was increased by 2,709,054 shares as a result of the automatic increase provision in the 2021 Plan.

Activity under the Stock Plans is set forth below:

	Outstanding Options		
	Number of Shares	Weighted-Average Remaining Contractual Term (in Years)	Weighted-Average Exercise Price
Balance, December 31, 2020	8,081,828	6.86	$ 1.82
Options granted	2,106,247		$ 17.49
Options exercised	(2,368,705)		$ 0.79
Options canceled	(354,790)		$ 6.17
Balance, December 31, 2021	7,464,580	6.89	$ 6.36
Options vested and expected to vest at December 31, 2021	6,281,149	6.48	$ 5.01
Options vested and exercisable at December 31, 2021	3,727,642	5.13	$ 1.76

The aggregate intrinsic value of options exercised during the years ended December 31, 2021, 2020 and 2019 was $39.1 million, $1.9 million and $0.9 million, respectively. The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money as of year-end. Aggregate intrinsic values of options outstanding, options vested and expected to vest and options exercisable were $97.2 million, $88.7 million and $62.9 million as of December 31, 2021, respectively.

Restricted Stock Awards

During the year ended December 31, 2021 the Company granted 24,895 restricted stock awards ("RSA") and 10,000 restricted stock units ("RSU"). RSAs and RSUs vests annually over 4 years in equal installments. The Company had 19,024 RSAs and 10,000 RSUs unvested as of December 31, 2021. The weighted average grant-date fair value per share of unvested RSAs and RSUs as of December 31, 2021 was $31.5 and $22.1, respectively. The Company did not grant RSAs and RSUs during the years ended December 31, 2020 and 2019, and had no unvested RSAs and RSUs as of December 31, 2020 and 2019.

Employee Share Purchase Plan

In April 2021, the Company's Board of Directors and stockholders approved the 2021 Employee Stock Purchase Plan ("ESPP"). The Company has initially reserved 504,627 shares of common stock for purchase under the ESPP. The number of shares of common stock reserved for issuance under the 2021 ESPP will be automatically increased each year for ten calendar years beginning in 2022 by the number of shares equal to the lesser of 1% of the total number of shares of common stock outstanding as of the last day of the immediately preceding fiscal year or such number of shares as may be determined by the Board of Directors of the Company; provided that the maximum number of shares that may be issued under the ESPP is 7,064,790 shares. Each offering to the employees to purchase stock under the ESPP will begin on a date to be determined by the Company's Compensation Committee and will end no later than six months thereafter. The ESPP allows an eligible employee to purchase shares of our common stock at a discount through payroll deductions of up to 15% of the employee's eligible compensation. At the end of each offering period, employees are able to purchase shares at 85% of the lower of the fair market value of our common stock at the beginning of the offering period or at the end of each applicable offering period. The occurrence and duration of offering periods under the ESPP are subject to the determinations of the Company's Compensation Committee, in its sole discretion. The Company has not yet commenced any enrollment periods under the ESPP.

In January 2022, the number of shares of common stock available for issuance under the ESPP was increased to 541,810 shares as a result of the automatic increase provision in the ESPP.

Stock-Based Compensation

The weighted-average grant date fair values of the stock options granted were $6.19, $2.26 and $0.93 per share for the years ended December 31, 2021, 2020 and 2019, respectively.

The Company uses the Black-Scholes option pricing model to determine the fair value of stock options at the grant dates with the following assumptions for options granted during 2021, 2020 and 2019 fiscal years:

	December 31,		
	2021	2020	2019
Expected term (in years)	2.1-6.25	2.7 - 3.3	3
Expected volatility	35.57% - 55.60%	37.09% - 51.29%	49.19%
Risk-free interest rate	0.08% - 1.39%	0.18% - 1.53%	2.30%
Expected dividend yield	0.00%	0.00%	0.00%

Stock-based compensation expense is reflected in the statements of operations and comprehensive loss as follows (in thousands):

	Years Ended December 31,		
	2021	2020	2019
Sales and marketing expense	$ 1,231	$ 479	$ 405
Research and development expense	475	199	160
General and administrative expense	1,703	241	250
Total	$ 3,409	$ 919	$ 815

As of December 31, 2021, there was $12.1 million of unrecognized stock-based compensation expense related to common stock options, which the Company expects to recognize over a weighted-average period of 3.2 years. As of December 31, 2021, there was $0.6 million of unrecognized stock-based compensation expense related to RSAs and RSUs, which the Company expects to recognize over a weighted-average period of 2.73 years.

The total grant date fair value of shares vested during the years ended December 31, 2021, 2020 and 2019 were $2.0 million, $0.9 million and $0.8 million, respectively.

11. Employee Benefit Plan

Effective as of January 2021, the Company began sponsoring a 401(k) profits sharing plan trust for its employees who satisfy certain eligibility requirements. An employee will be eligible to become a participant in the plan for purposes of 1) elective deferrals and matching contributions after completing 3 consecutive months of service beginning on the employee's date of hire and 2) employer profit sharing contributions after completing 1 year of service.

The Company matches employee contributions to the 401(k) plan at a rate equal to 100% of the first 3% of the employee's pre-tax salary contributed and 50% of any additional contributions, including and up to 5% of the employee's pre-tax salary. Participants vest in their Company matching contributions after 90 days of service and in any potential future nonelective contributions by the Company on a one-to-six year graded vesting schedule.

There were $0.7 million employer contributions under this plan for the year ended December 31, 2021.

12. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders which is computed by dividing the net loss attributable to common stockholders by the weighted- average number of shares of common stock outstanding for the period. As the Company reported a net loss for the years ended December 31, 2021, 2020 and 2019, respectively, basic net loss per share attributable to common stockholders was the same as diluted net loss per share attributable to common stockholders as the inclusion of potentially dilutive shares would have been antidilutive if included in the calculation (in thousands, except share and per share amounts):

	Years Ended December 31,		
	2021	2020	2019
Numerator			
Net loss	$ (20,552)	$ (3,668)	$ (4,265)
Adjust: Convertible preferred stock cumulative and undeclared dividends	(196)	(640)	(640)
Net loss attributable to common stockholders	(20,748)	(4,308)	(4,905)
Denominator			
Weighted-average common stock outstanding, basic and diluted	48,415,679	37,068,965	36,911,586
Net loss per share attributable to common stockholders, basic and diluted	$ (0.43)	$ (0.12)	$ (0.13)

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding because such securities have an antidilutive impact due to the Company's net loss, in common stock equivalent shares:

	December 31,		
	2021	2020	2019
Series A convertible preferred stock outstanding	—	6,687,475	6,687,475
Warrants to purchase Class A common stock	—	713,330	713,330
Common stock options issued and outstanding	7,464,580	8,081,828	7,474,401
Unvested restricted stock awards and restricted stock units	29,024	—	—
Total	7,464,580	15,482,633	14,875,206

13. Subsequent Events

On February 9, 2022, the Company entered into a ten-year, triple-net lease agreement for a new headquarters building consisting of 125,562 square feet ("SF") in Ponte Vedra, FL. The Company will occupy the building in phases, with the Company occupying by the earlier of (i) the date the Company commences business operations from the building or (ii) the later of the date of substantial completion of certain tenant improvements or July 1, 2022 for the first phase and occupying the full building by the second anniversary of lease commencement. The rent begins at $22.60 per SF and increases each year to $27.00 per SF for the last 12 months of the lease term.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) before filing this Annual Report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2021, the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

Changes in internal control over financial reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control

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

Item 9B. Other Information.

None.

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

Not applicable

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

We have adopted a code of conduct applicable to our principal executive, financial and accounting officers and all persons performing similar functions. A copy of our code of conduct is available on our principal corporate website at www.treace.com in the Investors section under “Corporate Governance”. We intend to post any required disclosures regarding an amendment to, or waiver from, a provision of our code of conduct on the same website.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2022 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2021.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2022 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2021.

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

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2022 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2021.

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

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2022 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2021.

Item 14. Principal Accounting Fees and Services.

Our independent registered public accounting firm is GRANT THORNTON LLP, Jacksonville, FL, Auditor Firm ID: 248.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2022 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2021.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) FINANCIAL STATEMENTS

Our financial statements are listed in the "Index to the Financial Statements" under Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

(2) FINANCIAL STATEMENT SCHEDULES

All schedules to the financial statements are omitted because they are not applicable, not material or the required information is shown in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

(3) EXHIBITS

The documents listed in the Exhibit Index of this Annual Report on Form 10-K are incorporated by reference or are filed with this Annual Report on Form 10-K, in each case as indicated therein.

EXHIBIT INDEX

		Incorporated by Reference				
Exhibit Number	**Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed Herewith**
3.1	Amended and Restated Certificate of Incorporation of Treace Medical Concepts, Inc.	8-K	001-40355	3.1	4-27-21	
3.2	Amended and Restated Bylaws of the Treace Medical Concepts, Inc.	8-K	001-40355	3.2	4-27-21	
4.1	Form of Common Stock Certificate	S-1/A	333-254863	4.2	4-19-21	
4.2	Description of common stock of Treace Medical Concepts, Inc.					X
10.1+	Offer Letter Agreement by and between the Treace Medical Concepts, Inc. and Jaime A. Frias, dated as of June 8, 2017	S-1	333-254863	10.10	3-30-21	
10.2+	Offer Letter Agreement by and between the Treace Medical Concepts, Inc. and Mark L. Hair dated as of September 11, 2020.	S-1	333-254863	10.9	3-30-21	
10.3+	Change in Control Severance Agreement by and between Treace Medical Concepts, Inc. and John T. Treace	S-1/A	333-254863	10.13	4-19-21	
10.4+	Change in Control Severance Agreement by and between Treace Medical Concepts, Inc. and Mark Hair	S-1/A	333-254863	10.6	4-19-21	
10.5+	Change in Control Severance Agreement by and between Treace Medical Concepts, Inc. and Jaime Frias	S-1/A	333-254863	10.7	4-19-21	
10.6+	Change in Control Severance Agreement by and between Treace Medical Concepts, Inc. and Aaron Berutti	10-Q	001-40355	10.2	11-4-21	
10.7+	Change in Control Severance Agreement by and between Treace Medical Concepts, Inc. and Scot Elder					X

10.8+	Change in Control Severance Agreement by and between Treace Medical Concepts, Inc. and Terry Lubben	10-Q	001-40355	10.3	11-4-21	
10.9+	Change in Control Severance Agreement by and between Treace Medical Concepts, Inc. and Daniel E. Owens	10-Q	001-40355	10.4	8-5-21	
10.10+	Change in Control Severance Agreement by and between Treace Medical Concepts, Inc. and Sean F. Scanlan	10-Q	001-40355	10.7	8-5-21	
10.11+	Release Agreement with Dipak Rajhansa	10-Q	001-40355	10.1	11-4-21	
10.12+	Severance Agreement with Joe W. Ferguson					X
10.13+	Form of Indemnification Agreement for directors and executive officers.	S-1/A	333-254863	10.1	4-19-21	
10.14+	2014 Stock Plan, as amended.	S-1	333-254863	10.2(a)	3-30-21	
10.15+	Form of Stock Option Agreement for Directors under 2014 Stock Plan	S-1	333-254863	10.2(b)	3-30-21	
10.16+	Form of Stock Option Agreement for Employees under 2014 Stock Plan	S-1	333-254863	10.2(c)	3-30-21	
10.17+	Form of Notice of Option Exercise under 2014 Stock Plan.	S-1	333-254863	10.2(d)	3-30-21	
10.18+	2021 Incentive Award Plan and related form agreements	S-1/A	333-254863	10.3	4-19-21	
10.19+	2021 Employee Stock Purchase Plan.	S-1/A	333-254863	10.11	4-19-21	
10.20+	Non-Employee Director Compensation Policy					X
10.21	Form of Product Development Royalty Agreement.	S-1	333-254863	10.12	3-30-21	
10.22	Term Loan Agreement by and among the Registrant, the subsidiary guarantors from time to time party thereto, certain lenders, and CRG Servicing LLC, as administrative agent and collateral agent for the lenders, dated July 31, 2020.	S-1	333-254863	10.4	3-30-21	
10.23	Loan and Security Agreement by and between the Registrant and Silicon Valley Bank dated April 18, 2018, as amended by the First Amendment dated February 14, 2019, the Second Amendment dated December 20, 2019 and the Third Amendment dated August 3, 2020.	S-1	333-254863	10.5	3-30-21	
23.1	Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm					X
24.1	Power of Attorney (included on signature page hereto).					
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1#	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2#	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X

101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

+ Indicates management contract or compensatory plan.

The certifications attached as Exhibit 32.1 and 32.2 that accompany this Annual Report on Form 10-K are deemed furnished and not filed with the U.S. Securities and Exchange Commission and are not to be incorporated by reference into any filing of Treace Medical Concepts, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Treace Medical Concepts, Inc.

Date: March 4, 2022

By: /s/ John T. Treace
Name: John T. Treace
Title: Chief Executive Officer (Principal Executive Officer)

Date: March 4, 2022

By: /s/ Mark L. Hair
Name: Mark L. Hair
Title: Chief Financial Officer (Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John T. Treace, Mark L. Hair, and Jaime A. Frias, and each of them, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, 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 each of them, 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 to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

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.

Signature	Title	Date
/s/ John T. Treace John T. Treace	Chief Executive Officer, Founder and Director (Principal Executive Officer)	March 4, 2022
/s/ Mark L. Hair Mark L. Hair	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 4, 2022
/s/ James T. Treace James T. Treace	Chairman of the Board of Directors	March 4, 2022
/s/ Deepti Jain Deepti Jain	Director	March 4, 2022
/s/ Elizabeth Hanna Elizabeth Hanna	Director	March 4, 2022
/s/ F. Barry Bays F. Barry Bays	Director	March 4, 2022
/s/ John K. Bakewell John K. Bakewell	Director	March 4, 2022
/s/ John R. Treace John R. Treace	Director	March 4, 2022
/s/ Lawrence W. Hamilton Lawrence W. Hamilton	Director	March 4, 2022
/s/ Richard W. Mott Richard W. Mott	Director	March 4, 2022
/s/ Thomas E. Timbie Thomas E. Timbie	Director	March 4, 2022

Exhibit 4.2

DESCRIPTION OF CAPITAL STOCK DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Treace Medical Concepts, Inc. (the "Company" or "we" or "our" or "us" or "Treace Medical Concepts") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, par value $0.001 per share.

Description of Common Stock

The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, and of the Delaware General Corporation Law (the "DGCL"). Because the following is only a summary, it does not contain all of the information that may be important to you. This summary is subject to, and is qualified in its entirety by express reference to, the applicable provisions of our amended and restated certificate of incorporation and our amended and restated bylaws. For a complete description, you should refer to our amended and restated certificate of incorporation and amended and restated bylaws, each of which may be amended from time to time and are included as exhibits to the Annual Report on Form 10-K to which this description is an Exhibit.

General

As of December 31, 2022, our authorized capital stock consists of 300 million shares of common stock, par value $0.001 per share, and 5 million shares of preferred stock, par value $0.001 per share.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors.

Dividends

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

Liquidation

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

Rights, Preferences and Privileges

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

Fully Paid and Nonassessable

All of our outstanding shares of common stock are fully paid and nonassessable.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 5 million shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preferences, sinking fund provisions and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. As of December 31, 2021, no shares of preferred stock are outstanding, and we have no present plan to issue any shares of preferred stock.

Annual Stockholder Meetings

Our amended and restated bylaws provide that annual stockholder meetings will be held at a date, time and place, if any, as exclusively selected by our board of directors, our Chief Executive Officer or the chairman of the board of directors. To the extent permitted under applicable law, we may conduct meetings by remote communications, including by webcast.

Anti-Takeover Effects or Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware Law

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

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

Delaware Anti-Takeover Statute

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- Before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;
- Prior to the completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares

owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- On or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- Any merger or consolidation involving the corporation and the interested stockholder;
- Any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- Subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- Any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- The receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation or any entity or person affiliated with or controlling or controlled by such entity or person.

Undesignated Preferred Stock

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

Special Stockholder Meetings

Our amended and restated bylaws provides that a special meeting of stockholders may be called only by our board of directors, the chairperson of our board of directors, or our Chief Executive Officer or President. This provision might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors. Our amended and restated bylaws also specify certain requirements regarding the form and content of a stockholder’s notice.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and our amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Classified Board; Election and Removal of Directors

Our amended and restated certificate of incorporation and amended and restated bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors

constituting our board of directors are permitted to be set only by a resolution adopted by our board of directors. These provisions prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.

Our board of directors is divided into three classes. The directors in each class serve for a three-year term, one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors up for election. In addition, our amended and restated certificate of incorporation provides that directors may only be removed for cause. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Exclusive Forum

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. As a result, any action brought by any of our stockholders with regard to any of these matters will need to be filed in the Court of Chancery of the State of Delaware and cannot be filed in any other jurisdiction. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that the federal district courts of the United States is the exclusive forum for the resolution of any complaint asserting a cause of action against any defendant arising under the Securities Act. Such provision is intended to benefit and may be enforced by us, our officers and directors, employees and agents. Although our amended and restated certificate of incorporation and amended and restated bylaws contain the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable. The choice of forum provision requiring that the Court of Chancery of the State of Delaware be the exclusive forum for certain actions would not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware.

If any action the subject matter of which is within the scope described above is filed in a court other than a court located within the State of Delaware (a Foreign Action), in the name of any stockholder, such stockholder shall be deemed to have consented to the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce the applicable provisions of our amended and restated certificate of incorporation and amended and restated bylaws and having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder.

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 or make such lawsuits more costly for stockholders, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least 66 2/3% of the voting power of our then outstanding voting stock.

The provisions of the DGCL, our amended and restated certificate of incorporation and our amended and restated bylaws may have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Exchange Listing

Our common stock is listed on the Nasdaq Global Market under the symbol "TMCI."

Transfer Agent

The transfer agent for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, NY 11219. Our shares of common stock are issued in uncertificated form only, subject to limited exceptions.

Exhibit 10.7

CHANGE IN CONTROL
SEVERANCE AGREEMENT

This CHANGE IN CONTROL SEVERANCE AGREEMENT is dated as of October 25, 2021, by and between TREACE MEDICAL CONCEPTS, INC., a Delaware corporation (the "Company"), and SCOT M. ELDER (the "Executive").

PURPOSE

In order to induce the Executive to remain in the employment of the Company and its Affiliates in the event of a potential Change in Control (as defined below) or potential involuntary terminations, the Company desires to enter into this Change in Control Severance Agreement (the "Agreement") to provide the Executive with certain benefits if the Executive's employment is terminated in connection with or following the occurrence of a Change in Control or upon certain qualifying terminations.

NOW, THEREFORE, in consideration of the respective agreements of the parties contained herein, it is agreed as follows:

SECTION 1. ***Definitions***

For purposes of this Agreement, the following terms have the meanings set forth below:

"Affiliate" means, with respect to any individual or entity, any other individual or entity who, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, such individual or entity.

"Annual Base Salary" means the Executive's annual base salary in effect immediately before his Severance.

"Annual Target Bonus Opportunity" means the amount of the annual cash incentive payable to an Executive under a Company or Affiliate annual incentive plan with respect to a given fiscal year of the Company or Affiliate, as applicable, assuming that the target level of performance under the plan was achieved.

"Board" means the Board of Directors of the Company.

"Cause" shall mean:

(a) the Executive's willful and continued failure to attempt in good faith (other than as a result of incapacity due to mental or physical impairment) to substantially perform the duties of his position, and such failure is not remedied within 30 days after receipt of written notice from the Board or the Chief Executive Officer specifying such failure;

(b) the Executive's failure to attempt in good faith to carry out, or comply with, in any material respect any lawful and reasonable directive of the Board or the Chief Executive Officer consistent with the duties of his position, which is not remedied within 30 days after receipt of written notice from the Board or the Chief Executive Officer specifying such failure;

(c) a material breach by the Executive of the Company's code of ethics, which is not remedied within 30 days after receipt of written notice from the Board or the Chief Executive Officer specifying such failure;

(d) the Executive's conviction, plea of no contest or plea of *nolo contendere*, or imposition of unadjudicated probation for any felony (other than a traffic violation or arising purely as a result of the Executive's position with the Company or an Affiliate and not in connection with any act or omission of the Executive);

(e) the Executive's knowing unlawful use (including being under the influence) or possession of illegal drugs; or

(f) the Executive's commission of a material bad faith act of fraud, embezzlement, misappropriation, willful misconduct, gross negligence, or breach of fiduciary duty, in each case against the Company or any Affiliate.

For the purposes of this definition, no act (or omission) that is (i) taken in good faith and (ii) not adverse to the best interests of the Company or its Affiliates shall be considered to be willful.

"Change in Control" shall have the same meaning as assigned to that term in the Company's 2021 Incentive Award Plan (or any successor to or replacement of such plan); provided, that such transaction must also constitute a "change in control event" within the meaning of Treasury Regulation Section 1.409A-3(i)(5).

"Change in Control Period" shall mean the period of time commencing three months prior to the closing of a Change in Control and ending 18 months following the closing of such Change in Control.

"Code" means the Internal Revenue Code of 1986, as amended.

"Disability" means a disability within the meaning of Code section 409A(a)(2)(C) and U.S. Treasury Regulations section 1.409A-3(i)(4) (or any successor provision).

"Effective Date" shall mean the first day of Executive's employment with the Company.

"Good Reason" means the occurrence of any of the following events, unless the Executive otherwise consents in writing to such event:

(a) a material reduction in the Executive's Annual Base Salary (other than a reduction that is applicable to all similarly situated employees generally and that occurs outside a Change in Control Period);

(b) with respect to a Change in Control Period only, a material reduction in the Executive's Annual Target Bonus Opportunity as compared to his Annual Target Bonus Opportunity for the fiscal year of the Company in which the Change in Control occurred;

(c) requiring the Executive to relocate his principal place of employment to a location more than fifty (50) miles from the Executive's current principal place of employment; or

(d) the failure or refusal by a successor or acquiring company, upon the consummation of a Change in Control, to (i) assume the obligations of the Company under this Agreement or (ii) assume obligations to Executive that are substantially equivalent to or more favorable than the obligations under this Agreement.

The Executive shall provide the Company with a written notice of resignation within ninety (90) days following the occurrence of the event constituting Good Reason and the Company (or its Affiliate, if applicable) shall have a period of thirty (30) days following its receipt of such notice in which to cure such event without such event constituting Good Reason. If the Company (or its Affiliate, if applicable) does not cure the condition or conditions by the end of such thirty (30) day period, the Executive may voluntarily terminate employment within thirty (30) days after the last day of the thirty (30) day cure period. The Executive's voluntary termination of employment other than in accordance with the requirements of this definition shall not constitute termination for Good Reason.

"Release" means a general release of claims against the Company and the other persons specified therein in the form attached hereto as Exhibit A, or in such other form as is required to comply with applicable law.

"Separation from Service" means a "separation from service" with the Company within the meaning of Section 409A of the Code and the Department of Treasury regulations and other guidance promulgated thereunder.

"Severance" means (a) the involuntary termination of the Executive's employment by the Company or any Affiliate thereof, other than for Cause, death or Disability or (b) a termination of the Executive's employment with the Company and its Affiliates by the Executive for Good Reason in each case that, to the extent necessary, constitutes a Separation from Service.

"Severance Date" means the date on which the Executive incurs a Severance.

"Severance Period" means the period following the Executive's Severance pursuant to which the Company owes payments and/or benefits to the Executive pursuant to this Agreement.

"Treasury Regulations" means the final, temporary or proposed regulations issued by the Treasury Department and/or Internal Revenue Service as modified in Title 26 of The United States Code of Federal Regulations. Any references made in this Agreement to specific Treasury Regulations shall also refer to any successor or replacement regulations thereto.

SECTION 2. ***Term of Agreement.*** The term of this Agreement (the "Term") will commence on the Effective Date, and will continue until (a) in the event the Executive's employment is terminated for any reason other than the Executive's Severance, the date of such termination of employment, or (b) in the event the Executive incurs a Severance, the date on which the Company has fulfilled all obligations owed to the Executive pursuant to this Agreement.

SECTION 3. ***Severance Benefits***

3.1 Generally. **Su**bject to Sections 3.6, 5 and 7.2 of this Agreement, the Executive shall be entitled to the severance payments and benefits described below.

3.2 Payment of Accrued Obligations. The Company shall pay to the Executive upon the Executive's Severance a lump sum payment in cash, paid in accordance with applicable law, as soon as practicable but no later than ten (10) days after the Severance Date, equal to the sum of (a) the Executive's accrued annual base salary and any accrued vacation pay through the Severance Date, and (b) any annual bonus earned by the Executive from the year preceding the Severance Date but not yet paid as of the Severance Date.

3.3 Severance Payments and Benefits Outside of a Change in Control Period. Subject to Section 3.6, upon the Executive's Severance that occurs outside of a Change in Control Period, then in addition to the payments and benefits set forth in Section 3.2 above, the Company shall provide Executive with the following:

(a) During the period of time commencing on the Severance Date and ending on (i) the nine (9) month anniversary of the Severance Date if the Executive has less than three years of service with the Company or (ii) the twelve (12) month anniversary of the Severance Date if the Executive has three or more years of service with the Company, the Company shall continue to pay Executive his Annual Base Salary. Such payments shall be made in accordance with the Company's standard payroll practices, less applicable withholdings, beginning on the first payroll date following the date the Release becomes effective and irrevocable in accordance with Sections 3.6 and 10.4 below, and with the first installment including any amounts that would have been paid had the Release been effective and irrevocable on the Severance Date.

(b) Executive shall be entitled to receive an amount equal to 100% percent of Executive's Annual Target Bonus Opportunity (pro-rated based on the number of days Executive was employed by the Company during the calendar year in which the Severance Date occurs), payable at the same time annual bonuses are paid generally to other executives of the Company for the relevant year, less applicable withholdings and deductions, but in no event later than March 15th of the year immediately following that in which the Severance Date occurs.

(c) The Company shall directly pay Executive's total COBRA premiums for the period commencing on the Severance Date and ending on (i) the nine (9) month anniversary of the Severance Date if the Executive has less than three years of service with the Company or (ii) the twelve (12) month anniversary of the Severance Date if the Executive has three or more years of service with the Company of COBRA continuation coverage under the Company's health benefit plan (i.e., medical, dental and vision coverage) (the "Non-CiC COBRA

Period"). To the extent permitted by applicable law, Executive shall have the right to change Executive's coverage elections under the Company's health benefit plan during the COBRA continuation period and any such change in elections shall not reduce or eliminate the Company's obligation to pay applicable premiums. Notwithstanding Section 3.3(c), in the event that (i) the direct COBRA payment arrangement described in Section 3.3(c) would result in adverse tax consequences for the Executive under Code Section 105(h) (or similar law), (ii) any plan pursuant to which such benefits are provided is not, or ceases prior to the expiration of the period of continuation coverage to be, exempt from the application of Section 409A of the Code under Treasury Regulation Section 1.409A-1(a)(5), or (iii) the Company is otherwise unable to continue to cover Executive under its group health plans without penalty under applicable law (including without limitation, Section 2716 of the Public Health Service Act), the Company shall pay to the Executive an amount equal to one hundred and twenty five percent (125%) of the total premiums the Executive would be required to pay for the remaining Non-CiC COBRA Period under the Company's health benefit plan, determined using the COBRA premium rate in effect for the level of coverage that the Executive has in place immediately prior to the Severance Date (the "COBRA Payment"). The Company shall pay the COBRA Payment in substantially equal monthly installments over the remaining Non-CiC COBRA Period. In the event that the Company makes a payment pursuant to this Section 3.3(c), the Executive shall not be required to purchase COBRA continuation coverage in order to receive the COBRA Payment nor shall the Executive be required to apply the COBRA Payment to payment of applicable premiums for COBRA continuation coverage.

(d) In addition, to the extent permitted by applicable law and the Company's applicable benefit plans, during the Non-CiC COBRA Period the Company shall permit the Executive (and his eligible dependents) to participate in any optional life insurance and optional personal accident plans of the Company for which senior executives of the Company are eligible, to the same extent and at the same premium rates as if the Executive had continued to be an employee of the Company during such period.

3.4 Outplacement Services. Subject to Section 3.6, in addition to the benefits provided in Sections 3.3 and 3.5, upon Executive's Severance (whether during or outside a Change in Control Period), the Executive shall be entitled to receive outplacement services of up to $10,000 for the period ending on the first anniversary of the Executive's Severance Date.

3.5 Severance Payments and Benefits During a Change in Control Period. Subject to Section 3.6, upon the Executive's Severance that occurs during a Change in Control Period, then, in lieu of the severance payments and benefits set forth in Section 3.3 above and in addition to the payments and benefits set forth in Section 3.2 above, the Company shall provide Executive with the following:

(a) During the period of time commencing on the Severance Date and ending on the twelve (12) month anniversary of the Severance Date, the Company shall continue to pay Executive his Annual Base Salary. Such payments shall be made in accordance with the Company's standard payroll practices, less applicable withholdings, beginning on the first payroll date following the date the Release becomes effective and irrevocable in accordance with Sections 3.6 and 10.4 below, and with the first installment including any amounts that would have been paid had the Release been effective and irrevocable on the Severance Date.

(b) Executive shall be entitled to receive an amount equal to one hundred percent (100%) of Executive's Annual Target Bonus Opportunity, payable in a cash lump sum, less applicable withholdings, on the first payroll date following the date the Release becomes effective and irrevocable becomes effective and irrevocable in accordance with Sections 3.6 and 10.4 below.

(c) The Company shall directly pay Executive's total COBRA premiums for the period commencing on the Severance Date and ending on the eighteen (18) month anniversary of the Severance Date of COBRA continuation coverage under the Company's health benefit plan (i.e., medical, dental and vision coverage) (the "CiC COBRA Period"). To the extent permitted by applicable law, Executive shall have the right to change Executive's coverage elections under the Company's health benefit plan during the COBRA continuation period and any such change in elections shall not reduce or eliminate the Company's obligation to pay applicable premiums. Notwithstanding Section 3.5(c), in the event that (i) the direct COBRA payment arrangement described in Section 3.5(c) would result in adverse tax consequences for the Executive under Code Section 105(h) (or similar law), (ii) any plan pursuant to which such benefits are provided is not, or ceases prior to the

expiration of the period of continuation coverage to be, exempt from the application of Section 409A of the Code under Treasury Regulation Section 1.409A-1(a)(5), or (iii) the Company is otherwise unable to continue to cover Executive under its group health plans without penalty under applicable law (including without limitation, Section 2716 of the Public Health Service Act), the Company shall pay to the Executive an amount equal to one hundred and twenty five percent (125%) of the total premiums the Executive would be required to pay for the remaining CiC COBRA Period under the Company's health benefit plan, determined using the COBRA premium rate in effect for the level of coverage that the Executive has in place immediately prior to the Severance Date (the "COBRA Payment"). The Company shall pay the COBRA Payment shall be paid in substantially equal monthly installments over the remaining CiC COBRA Period. In the event that the Company makes a payment pursuant to this Section 3.5(c), the Executive shall not be required to purchase COBRA continuation coverage in order to receive the COBRA Payment nor shall the Executive be required to apply the COBRA Payment to payment of applicable premiums for COBRA continuation coverage.

(d) In addition, to the extent permitted by applicable law and the Company's applicable benefit plans, during the CiC COBRA Period the Company shall permit the Executive (and his eligible dependents) to participate in any optional life insurance and optional personal accident plans of the Company for which senior executives of the Company are eligible, to the same extent and at the same premium rates as if the Executive had continued to be an employee of the Company during such period.

(e) In addition, each outstanding and unvested equity award (excluding any such awards that vest in whole or in part based on the attainment of performance-vesting conditions), including, without limitation, each restricted stock, stock option, restricted stock unit and stock appreciation right, held by Executive shall be subject to the accelerated vesting as set forth in the Plan.

3.6 Release and Restrictive Covenant Agreement. The Executive shall be eligible to receive the payments and other benefits under this Agreement (other than payments under Section 3.2) only if after the Severance Date (a) the Executive first executes the Release in favor of the Company and others attached hereto as Exhibit A and the Release has not been revoked by the Executive, by the sixtieth (60th) day following the Severance Date (or such short time specified by the Company) (such date, the "Release Expiration Date"), and (b) the Executive provides the Company written attestation that the Confidentiality, Non-Competition, Non-Solicitation and Inventions Agreement attached hereto as Exhibit B (the "Restrictive Covenants Agreement") is in effect and enforceable. If the Executive does not execute and return the Release and attestation such that either or both agreements do not become effective (or, in the case of the Release, is revoked) before the Release Expiration Date immediately following the Severance Date, the Executive shall not be entitled to any payments or benefits under this Agreement (other than payments under Section 3.2).

3.7 Forfeiture. If the Executive is found in a judgment no longer subject to review or appeal to have breached the oblig7tions set forth in the Restrictive Covenants Agreement, then the Executive shall immediately forfeit any amounts payable or benefits to be received and shall promptly reimburse the Company any amounts actually paid to the Executive pursuant to this Agreement (other than payments made pursuant to Section 3.2).

3.8 No Duplication of Benefits. Except as otherwise noted herein, during the Term of this Agreement the compensation to be paid to the Executive hereunder will be in lieu of any similar severance or termination compensation (compensation based directly on the Executive's annual salary or annual salary and bonus) to which the Executive may be entitled under any other Company or Affiliate severance or termination agreement, plan, program, policy, practice or arrangement (collectively, "Severance Plans"). The Executive affirmatively waives any rights he may have to payments or benefits provided under the Severance Plans to the extent the Executive receives similar payments or benefits under this Agreement. The Executive's entitlement to any compensation or benefits of a type not provided in this Agreement will be determined in accordance with the Company's or its Affiliates' employee benefit plans and other applicable programs, policies and practices as in effect from time to time.

3.9 No Mitigation or Offset. In the event of any termination of the Executive's employment, the Executive shall not be required to seek other employment to mitigate damages, and any income earned by the Executive from other employment or self-employment shall not be offset against any obligations of the Company and its Affiliates to Executive under this Agreement.

SECTION 4. ***Golden Parachute Tax*****.** It is the intention of the Company and the Executive that the Executive receive the full benefits available under this Agreement and any other agreement, plan, program, policy or similar arrangement providing for compensation or benefits in the event of a Change in Control. If a Change of Control occurs and a determination is made by legislation, regulation, ruling directed to the Executive or the Company, or court decision that the aggregate amount of any payment made to the Executive hereunder, or pursuant to any plan, program, policy or similar arrangement of the Company (or any subsidiary or affiliate or successor thereto) in connection with, on account of, or as a result of, such Change in Control constitutes "excess parachute payments" as defined in Code Section 280G (as well as any successor or similar sections thereof), subject to the excise tax provisions of Code Section 4999 (as well as any successor or similar sections thereof), the Executive shall be entitled to receive from the Company, in addition to any other amounts payable hereunder, a lump sum payment equal to 100% of such excise tax, plus an amount equal to the federal and state income tax, FICA, and Medicare taxes (based upon Executive's projected marginal income tax rates) on such lump sum payment. The amounts under this Section 4 shall be paid to Executive as soon as may be practicable after such final determination is made and in all events shall be made no later than the end of the Executive's taxable year next following his taxable year in which he remitted the related taxes. The Executive and the Company shall mutually and reasonably determine whether or not such determination has occurred or whether any appeal to such determination should be made.

SECTION 5. ***Death During the Severance Period.*** If the Executive dies during the Severance Period, any unpaid amounts shall be paid to the Executive's estate within ten (10) days following the Executive's death. The Executive's right to outplacement services described in Section 3.4 and continued participation in the life insurance and accident plans described in Sections 3.3 or 3.5 shall terminate as of the date of the Executive's death.

SECTION 6. ***Amendments; Waiver*****.** This Agreement contains the entire agreement of the parties with respect to severance payments and benefits payable in connection with a Severance. No amendment or modification of this Agreement shall be valid unless evidenced by a written instrument executed by the parties hereto. No waiver by either party of any breach by the other party of any provision or condition of this Agreement shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time.

SECTION 7. ***General Provisions*****.**

7.1 Except as otherwise provided herein or by law, no right or interest of the Executive under this Agreement shall be assignable or transferable, in whole or in part, either directly or by operation of law or otherwise, including without limitation by execution, levy, garnishment, attachment, pledge or in any manner; no attempted assignment or transfer thereof shall be effective; and no right or interest of the Executive under this Agreement shall be liable for, or subject to, any obligation or liability of such Executive. When a payment is due under this Agreement to the Executive and the Executive is unable to care for his affairs, payment may be made directly to his guardian or personal representative.

7.2 If the Company or any Affiliate thereof is obligated by law or by contract to pay severance pay, a termination indemnity, notice pay, or the like, or if the Company or any Affiliate thereof is obligated by law or by contract to provide advance notice of separation ("Notice Period"), then any severance pay under this Agreement shall be reduced by the amount of any such severance pay, termination indemnity, notice pay or the like, as applicable, and by the amount of any compensation received during any Notice Period. If the Executive is entitled to benefits under the Workers Adjustment Retraining Notification Act of 1988, or any similar state or local statute or ordinance (collectively the "WARN Act"), severance pay under this Agreement shall be reduced dollar-for-dollar by any benefits received pursuant to the WARN Act.

7.3 Neither this Agreement, nor any modification thereof, nor the creation of any fund, trust or account, nor the payment of any benefits shall be construed as giving the Executive, or any person whomsoever, the right to be retained in the service of the Company or any Affiliate thereof, and the Executive shall remain subject to discharge to the same extent as if this Agreement had never existed.

7.4 If any provision of this Agreement shall be held invalid or unenforceable, such invalidity or unenforceability shall not affect any other provisions hereof, and this Agreement shall be construed and enforced as if such provisions had not been included.

7.5 This Agreement shall inure to the benefit of and be binding upon the heirs, executors, administrators, successors and assigns of the parties, including the Executive, present and future, and any successor to the Company.

7.6 The headings and captions herein are provided for reference and convenience only, shall not be considered part of this Agreement, and shall not be employed in the construction of this Agreement.

7.7 The Agreement shall not be required to be funded unless such funding is authorized by the Board. Regardless of whether the Agreement is funded, the Executive shall not have any right to, or interest in, any assets of any Company which may be applied by the Company to the payment of benefits or other rights under this Agreement. For purposes of clarity, nothing in this Section 7.7 shall be construed to relieve the Company or its Affiliates from their obligations to the Executive pursuant to this Agreement.

7.8 All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by confirmed electronic mail or facsimile if sent during normal business hours of the recipient, and if not so confirmed, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one day after deposit with a nationally recognized overnight courier, specifying next-day delivery, with written verification of receipt. All communications shall be sent:

(i) To the Executive, at:

Last address in records of the Company

(ii) To the Company, at:

Treace Medical Concepts, Inc.
203 Fort Wade Rd., Suite 150
Ponte Vedra, FL 32081
Attention: Chief Legal & Compliance Officer

7.9 This Agreement shall be governed, construed, interpreted and enforced in accordance with the substantive laws of the State of Florida, without reference to principles of conflicts or choice of law under which the law of any other jurisdiction would apply.

7.10 The Company may withhold from any payments due to the Executive hereunder such amounts as are required to be withheld under applicable federal, state and local tax laws.

7.11 Notwithstanding anything to the contrary contained herein, nothing in this Agreement or the Restrictive Covenants Agreement prohibits Executive from reporting possible violations of federal law or regulation to any United States governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934 or Section 806 of the Sarbanes-Oxley Act of 2002, or any other whistleblower protection provisions of state or federal law or regulation (including the right to receive an award for information provided to any such government agencies). Furthermore, in accordance with 18 U.S.C. § 1833, notwithstanding anything to the contrary in this Agreement: (i) Executive shall not be in breach of this Agreement, and shall not be held criminally or civilly liable under any federal or state trade secret law (A) for the disclosure of a trade secret that is made in confidence to a federal, state, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (B) for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (ii) if Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose the trade secret to Executive's attorney, and may use the trade secret information in the court proceeding, if Executive files any document containing the trade secret under seal, and does not disclose the trade secret, except pursuant to court order.

SECTION 8. ***Entire Agreement.*** This Agreement constitutes the entire agreement between the parties hereto and supersedes all prior agreements, if any, understandings and arrangements, oral or written, between the parties hereto with respect to severance, except for any equity acceleration provided in the Plan.

SECTION 9. ***Disputes.***

9.1 Except as provided in the Restrictive Covenants Agreement, any dispute or controversy arising under, out of, in connection with or in relation to this Agreement shall, at the election and upon written demand of any party to this Agreement, be finally determined and settled by arbitration in Jacksonville, Florida in accordance with the rules and procedures of the American Arbitration Association, and judgment upon the award may be entered in any court having jurisdiction thereof.

9.2 If, with respect to any alleged failure by the Company or its Affiliates to comply with any of the terms of this Agreement, the Executive hires legal counsel with respect to this Agreement or institutes any negotiations or institutes or responds to legal action to assert or defend the validity of, enforce his rights under, or recover damages for breach of this Agreement, and thereafter the Company or its Affiliates are found in a judgment no longer subject to review or appeal to have breached this Agreement in any material respect, then the Company or its Affiliates (but not both) shall reimburse the Executive for his actual expenses for attorneys' fees and disbursements within thirty (30) days following receipt of any invoice for such expenses.

SECTION 10. ***Section 409A of the Code.***

10.1 It is intended that this Agreement shall comply with or be exempt from the provisions of Section 409A of the Code and the Treasury Regulations relating thereto, so as not to subject the Executive to the payment of additional taxes and interest under Section 409A of the Code. This Agreement shall be interpreted, operated, and administered in a manner consistent with and in furtherance of this intent.

10.2 Any payment required under this Agreement that is payable in installment payments shall be deemed to be a separate payment for purposes of Section 409A of the Code and the Treasury Regulations thereunder.

10.3 Notwithstanding any provision to the contrary in this Agreement, no payment or distribution under this Agreement which constitutes an item of deferred compensation under Section 409A of the Code and becomes payable by reason of the Executive's termination of employment with the Company or its Affiliates or an Executive's resignation for Good Reason will be made unless the Executive's termination of employment or resignation (as applicable) constitutes a Separation from Service. In addition and solely to the extent required by Code Section 409A, no such payment or distribution will be made to the Executive prior to the earlier of (a) the expiration of the six (6)-month period measured from the date of the Executive's "separation from service" (as such term is defined in Treasury Regulations issued under Section 409A of the Code) or (b) the date of the Executive's death, if the Executive is deemed at the time of such separation from service to be a "specified employee" within the meaning of that term under Section 409A(a)(2) of the Code and to the extent such delayed commencement is otherwise required in order to avoid a prohibited distribution under Section 409A(a)(2) of the Code. All payments and benefits which had been delayed pursuant to the immediately preceding sentence shall be paid (without interest) to the Executive in a lump sum upon expiration of such six-month period (or if earlier upon the Executive's death).

10.4 Notwithstanding anything to the contrary in this Agreement, to the extent that any payments due under this Agreement as a result of Executive's termination of employment are subject to Executive's execution and delivery of a Release, in any case where Executive's Severance Date and the Release Expiration Date fall in two separate taxable years, any payments required to be made to Executive that are conditioned on the Release and are treated as nonqualified deferred compensation for purposes of Section 409A of the Code shall be made in the later taxable year. To the extent that any payments of nonqualified deferred compensation (within the meaning of Section 409A) due under this Agreement as a result of Executive's termination of employment are delayed pursuant to this Section 10.4, such amounts shall be paid in a lump sum on the first payroll date to occur in the subsequent taxable year.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

TREACE MEDICAL CONCEPTS, INC.

/s/ John T. Treace
John T. Treace
Chief Executive Officer

EXECUTIVE

/s/ Scot M. Elder
Scot M. Elder

EXHIBIT A
RELEASE AGREEMENT
(To be signed after the Severance Date)

In return for payment of severance benefits pursuant to the Change in Control Severance Agreement between Treace Medical Concepts, Inc., and me (the "CIC Severance Agreement"), I hereby generally and completely release Treace Medical Concepts, Inc. ("Treace"), its parent and subsidiary entities (collectively the "Company"), and its or their directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, insurers, affiliates, and assigns (collectively "Released Parties"), from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to my signing this Release Agreement (the "Agreement"). This general release includes, but is not limited to: (1) all claims arising out of or in any way related to my employment with the Company or the termination of that employment; (2) all claims related to my compensation or benefits from the Company, including wages, salary, bonuses, commissions, vacation pay, expense reimbursements (to the extent permitted by applicable law), severance pay, fringe benefits, stock, stock options, or any other ownership interests in the Company; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including without limitation claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims, including without limitation claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) ("ADEA"), the federal Worker Adjustment and Retraining Notification Act (as amended) and similar laws in other jurisdictions, the Employee Retirement Income Security Act of 1974 (as amended), the Family and Medical Leave Act of 1993, and any similar laws in other jurisdictions; provided, however, that this Release does not waive, release or otherwise discharge any claim or cause of action arising after the date I sign this Agreement.

This Agreement includes a release of claims of discrimination or retaliation on the basis of workers' compensation status, but does not include workers' compensation claims. Excluded from this Agreement are any claims which by law cannot be waived in a private agreement between employer and employee, including but not limited to the right to file a charge with or participate in an investigation conducted by the Equal Employment Opportunity Commission ("EEOC") or any state or local fair employment practices agency. I waive, however, any right to any monetary recovery or other relief should the EEOC or any other agency pursue a claim on my behalf.

I acknowledge and represent that I have not suffered any age or other discrimination, harassment, retaliation, or wrongful treatment by any Released Party. I also acknowledge and represent that I have not been denied any rights including, but not limited to, rights to a leave or reinstatement from a leave under the Family and Medical Leave Act of 1993, the Uniformed Services Employment and Reemployment Rights Act of 1994, or any similar law of any jurisdiction.

I agree that I am voluntarily executing this Agreement. I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA, as amended by the Older Workers Benefit Protection Act of 1990, and that the consideration given for this Release is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) my waiver and release specified in this paragraph does not apply to any rights or claims that may arise after the date I sign this Agreement; (b) I have been advised to consult with an attorney prior to signing this Agreement; (c) if a "Severance" (as defined in the CIC Severance Agreement) involves an employment termination program, I have received a disclosure from the Company that includes a description of the class, unit or group of individuals covered by the program, the eligibility factors for such program, and any time limits applicable to such program and a list of job titles and ages of all employees selected for this group termination and ages of those individuals in the same job classification or organizational unit who were not selected for termination; (d) I have at least twenty-one (21) or forty-five (45) days, depending on the circumstances of my Severance, from the date that I receive this Release (although I may choose to sign it any time on or after my Severance Date (as defined in the CIC Severance Agreement)) to consider the release; (e) I have seven (7) calendar days after I sign this Release to revoke it ("Revocation Period") by sending my revocation to the Human Resources Manager in writing at 203 Fort Wade Rd., Suite 150, Ponte Vedra, FL 32081; and (f) this Agreement will not be effective until I have signed it and returned it to the Company's Corporate Secretary and the Revocation Period has expired.

I UNDERSTAND THAT THIS AGREEMENT INCLUDES A RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS.

Scot M. Elder

Date

EXHIBIT B
RESTRICTIVE COVENANTS AGREEMENT

See attached Employee Confidentiality, Nonsolicitation and Noncompete Agreement between Executive and the Company dated October 25, 2021

Exhibit 10.12

RELEASE AND CONSULTING AGREEMENT

This Release and Consulting Agreement (the "Agreement") is entered into as of October 20, 2021 (the "Effective Date"), by and between Treace Medical Concepts, Inc. (the "Company") and Joe W. Ferguson ("Ferguson") (The Company and Ferguson sometimes referred to collectively herein as the "Parties").

Preliminary Statement. Ferguson was employed by the Company from July 14, 2014 through the Effective Date. The Parties are entering into this Agreement (1) to provide for Ferguson's release of claims against the Released Parties (as defined below) in return for the Company's payment of severance benefits to Ferguson, and (2) to set forth the terms pursuant to which Ferguson will provide continued assistance to the Company in the future with respect to certain matters in return for such severance benefits and additional consulting fees, all as set forth herein. Accordingly, for good and valuable consideration the receipt and sufficiency of which are hereby acknowledged by the Parties, the Company and Ferguson agree as follows:

1. Release; Attestation.

   a. In return for payment of severance benefits pursuant to the Change in Control Severance Agreement between the Company and Ferguson dated May 27, 2021 (the "CIC Severance Agreement"), Ferguson hereby generally and completely releases Treace Medical Concepts, Inc., its parent and subsidiary entities, and its or their directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, insurers, affiliates, and assigns (collectively "Released Parties"), from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to my signing this Agreement. This general release includes, but is not limited to: (1) all claims arising out of or in any way related to Ferguson's employment with the Company or the termination of that employment; (2) all claims related to Ferguson's compensation or benefits from the Company, including wages, salary, bonuses, commissions, vacation pay, expense reimbursements (to the extent permitted by applicable law), severance pay, fringe benefits, stock, stock options, or any other ownership interests in the Company; (3) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (4) all tort claims, including without limitation claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (5) all federal, state, and local statutory claims, including without limitation claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) ("ADEA"), the federal Worker Adjustment and Retraining Notification Act (as amended) and similar laws in other jurisdictions, the Florida Civil Rights Act ("FCRA"), the Employee Retirement Income Security Act of 1974 (as amended), the Family and Medical Leave Act of 1993, and any similar laws in other jurisdictions; provided, however, that this Release does not waive, release or otherwise discharge any claim or cause of action arising after the date Ferguson signs this Agreement.

   b. This Agreement includes a release of claims of discrimination or retaliation on the basis of workers' compensation status, but does not include workers' compensation claims. Excluded from this Agreement are any claims which by law cannot be waived in a private agreement between employer and employee, including but not limited to the right to file a charge with or participate in an investigation conducted by the Equal Employment Opportunity Commission ("EEOC") or any state or local fair employment practices agency. Ferguson waives, however, any right to any monetary recovery or other relief should the EEOC, Ferguson or anyone else pursue a claim on Ferguson's behalf.

   c. Ferguson acknowledges and represents that he: (i) has not suffered any age or other discrimination, harassment, retaliation, or wrongful treatment by any Released Party; and (ii) has not been denied any rights including, but not limited to, rights to a leave or reinstatement from a leave under the Family and Medical Leave Act of 1993, the Uniformed Services Employment and Reemployment Rights Act of 1994, or any similar law of any jurisdiction.

d. Ferguson agrees that he is voluntarily executing this Agreement. Ferguson acknowledges that: (i) he is knowingly and voluntarily waiving and releasing any rights he may have under the ADEA, as amended by the Older Workers Benefit Protection Act of 1990, and that the consideration given for this Release is in addition to anything of value to which he was or may have been already entitled; and (ii) he has been advised by this writing, as required by the ADEA, that: (1) his waiver and release specified in this paragraph does not apply to any rights or claims that may arise after the date he signs this Agreement; (2) he has been advised to consult with an attorney prior to signing this Agreement; (3) if a "Severance" (as defined in the CIC Severance Agreement) involves an employment termination program, he has received a disclosure from the Company that includes a description of the class, unit or group of individuals covered by the program, the eligibility factors for such program, and any time limits applicable to such program and a list of job titles and ages of all employees selected for this group termination and ages of those individuals in the same job classification or organizational unit who were not selected for termination; (4) he has at least twenty-one (21) days from the date that he received this Agreement (although he may choose to sign it any time on or after his Severance Date (as defined in the CIC Severance Agreement)) to consider the Release contained herein; (5) he has seven (7) calendar days after he signs this Agreement to revoke it ("Revocation Period") by sending his revocation to the Company's Human Resources Manager in writing at 203 Fort Wade Rd., Suite 150, Ponte Vedra, FL 32081; and (6) this Agreement will not be effective until he has signed it and returned it to the Company's Corporate Secretary and the Revocation Period has expired.

e. FERGUSON UNDERSTANDS THAT THIS AGREEMENT INCLUDES A RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS.

f. Attestation. Ferguson hereby acknowledges that he has executed that certain Employee Confidentiality, Non-Competition, Non-Solicitation and Inventions Agreement effective June 24, 2014 (the "Restrictive Covenants Agreement"), which is attached as Exhibit 1 to this Agreement, with the Company. Ferguson acknowledges, agrees and attests that the Restrictive Covenants Agreement is in full effect and enforceable. Ferguson further affirms that he has complied and shall continue to comply with his current and continuing obligations under the Restrictive Covenants Agreement. Ferguson understands and agrees that if he is found in a judgment no longer subject to review or appeal to have breached the obligations set forth in the Restrictive Covenants Agreement, then he shall immediately forfeit any amounts payable or benefits to be received and shall promptly reimburse the Company any amounts actually paid to him pursuant to his CIC Severance Agreement with the Company (other than payments made pursuant to Section 3.2 thereof).

2. Consulting Provisions.

a. The Parties recognize that, after more than 7 years of employment with the Company, Ferguson is in possession of considerable historical information relating to the Company that may be valuable to the Company's ongoing operations. As a condition of this Agreement and the consideration offered to Ferguson pursuant to this Agreement, Ferguson further agrees to provide, for a period of four (4) years from the Effective Date, assistance to the Company upon receipt of reasonable notice from the Company. This term shall be extendable upon written request by the Company. The Parties agree that such assistance may include, but not be limited to, attendance at in-person or remote meetings with the Company's personnel, representatives and agents, attendance at legal proceedings, execution of legal documents, including patent documents, and assistance with locating and identifying relevant Company documents. Ferguson agrees that the initial 100 hours provided pursuant to this paragraph shall be deemed fully paid by the Severance contemplated by this Agreement. For any hours in excess thereof, Ferguson shall be paid by the Company at the hourly rate of $300. Time spent by Ferguson to ensure a smooth transition of his current role shall not be considered part of the services provided under this paragraph. Ferguson further agrees that as a condition of this Agreement, he shall indefinitely maintain in strictest confidence all privileged and confidential information that he has generated, received or learned of during the term of his employment with the Company ("Information"). Ferguson further agrees that he shall not disclose such Information to any third party without the express written consent of the Company. Ferguson further agrees that he shall not accept employment from or engage with any third party whether as an employee, advisor, consultant, greater than 1% owner (whether directly or indirectly), paid fact witness, expert or any other role in any matter (legal, administrative or otherwise) in which (i) he performs services or provides advice to another company offering instrumentation and implants for bunion and ancillary surgeries or (ii) his

involvement would be adverse to the Company's or its successor's interests. Ferguson acknowledges and agrees that his service in any such role is likely to result in the disclosure, including the inadvertent disclosure, of Information. Ferguson agrees that this prohibition shall extend for a period of five (5) years from the Effective Date of this Agreement.

b. After the Effective Date and in connection with performance of services under Section 2a, Ferguson's relationship with the Company will be that of an independent contractor, and nothing in this Agreement should be construed to create a partnership, joint venture, or employer-employee relationship. Ferguson will be solely responsible for all tax returns and payments required to be filed with or made to any federal, state or local tax authority with respect to Ferguson's performance of services and receipt of amounts under Section 2 of this Agreement. Because Ferguson is an independent contractor after the Effective Date, with respect to the services performed and amounts paid under Section 2, the Company will not withhold or make payments for social security; make unemployment insurance or disability insurance contributions; or obtain worker's compensation insurance on Ferguson's behalf; or undertake any other responsibility inconsistent with the independent contractor relationship.

3. General Provisions.

a. The parties have carefully read this Agreement in its entirety; fully understand and agree to its terms and provisions; intend and agree that it is final and binding and understand that, in the event of a breach, either party may seek relief, including damages, restitution and injunctive relief, at law or in equity, in a court of competent jurisdiction.

b. Ferguson agrees that he is not signing this Agreement in reliance upon any promise, representation or warranty not expressly contained in this Agreement, including its exhibits. Any oral representations regarding this Agreement, including its exhibits, shall have no force or effect. No modification, termination, or attempted waiver of any of the provisions of this Agreement shall be binding upon the Company unless reduced to writing and signed by a duly authorized official. Each provision of this Agreement is severable from each other provision of this Agreement. If any provision of this Agreement is determined to be invalid or unenforceable, the remaining portions of this Agreement will continue to be operative and in full force and effect. This Agreement shall be construed according to a plain reading of its terms and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provision in this Agreement. The Company's failure or delay in enforcing any provision of this Agreement will not be a waiver of enforcement of that provision or any other provision. All rights and remedies provided for in this Agreement are cumulative, are in addition to any other rights and remedies provided for by law, and may, to the extent permitted by law, be exercised concurrently or separately. The exercise of any one right or remedy shall not be deemed to be an election of such right or remedy or to preclude the exercise or pursuit of any other right or remedy.

c. Except as otherwise provided herein or by law, no right or interest of Ferguson under this Agreement shall be assignable or transferable, in whole or in part, either directly or by operation of law or otherwise, including without limitation by execution, levy, garnishment, attachment, pledge or in any manner; no attempted assignment or transfer thereof shall be effective.

d. This Agreement and any dispute arising under this Agreement will be governed by Florida law, without regard to any conflict of law principles. Any litigation under this Agreement will be brought by either party exclusively in the federal courts located in Federal District Court, Middle District of Florida, Jacksonville Division and in no other venue. As such, the parties irrevocably consent to the jurisdiction of the courts in Federal District Court, Middle District of Florida, Jacksonville Division for all such disputes and to service of process via nationally recognized overnight carrier, without limiting other service methods available under applicable law, and waive the right to have a trial by jury under or in connection with this Agreement.

[signatures on following page]

IN WITNESS WHEREOF, the Parties have duly executed and delivered this Agreement.

TREACE MEDICAL CONCEPTS, INC.

By: /s/ Daniel E. Owens
Name: Daniel E. Owens
Title: Chief Human Resources Officer

/s/ Joe W. Ferguson
Joe W. Ferguson

Ferguson Confidentiality, Non-Competition, Non-Solicitation and Inventions Agreement

[*Omitted*]

AMENDED AND RESTATED DIRECTOR COMPENSATION PROGRAM

Board Compensation Program -- Compensation for Non-Employee Director Positions

This Treace Medical Concepts, Inc. (the "*Company*") Non-Employee Director Compensation Program (this "*Program*") has been adopted under the Company's 2021 Incentive Award Plan (the "*Plan*") and shall be effective as of the closing of the Company's initial public offering of its common stock (the "*Effective Date*"). Capitalized terms not otherwise defined herein shall have the meaning ascribed in the Plan. The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board of Directors of the Company (the "*Board*"), to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "*Non-Employee Director*") unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. The notice shall be effective for all subsequent compensation payable after the Company's receipt of such notice unless otherwise agreed in writing between the Company and the Non-Employee Director.

Cash Compensation – All Non-Employee Directors are entitled to receive the following annual cash compensation for his or her services:

- $40,000 per year for services as a board member
- $~~4~~5,000 per year additionally for services as Chairperson of the Board of Directors
- $20,000 per year additionally for services as Chairperson of Audit Committee
- $10,000 per year additionally for service as an Audit Committee member
- $15,000 per year additionally for service as Chairperson of the Compensation Committee
- $7,000 per year additionally for service as a Compensation Committee member
- $10,000 per year additionally for service as the Nominating, Compliance and Governance Chairperson
- $5,000 per year additionally for service as a Nominating, Compliance and Governance Committee member

Each annual cash retainer and additional annual fee is paid quarterly in arrears on a prorated basis. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described above, for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

Cash compensation portion of plan for directors joining the Board after November 1, 2020 begins when the first new director is appointed to the Board. Cash compensation for directors serving before November 1, 2020 begins with the Effective Date.

Initial Option Grant for Non-Employee Board Directors: Each Non-Employee Director who is initially elected or appointed to serve on the Board after November 1, 2020 shall be granted under the Plan or any other applicable Company equity incentive plan then-maintained by the Company an option to purchase shares of Common Stock (the "*Initial Option*") with a value equivalent to $250,000 at "Black-Scholes" Value (as defined below). The Initial Option will be automatically granted on the date on which such Non-Employee Director commences service on the Board. The Initial Option will vest and become exercisable over a 3 year period at $1/36^{th}$ per month from the grant date, subject to the Non-Employee Director's continued service through the applicable vesting date. For purposes hereof, *"Black Scholes" Value* means the fair value of an option determined using the Black-Scholes pricing model based on the Fair Market Value of the Company's Common Stock and the volatility, risk-free rate and life expectancy assumptions in the Company's financial statements disclosing those assumptions.

Annual Option Grant for Non-Employee Directors: Each Non-Employee Director who (i) has been serving on the Board for at least four months as of each annual meeting of the Company's stockholders after the Effective Date (each, an "*Annual Meeting*"), beginning with the 2022 Annual Meeting, and (ii) will continue to serve as a Non-Employee Director immediately following such Annual Meeting, shall be granted under the Plan an option to purchase shares of Common Stock (the "*Annual Option*") with a "Black Scholes" Value equivalent to $145,000. The Annual Option will be automatically granted on the date of the applicable Annual Meeting. The Annual Option shall vest and become exercisable over a 1 year period at the rate of 1/12th per month from the grant date, subject to the Non-Employee Director's continued service through the applicable vesting date.

IPO Option Grants: If individuals agree to become Non-Employee Directors and do not begin their director term until on the Effective Date, they would receive the Initial Option with an exercise price equal to the IPO offering price. Each Non-Employee Director serving before the Effective Date who continues after the Effective Date will receive an Annual Option on the Effective Date with an exercise price equal to the IPO offering price.

Unless otherwise provided by the Board, no portion of an Initial Option or Annual Option which is unvested or, as applicable, unexercisable at the time of a Non-Employee Director's termination of service with the Company (as determined by the Board) shall become vested and, as applicable, exercisable thereafter. Any Initial Option or Annual Option granted hereunder shall be subject to the Plan and the applicable standard form of award agreement thereunder, as modified to reflect the terms herein.

Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Option, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Annual Options as described above.

Change in Control: Upon a Change in Control, all outstanding equity awards granted under the Plan and any other equity incentive plan maintained by the Company that are held by a Non-Employee Director shall become fully vested and/or exercisable, irrespective of any other provisions of the Non-Employee Director's award agreement, subject to such Non-Employee Director's continued service as of immediately prior to such Change in Control.

Reimbursements: The Company shall reimburse each Non-Employee Director for all reasonable, documented, out-of-pocket travel and other business expenses incurred by such Non-Employee Director in the performance of his or her duties to the Company in accordance with the Company's applicable expense reimbursement policies and procedures as in effect from time to time.

Miscellaneous: The other provisions of the Plan shall apply to the equity awards granted automatically pursuant to this Program, except to the extent such other provisions are inconsistent with this Program. All applicable terms of the Plan apply to this Program as if fully set forth herein, and all grants of equity awards hereby are subject in all respects to the terms of the Plan. The grant of any equity award under this Program shall be made solely by and subject to the terms set forth in a written agreement in a form approved by the Board and duly executed by an executive officer of the Company.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 4, 2022, with respect to the financial statements included in the Annual Report of Treace Medical Concepts, Inc. on Form 10-K for the year ended December 31, 2021. We consent to the incorporation by reference of said report in the Registration Statement of Treace Medical Concepts, Inc. on Form S-8 (File No. 333-255541).

/s/ GRANT THORNTON LLP

Jacksonville, Florida

March 04, 2022

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John T. Treace, certify that:

(1) I have reviewed this Annual Report on Form 10-K of Treace Medical Concepts, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) [Reserved]

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 4, 2022

By: /s/ John T. Treace
John T. Treace
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark L. Hair, certify that:

(1) I have reviewed this Annual Report on Form 10-K of Treace Medical Concepts, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) [Reserved]

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 4, 2022

By: /s/ Mark L. Hair
Mark L. Hair
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Treace Medical Concepts, Inc. (the "Company") on Form 10-K for the year ending December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 4, 2022

By: /s/ John T. Treace
John T. Treace
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Treace Medical Concepts, Inc. (the "Company") on Form 10-K for the year ending December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 4, 2022

By: /s/ Mark L. Hair
Mark L. Hair
Chief Financial Officer
(Principal Financial and Accounting Officer)