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As filed with the U.S. Securities and Exchange Commission on March 30, 2021.

Registration No. 333-

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

FORM S-1
REGISTRATION STATEMENT
Under
The Securities Act of 1933

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

Delaware	**3841**	**47-1052611**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

203 Fort Wade Rd., Suite 150
Ponte Vedra, Florida 32081
(904) 373-5940
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

John T. Treace
Chief Executive Officer
203 Fort Wade Rd., Suite 150
Ponte Vedra, Florida 32081
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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. (Check one):

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Proposed maximum aggregate offering price(1)**	**Amount of registration fee(2)**
Common Stock, $0.001 par value per share	$100,000,000	$10,910

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended. Includes the aggregate offering price of additional shares that the underwriters have the option to purchase.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

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

Paragon 28, Inc. v. Treace Medical Concepts, Inc.
PGR2026-00022
Treace Ex. 2008

Explanatory Note:

We presently have Class A common stock authorized, issued and outstanding. We also have Class B common stock authorized, but with none issued and outstanding. We refer to both our Class A common stock and Class B common stock as our common stock in this prospectus, as well as for financial reporting purposes and in the financial tables included in this prospectus, as more fully explained in Note 10 to our financial statements included elsewhere in this prospectus. Before the launch of the roadshow for this offering, we will file an amended and restated certificate of incorporation to eliminate the Class B common stock so that following the filing of such amended and restated certificate of incorporation, our only authorized, issued and outstanding stock will be our Class A common stock and our Series A convertible preferred stock.

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

SUBJECT TO COMPLETION, DATED MARCH 30, 2021

Shares

Common Stock

This is an initial public offering of shares of common stock by Treace Medical Concepts, Inc. We are offering shares of our common stock to be sold in the offering. The selling stockholders identified in this prospectus are offering an additional shares of our common stock. We will not receive any proceeds from the sale of the shares by the selling stockholders. The initial public offering price is expected to be between $ and $ per share.

Prior to this offering, there has been no public market for our common stock. We have applied to list our common stock on the Nasdaq Global Market under the symbol "TMCI."

We are an "emerging growth company" and a "smaller reporting company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced requirements.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 16.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to Treace Medical Concepts, Inc., before expenses	$	$
Proceeds to the selling stockholders, before expenses	$	$

(1) See"Underwriting" for a description of the compensation payable to the underwriters.

We have granted the underwriters an option exercisable for 30 days after the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price less underwriting discounts and commissions.

The underwriters expect to deliver the shares to purchasers on or about , 2021.

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

J.P. Morgan **Morgan Stanley**

SVB Leerink **Stifel**

, 2021

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Through and including , 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

We and the selling stockholders have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We and the selling stockholders take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is accurate only as of the date.

For investors outside of the United States: we have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read the entire prospectus, including the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes thereto included elsewhere in this prospectus. As used in this prospectus, references to "we," "our," "us," "the company" and "TMC" refer to Treace Medical Concepts, Inc.

Overview

We are a commercial-stage orthopaedic medical device 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 novel 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.

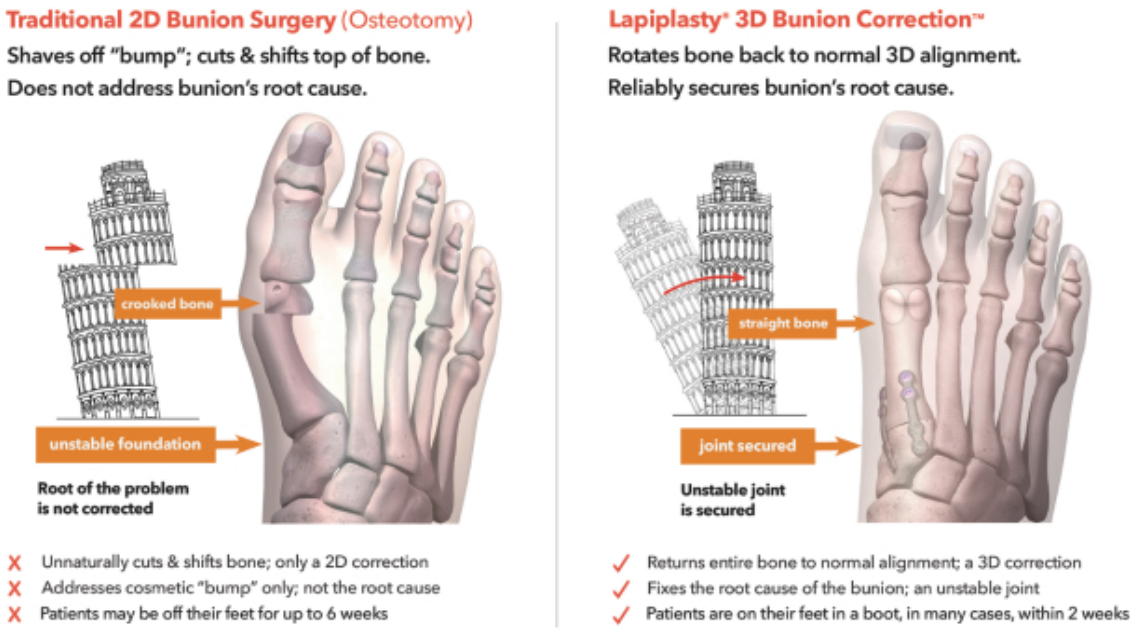
A bunion is a painful, disfiguring deformity characterized by a deviated position of the great toe, and easily identified visually by the "bump" at its base. Bunions affect approximately 65 million Americans, and generally increase in prevalence and severity over time. Nearly 25% of adults between the 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.

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 recent 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.*

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. 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 25,000 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 market and sell our products in the United States through a combination of a direct employee sales force and independent sales agents across 98 territories focused on driving adoption and supporting utilization of the Lapiplasty System among the approximately 7,400 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 our 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, 2020, surgeons who performed their first Lapiplasty Procedure in 2020, on average, performed 3.2 procedures during the year while surgeons who performed their first procedure in 2017 or earlier on average performed 17.7 Lapiplasty Procedures in 2020.

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 provides 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 Lapiplasty System is comprised of single-use implant kits (Lapiplasty Procedure Kit) and reusable instrument trays. The number of Lapiplasty Procedure Kits sold increased from 7,714 in 2019 to 11,113 in 2020, representing growth of 44%, despite the impact of the COVID-19 pandemic on limiting elective procedures in 2020. Since 2017, our revenue has increased from $7.9 million in 2017 to $17.7 million in 2018 to $39.4 million in 2019 to $57.4 million in 2020, representing growth of 46% from 2019 to 2020. Our net losses were $4.3 million and $3.7 million for the years ended December 31, 2019 and December 31, 2020, respectively. We also increased our market share during this period from 0.4% in 2017, 0.8% in 2018 and 1.7% in 2019, to 2.5% in 2020.

We believe the following strengths differentiate our company and will continue to be significant factors in our success and growth:

- paradigm-shifting 3D approach to the surgical treatment of bunions;
- large and underserved market with established reimbursement;
- comprehensive and differentiated clinical evidence;
- robust intellectual property portfolio;
- effective patient outreach and surgeon education programs; and
- highly experienced, proven management team and board of directors.

Our Growth Strategy

Our mission is to be the leader in the surgical treatment of bunions by establishing the Lapiplasty System as the standard of care. We seek to achieve this through the following growth strategies:

- expanding our sales channel to accelerate market penetration;
- driving awareness with innovative direct-to-patient education;
- building upon our base of clinical evidence to further differentiate the Lapiplasty System;
- increasing facility approvals to provide even greater surgeon access to our products; and
- developing our pipeline of next-generation innovations.

While we have no plans to expand operations outside the United States at the present time, significant opportunities for the Lapiplasty System outside the United States exist, subject, in part, to obtaining applicable regulatory approvals.

Our Market

Our Addressable Market Opportunity

Bunions are a common foot deformity that affect approximately 65 million Americans. Nearly 25% of adults between 18 to 65 years of age, and over 35% of people over the age of 65, have bunions. Given the aging demographics of the U.S. population, we expect the current 4.4 million bunion patients seeking medical attention annually in the United States to continue to grow over time. We estimate that approximately 1.1 million of these patients are deemed surgical candidates once their deformity has progressed to a point that it cannot be treated with non-surgical treatment options. Despite the significant limitations of current traditional surgical approaches, approximately 450,000 surgical bunion procedures are performed every year.

Based on the estimated 1.1 million surgical candidates for bunion surgery in the United States each year, we believe a total annual addressable market opportunity of more than $5 billion exists for our Lapiplasty System.

Overview of Bunions

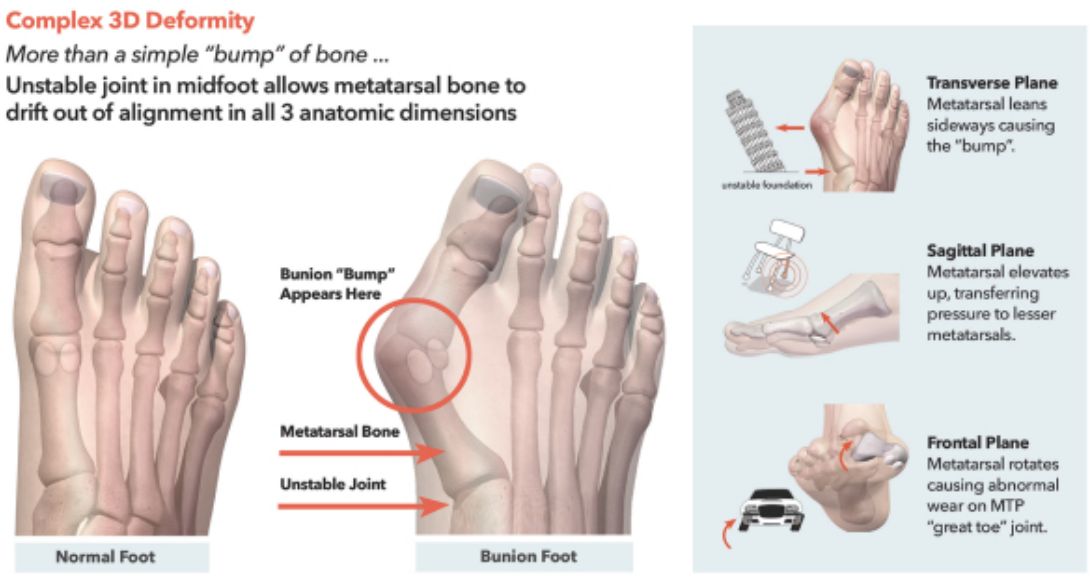
Hallux Valgus (commonly known as bunions) is a painful, disfiguring deformity characterized by a deviated position of the great toe. Bunions are easily identified visually by the "bump" on the joint at the base of the great toe (the metatarsophalangeal (MTP) joint). While this "bump" is widely considered 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.

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.



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. For additional information regarding these studies, see the section titled "Business—Limitations of Traditional Surgical Treatment Approaches." 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.

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 novel instruments, implants and surgical methods designed to improve the inconsistent clinical outcomes of traditional approaches to bunion surgery.

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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 novel 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:

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*

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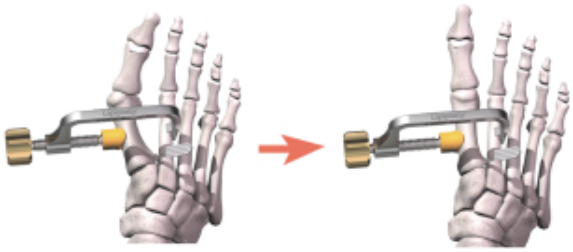
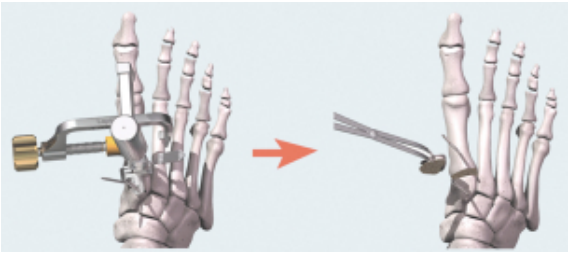
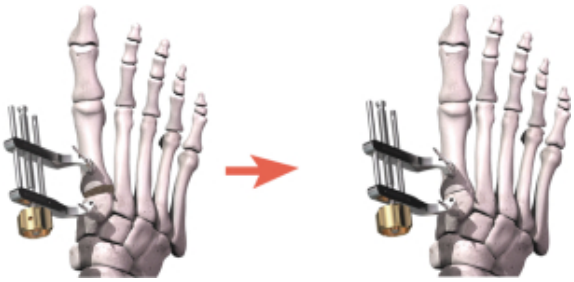
The following table illustrates our patented Lapiplasty System, with procedural instrumentation and implants used in each step of our proprietary Lapiplasty Procedure:

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 are fastened at ninety degree angles and the joint is secured and stabilized. This process is designed to allow for early return to weight-bearing in a post-operative boot while the bones fuse together.	

Expanding our Lapiplasty offerings, we recently 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. We believe the Lapiplasty Mini-Incision System offers an attractive option for patients and surgeons.

We have also commercialized products to address ancillary surgical procedures performed routinely within a Lapiplasty surgical case. 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.

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 has been cited in 15 peer-reviewed journal publications as of December 31, 2020.

Based on the outcomes from multiple studies 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 surgeon education and training programs are a key element of our commercial strategy, and we believe our 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.

Recent Developments

Preliminary Estimated Results for the Three Months ended March 31, 2021

We expect preliminary unaudited revenue for the three months ended March 31, 2021 will be approximately $ to $, as compared to $11.3 million for the same period in 2020, gross profit will be approximately $ to $, as compared to $8.9 million for the same period in 2020, net loss and comprehensive loss will be approximately $ to $, as compared to $1.6 million for the same period in 2020, the number of Lapiplasty Procedure Kits sold will be approximately to , as compared to 2,187 for the same period in 2020 and the number of active surgeons will be approximately to , as compared to 1,044 for the same period in 2020. We expect our preliminary unaudited cash and cash equivalents as of March 31, 2021 will be approximately $ to . We have provided a range for the preliminary and unaudited financial results and operating metrics described above primarily because our financial closing procedures for the three months ended March 31, 2021 are not yet complete. As a result, there is a possibility that our final results will vary from these preliminary estimates. We undertake no obligation to update or supplement the information provided above until we release our results of operations for the three months ended March 31, 2021, which will not occur until after this offering is completed. Accordingly,

you should not place undue reliance upon these preliminary financial results and operating metrics. For example, during the course of the preparation of the respective financial statements and related notes, additional items may be identified that would require material adjustments to be made to the preliminary estimated results presented above. There can be no assurance that these estimates will be realized and these estimates are subject to risks and uncertainties, many of which are not within our control. See the sections titled "Risk Factors" and "Special Notes Regarding Forward-Looking Statements." The preliminary estimates for the three months ended March 31, 2021 presented above have been prepared by, and are the responsibility of, management. Grant Thornton LLP, our independent registered public accounting firm, has not audited, reviewed, compiled, or performed any procedures with respect to such preliminary information. Accordingly, Grant Thornton LLP does not express an opinion or any other form of assurance with respect thereto.

Risks Related to Our Business

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors." These risks include, but are not limited to, the following:

- We have incurred losses in the past and may be unable to achieve or sustain profitability in the future.
- 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 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.
- 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 ability to grow sales.
- The ongoing global COVID-19 pandemic has adversely affected, and may continue to adversely affect, our business, financial condition and results of operations.
- 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, we may be unable to gain significant market share and be unable to operate our business profitably.
- If hospitals, ambulatory surgery centers and other health care facilities do not approve the use of our products, our sales may not increase.
- 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.
- 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.
- 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.
- If we were to lose one of our key suppliers, we may be unable to meet customer orders for our products in a timely manner or within our budget.
- We are subject to substantial government regulation that could have a material adverse effect on our business.

Our Corporate Information

We were originally formed as a medical device consulting business in July 2013, and began focusing on the foot and ankle market in January 2014. We converted from a Florida limited liability company to a Delaware corporation on July 1, 2014, changing our name to Treace Medical Concepts, Inc.

Our principal executive offices are located at 203 Fort Wade Rd., Suite 150, Ponte Vedra, Florida 32081, and our telephone number is (904) 373-5940. Our website address is www.treace.com. The information on, or that may be accessed through, our website is not incorporated by reference into this prospectus and should not be considered a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Trademarks

"Treace Medical Concepts®," the "Treace Medical Concepts®" logo, "Lapiplasty®," "Fast Grafter®," "Align My Toe™," "The Future of Hallux Valgus™," "Fix It Right The First Time™" and "Plantar Python®" are some of the trademarks or registered trademarks of our company. Our logo and our other tradenames, trademarks and service marks appearing in this prospectus are our property. Other tradenames, trademarks and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, our trademarks and tradenames referred to in this prospectus appear without the ™ or ® symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor, to these trademarks and tradenames.

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

We qualify as an "emerging growth company" (EGC), as defined in the Jumpstart Our Business Startups Act of 2012, as amended (JOBS Act). As an EGC, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus;
- exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002 (Sarbanes Oxley);
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements, including in this prospectus; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these exemptions until we are no longer an EGC. We will cease to be an EGC on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the completion of this offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) 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 Securities Exchange Act of 1934, as amended (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. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an EGC to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an EGC or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

As a result, the information in this prospectus and that we provide to our investors in the future may be different than what you might receive from other public reporting companies.

THE OFFERING

Common stock offered by us	shares.
Common stock offered by the selling stockholders	shares.
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of our common stock.
Common stock outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $ million, or approximately $ million if the underwriters exercise their option to purchase additional shares in full, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any net proceeds from the sale of shares of common stock by the selling stockholders in this offering. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to expand our sales force and operations, train additional physicians, develop new products, expand direct to patient education and outreach, conduct or sponsor clinical studies and trials, grow our marketing and patient outreach programs and the remainder, if any, to provide for working capital and other general corporate purposes. We may use a portion of the net proceeds to acquire complementary products, technologies, intellectual property or businesses; however, we currently do not have any agreements to complete any such transactions and are not involved in negotiations regarding such transactions. See the section titled “Use of Proceeds” for more information.
Directed share program	At our request, the underwriters have reserved up to % of the shares offered by this prospectus for sale at the initial public offering price to certain individuals through a directed share program, including our directors, officers and certain other individuals identified by our officers or management. The sales will be made at our direction by J.P. Morgan Securities LLC and its affiliates through a directed share program. The number of shares of our common stock available for sale to the general public in this offering will be reduced to the extent that such persons purchase such reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of our common stock offered by this prospectus. See the section titled “Underwriting” for additional information.
Risk factors	See the section titled “Risk Factors” and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Proposed Nasdaq Global Market symbol	“TMCI”

The number of shares of common stock that will be outstanding after this offering is based on shares of common stock outstanding as of December 31, 2020 (assuming the automatic conversion of all of our outstanding shares of our Series A convertible preferred stock as of December 31, 2020 and shares of common stock converted from the accrued and unpaid dividends on the Series A convertible preferred stock assuming a conversion date of , 2021 as agreed between us and the requisite holders of our Series A convertible preferred stock, into an aggregate of shares of our common stock prior to the completion of this offering), and excludes:

- 6,042,544 shares of our common stock issuable upon the exercise of options outstanding as of December 31, 2020, with a weighted-average exercise price of $2.43 per share;
- 382,500 shares of our common stock issuable upon the exercise of options granted subsequent to December 31, 2020, with a weighted-average exercise price of $9.40 per share;
- 533,332 shares of our common stock issuable upon the exercise of warrants outstanding as of December 31, 2020, with a weighted-average exercise price of $5.38 per share;
- shares of common stock reserved for future grants under our 2014 Stock Option Plan, which shares will be added to the shares to be reserved under our 2021 Incentive Award Plan (2021 Plan), which will become effective immediately before the effective date of this registration statement, and shares of common stock reserved for future grants under our 2021 Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan; and
- shares of our common stock reserved for issuance pursuant to future awards under our 2021 Employee Stock Purchase Plan (the ESPP), as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan, which will become effective immediately prior to the completion of this offering.

Unless otherwise indicated, this prospectus assumes or gives effect to the following:

- a -for- stock split of our capital stock, which was effected on , 2021;
- the automatic conversion of all shares of our outstanding Series A convertible preferred stock as of December 31, 2020 and shares of common stock converted from the accrued and unpaid dividends on the Series A convertible preferred stock, assuming a conversion date of , 2021 as agreed between us and the requisite holders of our Series A convertible preferred stock, into an aggregate of shares of our common stock immediately prior to the completion of this offering;
- the filing and effectiveness of our amended and restated certificate of incorporation in Delaware and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the completion of this offering;
- no exercise of outstanding stock options or warrants described above; and
- no exercise of the underwriters' option to purchase additional shares of our common stock from us.

SUMMARY FINANCIAL DATA

The following tables set forth a summary of our historical financial data as of and for the periods indicated. We have derived the summary statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2020 and the summary balance sheet data as of December 31, 2020 from our audited financial statements that are included elsewhere in this prospectus. You should read this data together with our financial statements and related notes thereto included elsewhere in this prospectus and the information in the sections titled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The summary financial data included in this section are not intended to replace the audited financial statements and related notes thereto included elsewhere in this prospectus and are qualified in their entirety by the audited financial statements and related notes thereto included elsewhere in this prospectus. Our historical results are not necessarily indicative of our future results.

	Year Ended December 31,	
	2019	2020
	(in thousands, except share and per share data)	
Statements of Operations and Comprehensive Loss Data:		
Revenue	$ 39,416	$ 57,365
Cost of goods sold	7,631	12,470
Gross profit	31,785	44,895
Operating expenses:		
Sales and marketing	25,786	31,654
Research and development	5,070	5,847
General and administrative	4,464	6,539
Total operating expenses	35,320	44,040
Income (loss) from operations	(3,535)	855
Interest and other income (expense), net	111	(1,746)
Interest expense	(841)	(2,777)
Interest and other expense, net	(730)	(4,523)
Net loss and comprehensive loss	(4,265)	(3,668)
Series A convertible preferred stock cumulative and undeclared dividends	(640)	(640)
Net loss attributable to common stockholders	$ (4,905)	$ (4,308)
Net loss per share attributable to common stockholders, basic and diluted(1)	$ (0.18)	$ (0.16)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted(1)	27,597,463	27,715,129
Pro forma net loss per share, basic and diluted (unaudited)(1)		
Weighted-average shares outstanding used in computing pro forma net loss per share, basic and diluted (unaudited)(1)		

(1) SeeNote 11 to our financial statements included elsewhere in this prospectus for further information on the calculations of net loss per share attributable to common stockholders.

	As of December 31, 2020		
	Actual	Pro Forma(1)	Pro Forma As Adjusted (2)(3)
		(in thousands) (unaudited)	
Balance Sheet Data:			
Cash and cash equivalents	$ 18,079	$	$
Working capital(4)	29,380		
Total assets	41,807		
Long-term liabilities	29,189		
Series A convertible preferred stock	7,935		
Additional paid-in capital	14,166		
Accumulated deficit	(21,353)		
Total stockholders' equity (deficit)	776		

(1) The pro forma balance sheet data gives effect to (i) the automatic conversion of all outstanding shares of our Series A convertible preferred stock into an aggregate of shares of our common stock, which includes the conversion of 5,000,000 shares of our Series A convertible preferred stock outstanding and shares of common stock converted from the accrued and unpaid dividends on the Series A convertible preferred stock, assuming a conversion date of , 2021, as agreed between us and the requisite holders of our Series A convertible preferred stock, and (ii) the filing and effectiveness of our amended and restated certificate of incorporation, in each case, immediately prior to the completion of this offering.

(2) The pro forma as adjusted column in the balance sheet data table above gives effect to (i) the pro forma adjustments described in footnote (1) above and (ii) the sale and issuance of shares of common stock by us in this offering, at the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) A $1.00 increase or decrease in the assumed initial public offering price of per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted amount of each of our cash and cash equivalents, additional paid-in capital and total stockholders' equity (deficit) by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase or decrease of 1.0 million shares in the number of shares of common stock offered would increase decrease, as applicable, each of our cash and cash equivalents, additional paid-in capital and total stockholders' equity (deficit) or total capitalization by $ million, assuming the initial public offering price remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price, the number of shares we sell and other terms of this offering that will be determined at pricing.

(4) We define working capital as current assets less current liabilities. See our financial statements and related notes thereto included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock 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 prospectus, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes thereto included elsewhere in this prospectus, before deciding whether to invest in shares of our common stock. 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 and future prospects. In that event, the market price of our common stock could decline, and you could lose all or part of your investment. Please also see the sections titled "Special Note Regarding Forward-Looking Statements" and "Market, Industry and Other Data."

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 2020, we incurred net losses of $3.7 million and as of December 31, 2020, we had an accumulated deficit of $21.4 million and $29.2 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 increase following this offering 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 System, 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 133 as of December 31, 2020. 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.

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.

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

Even if this offering is successful, 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 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 continue as a going concern or we may not be able to grow our business or respond to competitive pressures or unanticipated requirements, which could seriously harm our business.

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. 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.

We compete with large, diversified orthopaedic companies, including Stryker Corporation and its newly acquired Wright Medical Group, Inc. businesses, 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 agents, 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 plan to build 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.

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

We utilize a hybrid sales team with a mix of employee sales personnel and independent sales agents 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 agents, 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 agent 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.

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.

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

Market factors and disruptions in global markets may also affect our future operating results and cash flows. The COVID-19 pandemic has severely restricted the level of economic activity around the world. On January 30, 2020, the WHO declared the COVID-19 outbreak a Public Health Emergency of International Concern, and on March 13, 2020, the COVID-19 pandemic was declared a national emergency. Almost all U.S. states, including Florida where our headquarters is located, issued, and others in the future may issue, "shelter-in-place" orders, quarantines, executive orders and similar government orders, restrictions and recommendations to control the spread of COVID-19. As a result of those government restrictions, throughout 2020 and, in some cases, extending into 2021, temporary closures of businesses were ordered, numerous other businesses temporarily closed voluntarily and hospitals, ambulatory surgical centers and surgeons were ordered to delay elective surgeries in an attempt to free up medical resources to address the COVID-19 pandemic. While many elective surgery restrictions have been lifted, these and other restrictions may be reinstated in the future.

We have experienced disruptions to our revenue and may experience further business disruptions, including disruptions to our supply chain, independent sales agents, customers, study enrollment timelines and regulatory processes. Further, 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. The delayed or foregone bunion surgeries have had a significant impact on our operations and resulted in a rapid decrease in revenue and cash flows beginning in March 2020, as compared to prior periods and original expectations. Despite some recovery, this reduction in sales, as compared to original expectations, have continued. We expect the negative impacts to continue and may worsen in at least the short-term during the COVID-19 pandemic. While we cannot reasonably estimate the duration or severity of the COVID-19 pandemic, we expect that it will continue to have an adverse impact on our business, results of operations, financial position and liquidity for at least the remainder of 2021. 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, see the section titled "Management's Discussion and Analysis of Financial Conditions and Results of Operations—Factors Affecting Our Business—Impact of COVID-19 Pandemic."

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.

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 surgery market, 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.

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.

If the product liability claims brought against us involve uninsured liabilities or result in liabilities that exceed our insurance coverage, our business, financial condition and results of operations could be materially and adversely affected. Further, such product liability matters may negatively impact our ability to obtain insurance coverage or cost-effective insurance coverage in future periods.

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.
- 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 Affordable Care Act (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, see "—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 reimbursements for our products or reducing medical procedure volumes could have a material and adverse effect on our business, financial condition and results of operations.

In addition, the largest 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 consultants 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 consultants 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 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, 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, our reputation, business, financial condition and results of operations could be negatively impacted.

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

We believe that establishing and strengthening the Treace and Lapiplasty brands is important to achieving widespread acceptance of the Lapiplasty Procedure, 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 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 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 (see "Business — Product Development and our Surgeon Advisory Board"). We continue to place emphasis on the validation of the benefits of the Lapiplasty Procedure 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.

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 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 is a new procedure, 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 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.

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. 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.

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, we may be unable to gain significant market share and be unable to operate our business profitably.

We will rely on 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.

As of December 31, 2020, our patent portfolio included 21 owned U.S. patents, one licensed U.S. patent, 27 pending U.S. patent applications, three pending international PCT patent applications, and 20 corresponding non-U.S. 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. 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.

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 interests, 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.

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. 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.

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

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) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other health care professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives; 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 agents 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 products 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 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 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 intends 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 include plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. 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. Some of these proposals have not yet been finalized or adopted, and the FDA announced that it would seek public feedback before publication of any such proposals, and may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

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. For example, the new administration following the 2020 U.S. Presidential Election may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of executive orders, that could impose significant

burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities, such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. It is difficult to predict whether or how these executive actions will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of the incoming administration are unknown and could materially impact the regulations governing our product candidates. 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. Also, Medicare payments to providers are subject to a 2% reduction 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, such reductions have been temporarily suspended from May 1, 2020 through March 31, 2021.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA, and the U.S. Supreme Court is currently reviewing the constitutionality of the ACA, although it is unclear how the Supreme Court will rule. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs 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 the U.S. Supreme Court ruling, other such litigation, and the health care reform measures of the Biden administration will impact the ACA. There are additional state and federal health care reform measures under consideration that may be adopted in the future which could have a material adverse effect on our industry generally and on our customers. We cannot predict what health care programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation. However, any regulatory and legal changes that lower reimbursement for our products, increase taxes on our medical devices, increase cost containment pressures on us or others in the health care sector or reduce medical procedure volumes could adversely affect our business, financial condition, results of operations or cash flows.

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.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's ability to hire and

retain key personnel and accept the payment of user fees and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for medical devices or modifications to cleared medical devices to be reviewed by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on business.

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.

We cannot guarantee our ALIGN3D post-market clinical study, or any other clinical study we may conduct or sponsor in the future, will be successful, and such clinical trials could be lengthy and expensive to conduct. Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. 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.

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. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the California Privacy Rights Act (CPRA), recently passed in California. The CPRA 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. 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.

In Europe, the European Union General Data Protection Regulation (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, following the United Kingdom's withdrawal from the EEA and the European Union, and the expiry of the transition period, 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, for example around how data can lawfully be transferred between each jurisdiction, which may expose us to further compliance risk. If we do not comply with our obligations under the GDPR, we could be exposed to the fines discussed above. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations and financial condition.

Further, the Court of Justice of the European Union ruled in July 2020 that the Privacy Shield, used by thousands of companies to transfer data between the European Union and United States, was invalid and could

no longer be used. In September 2020, Switzerland concluded that the Swiss-U.S. Privacy Shield Framework does not provide an adequate level of protection for data transfers from Switzerland to the United States. Alternative transfer mechanisms may be used, including the standard contractual clauses (SCCs), while the authorities interpret the decisions and scope of the invalidated Privacy Shield, but the SCCs have also been called into question in the same ruling that invalidated Privacy Shield. At present, there are few if any viable alternatives to the SCCs, so future developments may necessitate further expenditures on local infrastructure, changes to internal business processes, or may otherwise affect or restrict sales and 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.

Risks Related to This Offering and Ownership of Our Common Stock

There may not be an active trading market for our common stock, which may cause shares of our common stock to trade at a discount from the initial public offering price and make it difficult to sell the shares of common stock you purchase.

Prior to this offering, there has been no public market for our common stock. It is possible that after this offering, an active trading market will not develop or, if developed, that any market will not be sustained, which would make it difficult for you to sell your shares of common stock at an attractive price or at all. The initial public offering price per share of common stock will be determined by agreement among us and the representatives of the underwriters, and may not be indicative of the price at which shares of our common stock will trade in the public market, if any, after this offering.

The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares in this offering.

The initial public offering price for our common stock was determined through negotiations with the underwriters. This initial public offering price may differ from the market price of our common stock after the offering. As a result, you may not be able to sell your common stock at or above the initial public offering price. Some of the factors that may cause the market price of our common stock to fluctuate include:

- 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;
- the success of existing or new competitive products or technologies;
- 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;
- actual or anticipated changes in estimates as to financial results;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- expiration of market standoff or lock-up agreements;

- 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 shortly following this 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 prospectus 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 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 will rely in part on the research and reports that industry or financial analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock could decrease. Even if we do obtain analyst coverage, 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.

A significant portion of our total outstanding shares is restricted from immediate resale but 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. These sales, upon the expiration of the market standoff and lock-up agreements, the early release of these agreements 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. After this offering and after giving effect to the automatic conversion of outstanding shares of our Series A convertible preferred stock into shares of our common stock immediately prior to the completion of this offering, we will have shares of our common stock outstanding based on shares of our common stock outstanding as of December 31, 2020. Of these shares, the shares we are selling in this offering may be resold in the public market immediately, unless purchased by our affiliates. The remaining shares, or % of our outstanding shares after this offering, are currently prohibited or otherwise restricted under securities laws, market standoff agreements entered into by our directors, officers and stockholders with us, or lock-up agreements entered into by our stockholders with the underwriters. However, subject to applicable securities law restrictions and excluding shares of restricted stock that will remain unvested, prohibitions and restrictions on the sale of these shares in the public market will be lifted beginning 180 days after the date of this prospectus. J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. Shares issued upon the exercise of stock options outstanding under our equity incentive plans, or pursuant to future awards granted under those plans, will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act of 1933, as amended (the Securities Act). See the section titled “Shares Eligible for Future Sale” for additional information.

Moreover, after this offering, holders of an aggregate of million shares of our common stock will have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also plan to register all shares of our common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described in the section titled “Underwriting.” 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 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 the value 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. 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.

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 investors in this offering 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.

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

After this offering, our directors, officers, holders of more than 5% of our outstanding stock and their respective affiliates will beneficially own shares representing approximately % of our outstanding common stock, assuming no exercise of the underwriters' option to purchase additional shares and without giving effect to any shares that certain of these holders may make through our directed share program or otherwise. 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.

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) the last day of the year following the fifth anniversary of the consummation of this offering, (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 this prospectus and our periodic reports and proxy statements.

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 amended and restated in connection with this offering, will 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. See "Description of Capital Stock."

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws to be effective immediately before to the completion of this offering and our indemnification agreements that we have entered into with our directors and officers will provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law

provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware will be 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 will 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 will 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 will 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 of this prospectus. Nothing in our amended and restated certificate of incorporation and amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

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 will be 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.

We have broad discretion to determine how to use the funds raised in this offering, and may use them in ways that may not enhance our operating results or the price of our common stock.

Our management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We currently expect to use the net proceeds of this offering, together with our existing cash and cash equivalents, to expand our sales force and operations, train additional physicians, develop new products, expand direct to patient education and outreach, conduct or sponsor clinical studies and trials, grow our marketing and patient outreach programs and provide for working capital and other general corporate purposes. However, our use of these proceeds may differ substantially from our current plans. If we do not invest or apply the proceeds of this offering in ways that improve our operating results, we may fail to achieve expected financial results, which could cause our stock price to decline.

New investors purchasing our common stock will experience immediate and substantial dilution.

Our initial public offering price is substantially higher than the book value per share of our common stock. If you purchase common stock in this offering, you will incur immediate dilution of $ in net tangible book value per share of common stock, based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus. In addition, the number of shares available for issuance under our stock option plans will increase annually without further stockholder approval. Investors will incur additional dilution upon the exercise of stock options and warrants. See "Dilution."

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 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 any international trade disputes, 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.

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 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.

The requirements of being a public company may divert our management's attention from our growth strategies and other business concerns.

As a public company, we will be subject to the reporting requirements of the Exchange Act and will be required to comply with the applicable requirements of the Sarbanes-Oxley Act and the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, the listing requirements of the Nasdaq Stock Market and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. Among other things, the Exchange Act requires that we file annual, quarterly and current reports with respect to our business and results of operations and maintain effective disclosure controls and procedures and internal controls over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal controls over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from executing our growth strategies and managing other business concerns and, which could have a material adverse effect on our business, financial condition and results of operations. Although we intend to hire additional employees to comply with these requirements, we may need to hire even more employees in the future, which will increase our costs and expenses. Additionally, as a public company, it will be more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

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 will 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 will devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and as a result of the new 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 will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

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.

After the closing of this offering, we will be 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.

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 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. 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.

We may be unable to obtain adequate insurance coverage.

We presently have general liability, workers’ compensation, directors’ and officers’ and product liability insurance coverage. Although we believe we will be able to maintain such coverage for a reasonable cost and obtain any additional coverages that our business may require, no assurances can be made that we will be able to do so.

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, 2020, 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.

SPECIAL NOTES REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements 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 this offering and our existing cash and cash equivalents;
- 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, most of whom 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 obtain, maintain and expand regulatory clearances for our products and any new products we create;
- 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 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;
- our ability to identify and develop new and planned products and/or acquire new products;
- the effect of the COVID-19 pandemic and the end of the COVID-19 pandemic 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 prospectus 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 prospectus. 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 prospectus. 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 prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

MARKET, INDUSTRY AND OTHER DATA

This prospectus contains estimates and information concerning our industry, including market size and growth rates of the markets in which we participate, that are based on industry publications and reports. We relied on industry, market data, peer-reviewed journals, formal presentations at medical society meetings and other sources, including market studies from IBM Watson and iData Research, Inc. We also rely on our own research and estimates in this prospectus. In some cases, we do not expressly refer to the sources from which this data is derived. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to these estimates. We have not independently verified the accuracy or completeness of the data contained in these industry publications and reports. We also rely on independent third-party sources for procedure data in the United States, as well as publicly available data.

Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information, including those described in the section titled “Risk Factors.” These and other factors could cause results to differ materially from those expressed in these publications and reports.

DIVIDEND POLICY

We have never declared or paid, and do not anticipate declaring or paying, any cash dividends on our common 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 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.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of shares of common stock that we are selling in this offering will be approximately $ million, or approximately $ million if the underwriters exercise their option to purchase additional shares in full, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We will not receive any proceeds from the sale of shares of common stock sold by the selling stockholders.

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

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our common stock and facilitate our future access to the public capital markets.

We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to expand our sales force and operations, train additional physicians, develop new products, expand direct to patient education and outreach, conduct or sponsor clinical studies and trials, grow our marketing and patient outreach programs and the remainder, if any, to provide for working capital and other general corporate purposes.

We may use a portion of the new net proceeds to acquire complementary products, technologies, intellectual property or businesses; however, we currently do not have any agreements to complete any such transactions and are not involved in negotiations regarding such transactions.

Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next months from the date of this offering. This expected use of the net proceeds from this offering represents our intentions based on our current plans and business conditions, which could change in the future as our plans and business conditions evolve.

Our management will have broad discretion over the use of the net proceeds from this offering, and our investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering. Due to the uncertainties inherent in the ongoing commercialization and development of the Lapiplasty System, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. The amounts we actually expend in these areas, and the timing thereof, may vary significantly from our current intentions and will depend upon a number of factors, including future sales growth, success of research and product development efforts, cash generated from future operations and actual expenses to operate our business.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in short-term, investment grade, interest bearing instruments, money market funds, certificates of deposit, commercial paper and U.S. government securities.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2020:

- an actual basis;
- a pro forma basis, giving effect to (i) the automatic conversion of all outstanding shares of our Series A convertible preferred stock into an aggregate of shares of our common stock, which includes the conversion of 5,000,000 shares of our Series A convertible preferred stock outstanding and shares of common stock converted from the accrued and unpaid dividends on the Series A convertible preferred stock, assuming a conversion date of , 2021, as agreed between us and the requisite holders of our Series A convertible preferred stock and (ii) the filing and effectiveness of our amended and restated certificate of incorporation, in each case, immediately prior to the completion of this offering; and
- a pro forma as adjusted basis, giving effect to (i) the pro forma adjustments described above and (ii) the sale and issuance of shares of common stock by us in this offering, at the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes thereto included elsewhere in this prospectus.

	As of December 31, 2020		
	Actual	Pro Forma	Pro Forma As Adjusted
	(unaudited) (in thousands, except share and per share data)		
Cash and cash equivalents	$18,079	$	$
Long-term debt	29,189		
Series A convertible preferred stock, $0.001 par value, 5,000,000 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	7,935		
Stockholders' equity (deficit):			
Preferred stock, $0.001 par value; no shares authorized, issued and outstanding, actual; shares authorized and no shares issued and outstanding pro forma and pro forma as adjusted	—		
Common stock, $0.001 par value; 50,000,000 shares authorized, shares issued and outstanding, actual; shares authorized, pro forma and pro forma as adjusted, shares issued and outstanding, pro forma and pro forma as adjusted	29		
Additional paid-in capital	14,166		
Accumulated deficit	(21,353)		
Total stockholders' equity (deficit)	776		
Total capitalization	$29,965	$	$

A $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted amount of each of our cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by $ million, assuming that the number of

shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase or decrease of 1.0 million shares in the number of shares of common stock offered would increase or decrease, as applicable, each of our cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by $ million, assuming the initial public offering price remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters' option to purchase additional shares from us is exercised in full, our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity (deficit), and total capitalization as of December 31, 2020, would be $ million, $ million, $ million, and $ million, respectively.

The number of shares of common stock issued and outstanding, pro forma and pro forma as adjusted in the table above is based on shares of common stock outstanding as of December 31, 2020 (assuming the automatic conversion of all of our outstanding shares of Series A convertible preferred stock as of December 31, 2020 and shares of common stock converted from the accrued and unpaid dividends on the Series A convertible preferred stock, assuming a conversion date of , 2021 as agreed between us and the requisite holders of our Series A convertible preferred stock, into an aggregate of shares of our common stock prior to the completion of this offering), and excludes:

- 6,042,544 shares of our common stock issuable upon the exercise of options outstanding as of December 31, 2020, with a weighted-average exercise price of $2.43 per share;
- 382,500 shares of our commons stock issuable upon the exercise of options granted subsequent to December 31, 2020, with a weighted-average exercise price of $9.40 per share;
- 533,332 shares of our common stock issuable upon the exercise of warrants outstanding as of December 31, 2020, with a weighted-average exercise price of $5.38 per share;
- shares of common stock reserved for future grants under our 2014 Stock Option Plan, which shares will be added to the shares to be reserved under our 2021 Plan, which will become effective immediately before the effective date of this registration statement and shares of common stock reserved for future grants under our 2021 Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan; and
- shares of our common stock reserved for issuance pursuant to future awards under our ESPP, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan, which will become effective immediately prior to the completion of this offering.

DILUTION

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

As of December 31, 2020, our historical net tangible book value (deficit) was $0.8 million, or $0.03 per share of common stock. Historical net tangible book value (deficit) per share represents our total tangible assets (total assets less deferred offering costs) less total liabilities, less Series A convertible preferred stock, divided by the number of our shares of common stock outstanding as of December 31, 2020.

As of December 31, 2020, our pro forma net tangible book value (deficit) was $ million, or $ per share of common stock. Pro forma net tangible book value before the issuance and sale of shares in this offering represents the amount of our total tangible assets (total assets less deferred offering costs) reduced by the amount of our total liabilities and divided by the total number of shares of our common stock outstanding as of December 31, 2020, assuming the automatic conversion of all of our outstanding shares of Series A convertible preferred stock into shares of our common stock immediately prior to the completion of this offering.

After giving further effect to the sale of shares of our common stock in this offering at the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, net of actual payments of offering expenses of $, our pro forma as adjusted net tangible book value as of December 31, 2020 would have been $ million, or $ per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to investors purchasing shares in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock.

The following table illustrates this dilution:

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of December 31, 2020	$0.03	
Pro forma increase in historical net tangible book value per share attributable to the pro forma transactions described above		
Pro forma net tangible book value per share as of December 31, 2020		
Increase in pro forma net tangible book value per share attributable to investors purchasing shares in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to investors in this offering		$

A $1.00 increase or decrease in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the total consideration paid by investors purchasing shares in this offering by $ million, or approximately $ per share, and would decrease or increase, as applicable, dilution to investors in this offering by approximately $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase or decrease of 1.0 million shares in the number of shares of common stock offered would increase or decrease, as applicable, the total

consideration paid by investors purchasing shares in this offering by $ million, or approximately $ per share, and would decrease or increase, as applicable, dilution to investors in this offering by approximately $ per share, assuming the initial public offering price remains the same, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

An increase of 1.0 million in the number of shares of common stock offered would increase our pro forma as adjusted net tangible book value by $ per share and the dilution per share to new investors in this offering by $ per share, assuming the initial public offering price remains the same, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a decrease of 1.0 million in the number of shares of common stock offered would decrease our pro forma as adjusted net tangible book value by $ per share and the dilution per share to new investors in this offering by $ per share, assuming the initial public offering price remains the same, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' option to purchase additional shares of common stock from the selling stockholders. If the underwriters exercise their option to purchase additional shares in full, our existing stockholders would own % and our new investors would own % of the total number of shares of common stock outstanding upon the completion of this offering.

Sales by the selling stockholders in this offering will cause the number of shares held by existing stockholders to be reduced to shares, or % of the total number of shares of our common stock outstanding following the completion of this offering, and will increase the number of shares held by new investors to shares, or % of the total number of shares outstanding following the completion of this offering.

The dilution information discussed above is illustrative only and may change based on the actual initial public offering price and other terms of this offering.

The following table summarizes, as of December 31, 2020, on a pro forma as adjusted basis as described above, the difference between existing stockholders and new investors with respect to the number of shares of common stock purchased from us, the total consideration paid to us, and the average price per share paid, before deducting estimated underwriting discounts and commissions and estimated offering expenses:

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders(1)		%	$	%	$
New investors					$
Total		100.0%	$	100.0%	

(1) The presentation in this table regarding ownership by existing stockholders does not give effect to any purchases that existing stockholders may make through our directed share program or otherwise purchase in this offering.

The foregoing tables and calculations (other than the historical net tangible book value calculation) are based on shares of common stock outstanding, (assuming the automatic conversion of all of our outstanding shares of Series A convertible preferred stock as of December 31, 2020 and shares of common stock converted from the accrued and unpaid dividends on the Series A convertible preferred stock assuming a conversion date of , 2021 as agreed between us and the requisite holders of our Series A convertible preferred stock, into an aggregate of shares of our common stock prior to the completion of this offering), and excludes:

- 6,042,544 shares of our common stock issuable upon the exercise of options outstanding as of December 31, 2020, with a weighted-average exercise price of $2.43 per share;

- 382,500 shares of our common stock issuable upon the exercise of options granted subsequent to December 31, 2020, with a weighted-average exercise price of $9.40 per share;
- 533,332 shares of common stock issuable upon the exercise of warrants outstanding as of December 31, 2020, with a weighted-average exercise price of $5.38 per share;
- shares of common stock reserved for future grants under our 2014 Stock Option Plan, which shares will be added to the shares to be reserved under our 2021 Plan, which will become effective immediately before the effective date of this registration statement and shares of common stock reserved for future grants under our 2021 Plan, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan; and
- shares of our common stock reserved for issuance pursuant to future awards under our ESPP, as well as any automatic increases in the number of shares of our common stock reserved for future issuance under this plan, which will become effective immediately prior to the completion of this offering

To the extent that any outstanding options or warrants to purchase shares of our common stock with an exercise price per share that is less than the as adjusted net tangible book value per share, before giving effect to the issuance and sale of shares in this offering, are exercised or new awards are granted under our equity compensation plans, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED FINANCIAL DATA

The following tables set forth our selected financial data for the periods and as of the dates indicated. We have derived the selected statements of operations and comprehensive loss data for the years ended December 31, 2019 and December 31, 2020 and the selected balance sheet data as of December 31, 2019 and December 31, 2020 from our audited financial statements included elsewhere in this prospectus. You should read this data together with our financial statements and related notes thereto included elsewhere in this prospectus and the information in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The selected financial data included in this section are not intended to replace the audited financial statements and related notes thereto included elsewhere in this prospectus and are qualified in their entirety by the audited financial statements and related notes thereto included elsewhere in this prospectus. Our historical results are not necessarily indicative of our future results.

	Year Ended December 31,	
	2019	2020
Statements of Operations and Comprehensive Loss Data:	(in thousands, except share and per share data)	
Revenue	$ 39,416	$ 57,365
Cost of goods sold	7,631	12,470
Gross profit	31,785	44,895
Operating expenses:		
Sales and marketing	25,786	31,654
Research and development	5,070	5,847
General and administrative	4,464	6,539
Total operating expenses	35,320	44,040
Income (loss) from operations	(3,535)	855
Interest and other income (expense), net	111	(1,746)
Interest expense	(841)	(2,777)
Interest and other expense, net	(730)	(4,523)
Net loss and comprehensive loss	(4,265)	(3,668)
Series A convertible preferred stock cumulative and undeclared dividends	(640)	(640)
Net loss attributable to common stockholders	$ (4,905)	$ (4,308)
Net loss per share attributable to common stockholders, basic and diluted (1)	$ (0.18)	$ (0.16)
Weighted-average common shares used in computing net loss per share attributable to common stockholders, basic and diluted(1)	27,597,463	27,715,129

(1) See Note 11 to our financial statements included elsewhere in this process for further information on the calculation of net loss per share attributable to common stockholders.

	As of December 31,	
	2019	2020
Balance Sheet Data:	(in thousands)	
Cash and cash equivalents	$ 12,139	$ 18,079
Working capital(1)	21,238	29,380
Total assets	29,716	41,807
Long-term liabilities	19,233	29,189
Series A convertible preferred stock	7,935	7,935
Additional paid-in capital	12,884	14,166
Accumulated deficit	(17,686)	(21,353)
Total stockholders' equity (deficit)	29,716	41,807

(1) We define working capital as current assets less current liabilities. See our financial statements and related notes thereto included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the section titled "Selected Financial Data" and our financial statements and related notes thereto included elsewhere in this prospectus. This discussion and other parts of this prospectus 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 commercial-stage orthopaedic medical device 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 novel 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 were formed in 2013 and since receiving 510(k) clearance for the Lapiplasty System in March 2015, we have sold more than 25,000 Lapiplasty Procedure Kits in the United States. We market and sell our Lapiplasty System 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 agents across 98 territories in the United States. As of December 31, 2020, we had 34 direct sales representatives, eight regional sales vice presidents who are responsible for managing the sales representatives and 59 independent sales agents. In 2020, employee sales representatives generated approximately 35% of revenues while approximately 65% of revenues came through independent sales agents.

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.

We have experienced considerable growth since we began commercializing our products in the United States in late 2015. The number of Lapiplasty Procedure Kits sold increased from 7,714 for 2019 to 11,113 for 2020, representing growth of 44%, despite the impact of COVID-19 on limiting the performance of elective

procedures in 2020. Correspondingly, our revenue increased from $39.4 million for 2019 to $57.4 million for 2020, representing growth of 46% and our net losses were $4.3 million and $3.7 million for 2019 and 2020, respectively.

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 of December 31, 2020, we had cash and cash equivalents of $18.1 million, an accumulated deficit of $21.4 million, $30.0 million of principal outstanding under our term loan agreement and $1.8 million in borrowings outstanding from the Paycheck Protection Program (PPP) loan program under the Coronavirus Aid Relief and Economic Recovery Act (CARES Act), which was repaid in March 2021. 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 the next 12 months. Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next months from the date of this offering.

We expect our expenses will increase for the foreseeable future, in particular as we to continue to make substantial investments in sales and marketing, and product development. Moreover, we expect to incur additional expenses as a result of 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. As a result of these and other factors, we may require or otherwise decide to incur additional financing to fund our operations and planned growth. 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.

Key Business Metric

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 plan and make strategic decisions.

The following table lists the number of Lapiplasty Procedure Kits sold, number of active surgeons and utilization rate in each of the three-month periods as indicated:

	Three Months Ended							
	Mar. 31, 2019	June 30, 2019	Sept. 30, 2019	Dec. 31, 2019	Mar. 31, 2020	June 30, 2020	Sept. 30, 2020	Dec. 31, 2020
Number of Lapiplasty Procedure Kits sold	1,177	1,521	1,721	3,295	2,187	1,535	2,782	4,609
Active surgeons(1)	635	757	848	997	1,044	1,057	1,133	1,275
Utilization rate(2)	6.5	6.6	7.0	7.7	7.9	8.3	8.6	8.7

(1) We define the number of active surgeons as the number of surgeons that performed at least one procedure using the Lapiplasty System in the trailing twelve-month period.
(2) We define utilization rate as the number of Lapiplasty Procedure Kits sold divided by the number of active surgeons.

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 those described below 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 1,000 facilities across the United States and plan to continue to increase access by convincing even more surgeons and facility administrators that our products are superior 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. If we are unable to raise adequate additional capital, we will be unable to maintain our commercialization efforts and our revenues could decline.

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 also 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 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. Moreover, in general and administrative, 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 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.

Impact of COVID-19 Pandemic

In March 2020, the World Health Organization declared the outbreak of a novel coronavirus (COVID-19) as a pandemic, which continues to spread throughout the United States. 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. As a result, our revenue growth was adversely impacted from March 2020 through May 2020 when such restrictions were largely eased.

There is significant 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. We cannot reasonably estimate the length or severity of this pandemic, and while we experienced revenue growth during the pandemic, we have reduced our revenue growth forecasts to reflect a lower number of surgical procedures.

As a result, we shifted our priorities to: (i) reducing discretionary spending, (ii) maintaining the existing employee base and (iii) preserving liquidity. We have taken the following actions:

- Implemented a remote working environment, except for a limited staff on-site for critical business continuity functions, from March 2020 to September 2020.
- Reduced or delayed patient and surgeon medical education events, which we expect to continue while quarantine and shelter-in-place restrictions continue.
- Reduced salaries for existing employees for a savings of $256,000 in 2020 and implemented a hiring freeze from March 2020 to June 2020. The aggregate amount from the temporary salary reductions was repaid to employees in February 2021.
- Received $1.8 million in Small Business Administration (SBA) loans under the PPP (Payroll Protection Plan) portion of the CARES Act, which was repaid in March 2021.
- Amended the Loan and Security Agreement with Silicon Valley Bank to increase our line of credit from $5.0 million to $10.0 million and entered into the Term Loan Facility Agreement with CR Group LP (CRG), which provides us with up to $50.0 million in financing.

While we are confident in our actions to address the negative impact of COVID-19 on the business to date, there can be no assurances that these actions will be sufficient to support our business growth during the pandemic or that the pandemic will not again more negatively impact our business.

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 (OPPS), 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 all of our revenue from the sale of our proprietary Lapiplasty System, and to a lesser extent ancillary products. The Lapiplasty System is comprised of single-use implant kits and reusable instrument trays. We sell the Lapiplasty System to physicians, surgeons, hospitals and ambulatory surgery centers in the United States through a network of independent agents 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 Procedure or other ancillary procedures performed in high frequency with bunion surgery. No single customer accounted for 10% or more of our revenue during the year ended December 31, 2020. 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 costs related to third-party manufacturing costs for the purchase of our Lapiplasty System 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, rent and information technology, certain direct costs such as those incurred for shipping our products and personnel costs. We expense all inventory 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 stock-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, patent costs, 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. Additionally, R&D expenses include costs associated with our clinical studies, including clinical trial design, clinical trial site initiation and study costs, data management, related travel expenses and the cost of products used for clinical trials, internal and external costs associated with our regulatory compliance and quality assurance functions and allocated overhead costs. 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 stock-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 our expand infrastructure to both drive and support the anticipated growth in our organization and due to additional 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 associated with operating as a public company, though it may fluctuate from quarter to quarter.

Interest Income

Interest income consists of interest received on our money market funds.

Interest Expense

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

Results of Operations

For the Years Ended December 31, 2019 and 2020

The following table summarizes our results of operations for the period presented below:

	Year Ended December 31,		Change	
	2019	2020	Amount	%
	(in thousands)			
Revenue	$ 39,416	$ 57,365	$17,949	46%
Cost of goods sold	7,631	12,470	4,839	63%
Gross profit	31,785	44,895	13,110	41%
Operating expenses				
Sales and marketing	25,786	31,654	5,868	23%
Research and development	5,070	5,847	777	15%
General and administrative	4,464	6,539	2,075	46%
Total operating expenses	35,320	44,040	8,720	25%
Net (loss) income from operations	(3,535)	855	4,390	124%
Interest and other income (expense), net	111	(1,746)	(1,857)	*
Interest expense	(841)	(2,777)	(1,936)	(230)%
Other expense, net	(730)	(4,523)	(3,794)	*
Net loss and comprehensive loss	(4,265)	(3,668)	(597)	14%

* Not meaningful

Revenue. Revenue increased $18.0 million, or 45.5%, from $39.4 million in 2019 to $57.4 million in 2020. The increase in revenue was primarily due to an increased number of Lapiplasty Procedure Kits sold and an expanded customer base.

Cost of Goods Sold Gross Profit and Gross Margin. Cost of goods sold increased $4.8 million, or 63.4%, from $7.6 million in 2019 to $12.5 million in 2020. The increase in cost of goods sold was primarily due to an increase of $2.0 million in direct costs of goods sold due to our increased sales, an increase of $1.2 million in the provision for inventory obsolescence, an increase of $0.7 million in royalty expense and an increase of $0.7 million in costs of surgical instruments used during procedures, and $0.1 million impairment of capitalized surgical instruments that no longer have a useful life. Gross margin decreased from 80.6% in 2019 to 78.3% for 2020 primarily due to the increased charges for inventory obsolescence and costs of surgical instruments used during procedures, and the impairment of capitalized surgical instruments, offset by reduction in direct costs per unit and sterilization costs.

Sales and Marketing Expenses. Sales and marketing expenses increased $5.9 million, or 22.8% from $25.8 million in 2019 to $31.7 million in 2020. The increase in sales and marketing expenses was primarily due to an increase of $4.7 million in professional services primarily for higher commissions from increased sales, an increase of $1.4 million in marketing expenses and an increase of $0.8 million in payroll expenses, which were partially offset by a decrease of $0.7 million in travel and entertainment expenses.

Research and Development Expenses. Research and development expenses increased $0.8 million, or 15.3%, from $5.1 million in 2019 to $5.8 million in 2020. The increase in research and development expenses was due to an increase of $0.5 million in salaries and wages as we increased headcount to continue scaling up our business and an increase of $0.3 million in clinical study expenses.

General and Administrative Expenses. General and administrative expenses increased $2.1 million, or 46.5%, from $4.5 million in 2019 to $6.5 million in 2020. The increase in general and administrative expenses was primarily due to an increase of $0.7 million in professional services primarily related to legal and audit

expenses, an increase of $0.4 million in salaries as we increased headcount in our business, an increase of $0.4 million in general business expenses such as insurance, taxes and fees and an increase of $0.3 million in facilities expense due to the expansion of our office building.

Interest and Other Income (Expense), Net. Interest and other income (expense), net increased $(1.9) million from $0.1 in 2019 to $(1.7) million in 2020. The year-over-year increase in other expense is primarily related to retirement of long-term debt and the resulting expense of $1.7 million of unamortized debt discount attributable to the retired debt.

Interest Expense. Interest expense increased $1.9 million from $0.8 million in 2019 to $2.8 million in 2020. The year-over-year increase in interest expense was primarily due to an increase of $1.9 million in interest incurred on our term loans and credit facility.

Selected Quarterly Results of Operations

The following table sets forth our unaudited statements of operations and comprehensive loss data for each of the quarters presented. We have prepared the unaudited quarterly information on a basis consistent with our audited financial statements included elsewhere in this prospectus and include, in our opinion, all normal recurring adjustments necessary for the fair statement of the results of operations for the periods presented. The following quarterly financial information should be read in conjunction with our financial statements and related notes included elsewhere in this prospectus. Our historical quarterly results are not necessarily indicative of the results that may be expected in the future.

	Three Months Ended							
	Mar. 31, 2019	June 30, 2019	Sept. 30, 2019	Dec. 31, 2019	Mar. 31, 2020	June 30, 2020	Sept. 30, 2020	Dec. 31, 2020
	(unaudited) (in thousands)							
Revenue	$ 5,900	$ 7,886	$ 8,886	$16,744	$11,256	$ 7,739	$14,266	$24,104
Cost of goods sold	1,086	1,484	1,777	3,284	2,389	2,085	2,911	5,085
Gross profit	4,814	6,402	7,109	13,460	8,867	5,654	11,355	19,019
Operating expenses:								
Sales and marketing	4,608	5,812	6,921	8,445	7,338	4,789	8,103	11,424
Research and development	1,076	999	1,475	1,520	1,433	981	1,511	1,922
General and administrative	949	985	1,195	1,335	1,295	1,401	1,804	2,039
Total operating expenses	6,633	7,796	9,591	11,300	10,066	7,171	11,418	15,385
Net (loss) income from operations	(1,819)	(1,394)	(2,482)	2,160	(1,199)	(1,517)	(63)	3,634
Interest and other income (expense), net	31	46	27	7	33	3	(1,784)	1
Interest expense	(106)	(213)	(240)	(282)	(441)	(458)	(808)	(1,070)
Interest and other expense, net	(75)	(167)	(213)	(275)	(408)	(455)	(2,592)	(1,069)
Net (loss) income and comprehensive (loss) income	(1,894)	(1,561)	(2,695)	1,885	(1,607)	(1,972)	(2,655)	2,565
Convertible preferred stock cumulative and undeclared dividends	(158)	(160)	(161)	(161)	(158)	(160)	(161)	(161)
Net (loss) income attributable to common stockholders	$(2,052)	$(1,721)	$(2,856)	$ 1,724	$ (1,765)	$(2,132)	$ (2,816)	$ 2,404

	Three Months Ended							
	Mar. 31, 2019	June 30, 2019	Sept. 30, 2019	Dec. 31, 2019	Mar. 31, 2020	June 30, 2020	Sept. 30, 2020	Dec. 31, 2020
Revenue	100%	100%	100%	100%	100%	100%	100%	100%
Cost of goods sold	18%	19%	20%	20%	21%	27%	20%	21%
Gross profit:	82%	81%	80%	80%	79%	73%	80%	79%
Operating expenses:								
Sales and marketing	78%	74%	78%	50%	65%	62%	57%	47%
Research and development	18%	13%	17%	9%	13%	13%	11%	8%
General and administrative	16%	12%	13%	8%	12%	18%	13%	8%
Total operating expenses	112%	99%	108%	67%	89%	93%	80%	64%
Net income (loss) from operations	(31%)	(18%)	(28%)	13%	(11%)	(20%)	0%	15%
Interest and other income (expense), net	1%	1%	0%	0%	0%	0%	(13%)	0%
Interest expense	(2%)	(3%)	(3%)	(2%)	(4%)	(6%)	(6%)	(4%)
Interest and other expense, net	(1%)	(2%)	(2%)	(2%)	(4%)	(6%)	(18%)	(4%)
Net (loss) income and comprehensive (loss) income	(32%)	(20%)	(30%)	11%	(14%)	(25%)	(19%)	11%
Convertible preferred stock cumulative and undeclared dividends	(3%)	(2%)	(2%)	(1%)	(1%)	(2%)	(1%)	(1%)
Net (loss) income attributable to common stockholders	(35%)	(22%)	(32%)	10%	(16%)	(28%)	(20%)	10%

Quarterly Revenue Trends

Revenue increased sequentially in each of the periods presented, primarily due to an increase in the number of Lapiplasty Procedure Kits sold. The increase in the Lapiplasty Procedure Kits sold was primarily driven by increased utilization of our existing surgeon base as well as adding new surgeon customers, due in part to our increased sales and marketing investments. We experience seasonality in our business, with our sales volumes in the fourth calendar quarter tending 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.

Quarterly Cost of Goods Sold and Gross Margins Trends

Cost of goods sold increased sequentially in each of the periods presented, primarily due to an increase in the number of Lapiplasty Procedure Kits sold. Our gross margins remained relatively stable during the periods presented due to higher percentage of our cost of goods sold being direct costs that vary with product sales compared to indirect costs.

Quarterly Operating Expenses Trends

Our sales and marketing, research and development, and general and administration expenses each increased sequentially in each of the periods presented, primarily due to increases in our personnel costs as we increased our headcount and commissions paid to our external sales agents and internal direct sales organization based on increased sales. In contrast, our R&D and general and administrative expenses remained relatively stable between the periods presented.

Liquidity and Capital Resources

To date, 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 of December 31, 2020, we had cash and cash equivalents of $18.1 million, an accumulated deficit of $21.4 million and $30.0 million of principal outstanding under our term loan agreement and $1.8 million in borrowings outstanding from the PPP Loan, which we repaid in March 2021. During 2020, we entered into the new term loan agreement with CRG to obtain up to $50.0 million in financing over three tranches. We borrowed $30.0 million under the new facility with CRG and repaid prior existing outstanding debt under our credit facility with SVB. We also amended our existing credit facility with SVB to increase the revolving line of credit from $5.0 million to $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 the next 12 months. We may be required or decide to raise additional financing, including the completing of this offering, to support further growth of our operations.

Short-Term and Long-Term Obligations

Silicon Valley Bank Loan

On December 31, 2019, we entered into the Second Amendment (Second Amendment) to the Loan and Security Agreement (LSA) with SVB. The Second Amendment represents a modification to the First Amendment to the LSA dated February 14, 2019 (the First Amendment), and the LSA, dated April 18, 2018. The Second Amendment provides for up to $25.0 million in term loans structured in three tranches and $5.0 million in revolving line of credit. On August 3, 2020, we entered into the Third Amendment to the LSA (the Third Amendment), with SVB which terminated the third tranche term loan and increased the revolving line of credit by $5.0 million. The LSA, First Amendment, Second Amendment, and Third Amendment, (collectively, the SVB Credit Facility), is secured by substantially all of our assets (excluding intellectual property) and 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, 2019, we had $20.0 million in borrowings outstanding related to the first and second tranche term loans and no borrowings outstanding related to our revolving line of credit. Subsequent to entering into the CRG Term Loan Facility agreement with CRG, we repaid all term loans outstanding under the SVB Credit Facility. As of December 31, 2020, we had $10.0 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, 2020, 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 amounts totaling $30 million were borrowed through December 31, 2020 and are currently outstanding.

The CRG Term Loan Facility matures on June 30, 2025, and we can elect to make quarterly interest- only payments, to pay interest in-kind through December 31, 2020 or, after December 31, 2020, 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, 2020, we were in compliance with all covenants under the CRG Term Loan Facility.

PPP Loan

We applied for and received a $1.8 million loan pursuant to the PPP Loan. The PPP Loan, which was in the form of a promissory note, dated April 22, 2020, between us and SVB as the lender, matures on April 22, 2022 and bears interest at a fixed rate of 1% per annum, payable monthly on the date that is the latter of (i) the date that is the 10th month after the end of the PPP Loan covered period and (ii) assuming we have applied for forgiveness within the period described in clause (i), the date on which SBA remits the loan forgiveness amount on the loan to SVB (or notifies such lender that no loan forgiveness is allowed). Under the terms of the PPP Loan, the principal may be forgiven if the loan proceeds are used for qualifying expenses as described in the CARES Act, such as payroll costs, benefits, mortgage interest, rent, and utilities. We repaid the $1.8 million borrowed under the PPP Loan in March 2021.

Funding Requirements

We use our cash to fund our operations, which primarily include the costs of manufacturing our Lapiplasty System 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. 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 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;
- 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;
- the emergence of 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 on our operations and business.

Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next months from the date of this offering. We have based this estimate on assumptions that may prove to be wrong, 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 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 period presented below:

	Years Ended December 31,		Change	
	2019	2020	Amount	%
	(in thousands, other than percent change)			
Net cash (used in) provided by:				
Operating activities	$ (7,673)	$ (4,494)	$ 3,179	41%
Investing activities	(1,211)	(1,069)	142	12%
Financing activities	19,739	11,503	(8,236)	(42%)
Net increase in cash and cash equivalents	$10,855	$ 5,940	$(4,915)	(45%)

Net Cash Used in Operating Activities

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 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 Investing Activities

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

Net Cash Provided by Financing Activities

Net cash provided by financing activities in 2019 of $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.

Net cash provided by financing activities in 2020 of $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.

Surgeon Advisory Board Royalty Agreements

Due to their historic involvement in some of our early product development, we entered into royalty agreements with certain members of our Surgeon Advisory Board (the SAB Royalty Agreements). The SAB Royalty Agreements provide for royalties based on each individual's level of contribution. We paid aggregate royalties of $1.7 million and $2.4 million for the years ended December 31, 2019 and 2020, respectively, resulting in an aggregate royalty rate of 4.3% and 4.1% for the years ended December 31, 2019 and 2020, 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. For additional information, see the section titled "Business—Royalty and License Agreements."

Off-Balance Sheet Arrangements

We did not have during the period presented, and we currently have no off-balance sheet arrangements, such as structured finance, special purpose entities, or variable interest entities.

Contractual Obligations and Commitments

Our principal obligations consist of the operating lease for our facility, our SVB Credit Facility and CRG Term Loan agreement. The following table sets out, as of December 31, 2020, our contractual obligations and commitments due by period:

	Payments Due By Period				
	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years	Total
	(in thousands)				
Operating lease obligations	$ 518	$ 744	$ 286	$ —	$ 1,548
Debt, including interest(1)	5,706	7,800	35,850	—	49,356
Total	$ 6,224	$8,544	$36,136	$ —	$50,904

(1) Amount reflects total anticipated cash payments, including anticipated interest payments based on the interest rate for the CRG Term Loan Facility as of December 31, 2020.

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 prospectus, 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.

Revenue Recognition

We generate revenue through the sale of our primary product, our proprietary Lapiplasty System. The Lapiplasty System is comprised of single-use implant kits and reusable instrument trays and is sold in the United States through a network of independent agents and employee sales representatives. We invoice hospitals and ambulatory surgery centers for the implant kits and pay commissions to the sales representatives and agents. Our invoices are generally payable within 30 days. We do not have any international sales.

For shipments to customers, we offer the right to return the product within thirty days for a full refund and for returns between thirty and ninety days, we offer a full refund less 15% restocking fee. We do not have a history of product returns for refund. Customer invoices are generally payable within 30 days. Our 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. Our liability is limited to providing, at our 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, we have had a negligible number of warranty claims or returns of any products alleged to be defective.

On January 1, 2019, we adopted Accounting Standards Codification (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, we 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 we perform 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) we enter 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) we determine that collection of substantially all consideration for our products that are transferred is probable based on the customer's intent and ability to pay the promised consideration. We consider signed agreements and purchase orders as a customer's contract.

We identify performance obligations based on the terms of the contract and customary business practices, which include products that are distinct. The delivery of our Lapiplasty System products is a distinct performance obligation. We do not have any contracts with customers that contain multiple performance obligations.

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

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. We consign products with our independent sales agents but do 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

We recognize the incremental costs of obtaining a contract as expense when incurred because the amortization period would be one year or less. These incremental costs include sales commissions payable to our independent sales agents or internal sales representatives.

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. We review inventory for obsolescence and write down our inventory, as necessary.

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 option holder is required to provide services in exchange for the option award, known as the requisite service period, which is typically the vesting period using the straight-line method. We accrue for estimated forfeitures on share-based awards and, adjust stock-based compensation cost to actual as forfeitures occur. The estimated forfeitures are based on a historical analysis of actual forfeitures of awards.

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. Our assumptions are as follows:

- *Fair Value of Common Stock.* The absence of an active market for our common stock requires us to estimate the fair value of our common stock. See the subsection titled "Fair Value of Common Stock" below.
- *Expected Term.* The expected term represents the period that the stock options are expected to remain outstanding. We determined the expected term based upon the probabilities of the anticipated timing of potential liquidity events.
- *Expected Volatility.* The expected volatility is derived from the historical stock volatilities of several comparable publicly listed peers over a period approximately equal to the expected term of the options as we have no trading history to determine the volatility of our 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 we have not paid nor do we anticipate paying any dividends on our common stock in the foreseeable future.

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

We recorded stock-based compensation expense of $0.9 million for 2020. As of December 31, 2020, there was $4.1 million of unrecognized stock-based compensation expense related to unvested common stock options which we expect to recognize over a weighted-average period of 3.01 years. We expect to continue to grant stock options and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods is expected to increase.

Based upon an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, the aggregate intrinsic value of options outstanding as of 2020 was $42.1 million, of which $ million related to vested options and $ million related to unvested options.

Fair Value of Common Stock

The estimated fair value of the common stock underlying our stock options was determined at each grant date by our board of directors, with input from management. All options to purchase shares of our common stock are 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.

In the absence of a public trading market for our common stock, on each grant date, we develop an estimate of the fair value of our common stock based on the information known to us on the date of grant, upon a review of any recent events and their potential impact on the estimated fair value per share of the common stock and considering independent third-party valuations of our common stock. Our valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the Practice Aid).
The assumptions used to determine the estimated fair value of our common stock are based on numerous
objective and subjective factors, combined with management judgment, including:

- external market conditions affecting our industry and trends within the industry;
- our stage of development and business strategy;
- the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock;
- the prices at which we sold shares of our convertible preferred stock;
- our financial condition and operating results, including our levels of available capital resources;
- the progress of our research and development and commercialization efforts;
- equity market conditions affecting comparable public companies; and
- general U.S. market conditions and the lack of marketability of our common stock.

The assumptions underlying these valuations represent our board of directors' best estimates at the time they were made, which involve inherent uncertainties and the application of the judgment of our board of directors. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

In determining the fair value of our common stock, we estimated the enterprise value of our business using equal weighting between the income and market approaches.

The market approach attempts to value an asset or security by examining observable market values for similar assets or securities. When applied to the valuation of equity, the analysis may include consideration of the financial condition and operating performance of the company being valued relative to those of publicly traded companies or to those of companies acquired in a single transaction, which operate in the same or similar lines of business. In order to achieve comparability, multiples may be adjusted to factor in differences in entity size, profitability, expected growth, working capital, liquidity, and investors' required rate of return. The specific market approaches employed in our third-party valuations include the following:

- *Guideline Public Company Approach.* Enterprise value is estimated based upon the observed valuation multiples of comparable public companies.
- *Guideline Transactions Approach.* Enterprise value is estimated based upon the observed valuation multiples paid in acquisitions of comparable companies.

The income approach attempts to value an asset or security by estimating the present value of the future economic benefits it is expected to produce. These benefits can include earnings, cost savings, tax deductions, and disposition proceeds from the asset. Projected cash flows are then discounted to a present value employing a discount rate that properly accounts for the estimated market weighted-average cost of capital, as well as any risk unique to the subject cash flows. Finally, an assumption is made regarding the sustainable long-term rate of growth and a residual value is estimated and discounted to a present value. The sum of the present value of the cash flows and the residual, or "terminal," value represents the estimated fair value of the total invested capital of the entity. The specific income approach employed in our third-party valuations was a discounted cash flow analysis. Specific inputs into the discounted cash flow analysis were forecasted by our management team and included:

- estimated future revenues;
- estimated future operating expenses;
- estimated future other income and expenses and provision for income taxes;
- estimated future capital expenditures; and
- estimated future working capital requirements.

The Practice Aid identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, we considered the following methods:

- *Option Pricing Method (OPM).* Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.
- *Probability-Weighted Expected Return Method (PWERM).* The PWERM is a scenario-based analysis that estimates value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

We determined that a hybrid approach of the OPM and the PWERM methods was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock. In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity. The estimated fair value of our common stock at each grant date reflected a non-marketability discount partially based on the anticipated likelihood and timing of a future liquidity event.

Following the closing of this offering, our board of directors intends to determine the fair value of our common stock based on the closing quoted market price of our common stock as reported on the Nasdaq Global Market on the date of grant.

Income Taxes

We account 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.

We also follow 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 our policy to include penalties and interest expense related to income taxes as part of the provision for income taxes.

Recently Issued Accounting Pronouncements

See Note 3 to our financial statements included elsewhere in this prospectus for new accounting pronouncements not yet adopted as of the date of this prospectus.

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 prospectus. As of December 31, 2020, our investments consisted only of money market funds. We do not currently use or plan to use financial derivatives in our investment portfolio.

Foreign Currency Risk

Our business is primarily conducted in U.S. dollars. We do not currently maintain a program to hedge exposures to non-U.S. dollar currencies. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows.

Emerging Growth Company and Smaller Reporting Company Status

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, while we are an emerging growth company, we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenues of $1.07 billion or more, (ii) the date on which we are deemed to be a “large accelerated filer” under the rules of the SEC with at least $700.0 million of outstanding equity securities held by non-affiliates, (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the previous three years, or (iv) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

BUSINESS

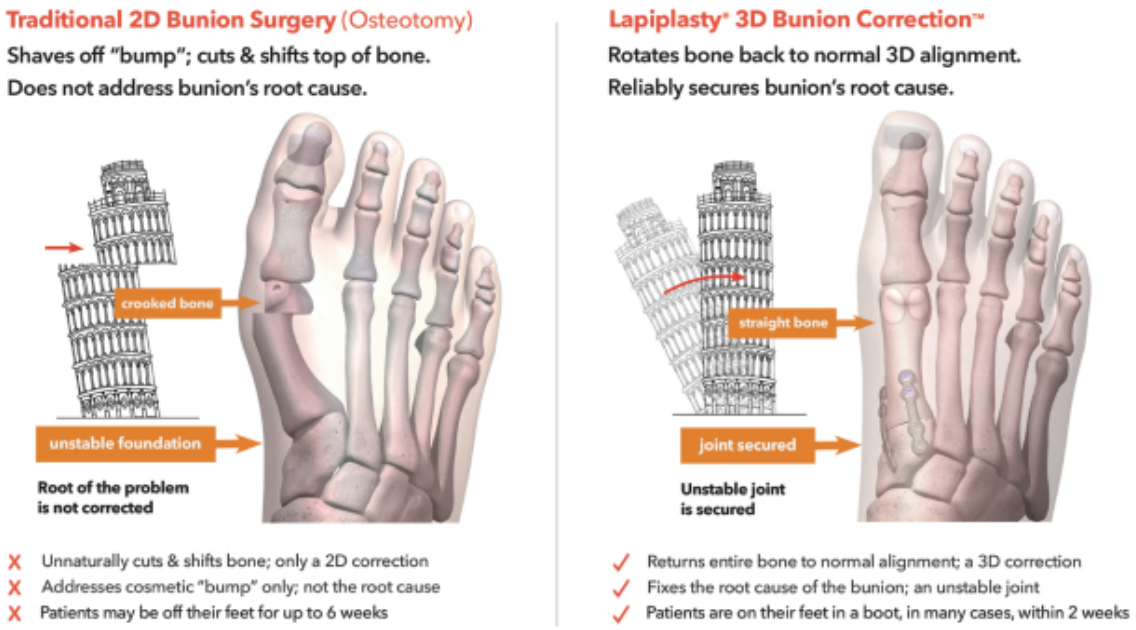
Overview

We are a commercial-stage orthopaedic medical device 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 novel 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.

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 recent 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. 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 25,000 Lapiplasty procedures have been performed in the United States.

Based on the estimated 1.1 million bunion patients deemed surgical candidates in the United States each year, we believe a total annual addressable market opportunity of more than $5 billion exists for our Lapiplasty System. Despite this large patient base, only approximately 450,000 surgical bunion procedures are performed annually in the United States. We believe there is a significant opportunity to convert these traditional surgical bunion procedures to our Lapiplasty System, representing an estimated annual addressable market opportunity of greater than $2.3 billion. In addition, through improved clinical outcomes relative to existing standards of care and effective patient education, we believe there is an opportunity to increase the number of surgical candidates who elect to have bunion surgery, representing an incremental annual addressable market opportunity of approximately $3 billion.

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 are actively enrolling our ALIGN3D prospective, multicenter study which will evaluate bunion correction status after two years and includes patient satisfaction scoring, range of motion results and radiographic outcomes.

To broaden our Lapiplasty offerings, we recently 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. 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 agents across 98 territories focused on driving adoption and supporting utilization of the Lapiplasty System among the approximately 7,400 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, 2020, surgeons who performed their first Lapiplasty Procedure in 2020, on average, performed 3.2 procedures during the year while surgeons who performed their first procedure in 2017 or prior, on average, performed 17.7 Lapiplasty Procedures in 2020.

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, representing growth of 44%, despite the impact of COVID-19 on elective procedures in 2020. Correspondingly, our revenue increased from $39.4 million in 2019 to $57.4 million in 2020, representing growth of 46%, from 2019 to 2020. Our net losses were $4.3 million and $3.7 million for the years ended December 31, 2019 and December 31, 2020, respectively.

What Sets Us Apart

We believe the following strengths differentiate our company and will continue to be significant factors in our success and growth:

- **Paradigm-Shifting 3D Approach to the Surgical Treatment of Bunions.** We are driving a paradigm shift in the understanding and surgical treatment of bunions as 3D rather than 2D deformities. While an estimated 87% of bunions involve a misalignment of the metatarsal bone in three anatomic dimensions, traditional 2D approaches to bunion surgery fail to reliably correct all three dimensions of the bunion deformity, reported to result in a 10 to 12 times increase in the rate of recurrence. We believe our proprietary 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. Our goal is to leverage our disruptive technology to establish the Lapiplasty System as the standard of care for the surgical treatment of bunions.

- **Large and Underserved Market With Established Reimbursement**. We believe our annual addressable United States market opportunity of approximately $5 billion is one of the largest and most underserved in the entire orthopaedic market. Of the 65 million Americans affected by bunions, an estimated 1.1 million are deemed bunion surgical candidates each year. Given that traditional surgical procedures are characterized by inconsistent outcomes and high levels of patient dissatisfaction, of these estimated 1.1 million potential patients, only approximately 450,000 surgical bunion procedures are performed annually. With 11,113 Lapiplasty Procedure Kits sold in 2020, it is estimated that the Lapiplasty Procedure was performed in less than 3% of total bunion surgical procedures in the United States. Utilizing existing, well-established reimbursement codes, we believe our differentiated products and procedures has potential to significantly penetrate this expansive market opportunity.
- **Comprehensive and Differentiated Clinical Evidence**. The safety, effectiveness and clinical advantages of the Lapiplasty System are supported by data from multiple peer-reviewed journal publications that collectively evaluated hundreds of subjects across multiple centers in the United States. Several of these peer-reviewed publications have demonstrated the ability of the Lapiplasty System to reproducibly correct the bunion deformity in all three dimensions and allow the patient to quickly and safely return to weight-bearing in a post-operative boot. We believe this robust body of clinical data supports the superiority of the Lapiplasty System over traditional approaches to bunion surgery and will continue to serve as a catalyst for attracting new surgeons and patients.
- **Robust Intellectual Property Portfolio.** We have a broad patent portfolio, with 21 patents granted in the United States covering the Lapiplasty System and related methodologies. These patents provide protection through at least 2035. Additionally, as of December 31, 2020, we had 50 patent applications pending globally. We believe our intellectual property and know-how presents a significant barrier to entry for our competitors.
- **Effective Patient Outreach and Surgeon Education Programs.** We have built a sophisticated patient outreach and surgeon medical education program focused on improving clinical outcomes that has resulted in continued adoption and utilization of our Lapiplasty System. Our direct-to-patient outreach program is effective at reaching prospective patients and educating them through our website on the benefits of the Lapiplasty System. Many patients find surgeons in their local markets who are experienced with the Lapiplasty Procedure through our website's "Find a Doctor" tool. Our leading medical education programs include highly accessible cadaveric training workshops and technical assistance to support new surgeons performing the Lapiplasty Procedure. We also conduct advanced training programs for our existing surgeon customers that improve their technical skills and clinical outcomes by teaching advanced techniques for use with the Lapiplasty Procedure.
- **Highly Experienced, Proven Management Team and Board of Directors**. We are led by a highly experienced management team and board with a successful track record of building businesses by identifying and providing solutions for underserved medical device market segments. Our senior management team and board has an average of over 25 years of experience leading the medical device industry and a track record of participating in multiple successful market conversions.

Our Growth Strategy

Our mission is to be the leader in the surgical treatment of bunions by establishing the Lapiplasty System as the standard of care. We seek to achieve this through the following growth strategies:

- **Expanding our Sales Channel to Accelerate Market Penetration.** We are dedicating meaningful resources to expand our sales force and management team in the United States. We are hiring additional employee sales representatives and field sales management to strategically access more regions with high densities of prospective patients. This has resulted in the revenue from our employee sales force as a percentage of our total revenue increasing from 10% in 2018 and 27% in 2019 to 35% in 2020. We also have initiatives that are designed to further focus our independent sales channel on our products. We believe these efforts will accelerate growth and market penetration.

- **Driving Awareness with Innovative Direct-to-Patient Education.** Our direct-to-patient initiatives have leveraged growing trends of patient engagement to broadly educate and raise awareness among prospective bunion patients about the benefits of the Lapiplasty Procedure. This patient education program has been effective at reaching prospective bunion patients and directing them to our website. We believe these direct-to-patient programs will create an educated and engaged patient population, enabling us to reach a growing number of the estimated 1.1 million bunion surgical candidates.
- **Building upon our Base of Clinical Evidence to Further Differentiate the Lapiplasty System**. We have generated, and are dedicated to continuing to develop, clinical evidence to support the safety and effectiveness of the Lapiplasty System. Clinical evidence is an important component of many physicians' decision to use, health care facilities' decision to purchase and payors' decision to reimburse for a medical device. In particular, we are finalizing enrollment in our ALIGN3D prospective, multicenter study, which will evaluate outcomes after two years and include patient satisfaction scoring, range of motion results and radiographic results. We believe that the data from our clinical studies will strengthen our ability to continue accelerated adoption of the Lapiplasty Procedure and advance the standard of care for bunion surgery.
- **Increasing Facility Approvals to Provide Even Greater Surgeon Access to our Products.** We currently have approval at over 1,000 facilities across the United States and plan to continue to increase access by convincing even more surgeons and facility administrators that our products are superior 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.
- **Developing our Pipeline of Next-Generation Innovations**. 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 commercialization of new products to address ancillary surgical procedures performed routinely in connection with the Lapiplasty Procedure. By introducing our next-generation innovations, we believe we have an opportunity to leverage and expand our position in the market and add incremental revenue to our business.

While we have no plans to expand operations outside the United States at the present time, significant opportunities for the Lapiplasty System outside the United States exist, subject, in part, to obtaining applicable regulatory approvals.

Our Market

Our Addressable Market Opportunity

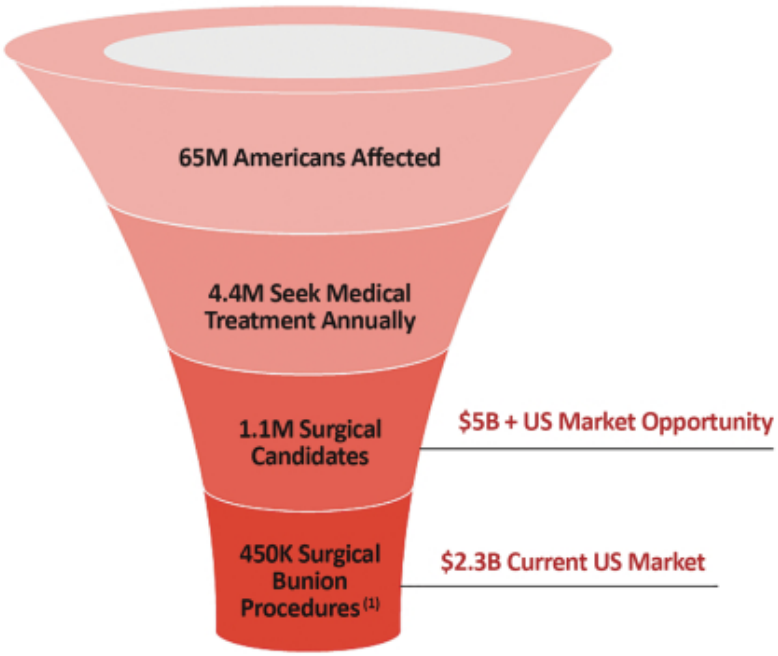
Bunions are a common foot deformity that affect approximately 65 million Americans. Nearly 25% of adults between 18 to 65 years of age, and over 35% of people over the age of 65, have bunions. Given the aging demographics of the U.S. population, we expect the current 4.4 million bunion patients seeking medical attention annually in the United States to continue to grow over time. We estimate that approximately 1.1 million of these patients are deemed surgical candidates once their deformity has progressed to a point that it cannot be treated with non-surgical treatment options. This large patient population often suffers from symptoms that worsen over time, including severe and debilitating pain, emotional burden and limited mobility. Additionally, bunion patients

are susceptible to further degeneration and common concomitant pathologies, including, for example, hammertoe deformity and arthritis of the great toe joint. Despite the significant limitations of current traditional surgical approaches, approximately 450,000 surgical bunion procedures are performed every year.

We have pioneered our proprietary Lapiplasty System—a combination of novel instruments, implants and surgical methods designed to improve the inconsistent clinical outcomes of traditional approaches to bunion surgery. The majority of bunion surgical procedures attempt to correct the deformity from a two-dimensional perspective and fail to address the root cause, an unstable joint in the middle of the foot. Research indicates that 87% of bunions have a three-dimensional, rotational issue in addition to horizontal and vertical misalignments. To effectively restore the normal anatomy of patients and improve the outcomes of bunion surgical procedures, we believe correcting the deformity across all three anatomic dimensions and focusing on the root cause of the disorder is critical.

Based on the estimated 1.1 million surgical candidates for bunion surgery in the United States each year, we believe a total annual addressable market opportunity of more than $5 billion exists for our Lapiplasty System. Despite the estimated 1.1 million surgical candidates, only approximately 450,000 annual surgical bunion procedures are performed annually in the United States. 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

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.

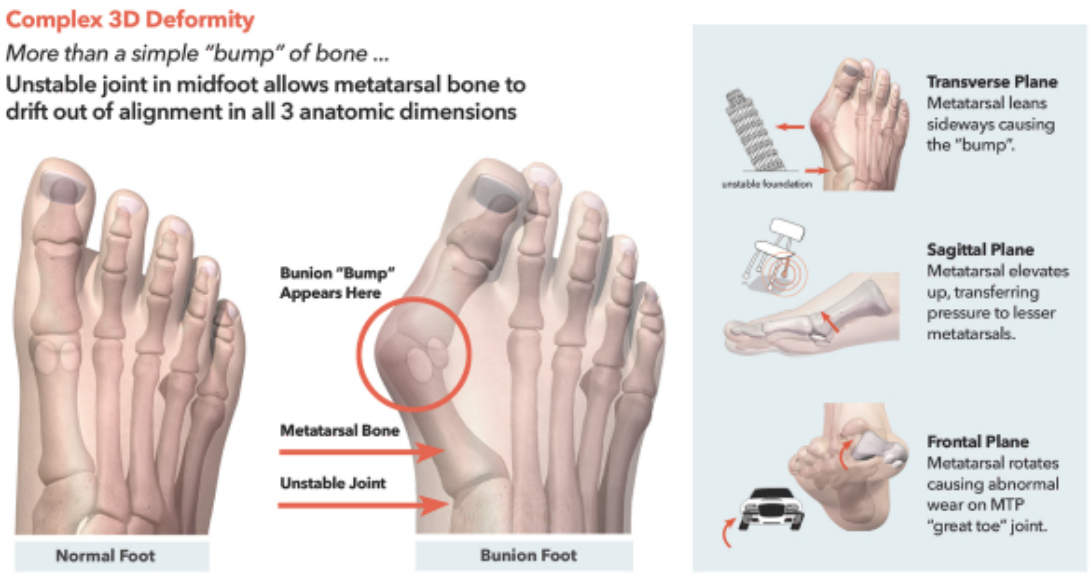
Bunion deformities are most commonly considered to be the consequence of a hereditary predisposition. Prevalence increases with age, and one study found that 70% of bunion sufferers are female, and that the disorder occurs in both feet, or bilaterally, in 56% of bunion sufferers. Bunions are progressive 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.

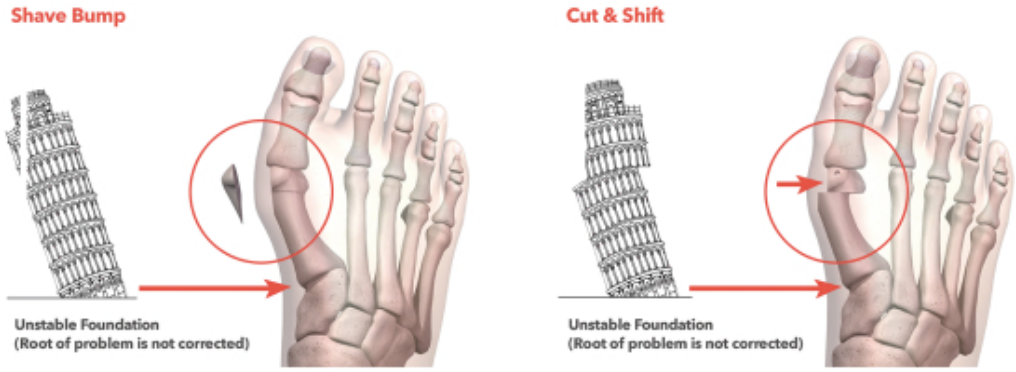
Limitations of Traditional Surgical Treatment Approaches

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 tarsometatarsal (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 novel 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.

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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 novel 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:

Procedural instrumentation

Lapiplasty Positioner

Engineered to quickly and reproducibly correct metatarsal alignment in all three dimensions

Lapiplasty Compressor

Delivers controlled compression to the precision-cut joint surfaces, while maintaining the three-dimensional correction

Lapiplasty Cut Guide and Fulcrum

Delivers precise cuts with the metatarsal held in the corrected position, ensuring optimal cut trajectory

Lapiplasty Light-Weight Tray

Includes the Positioner, Compressor and Cut Guide and Fulcrum

Sterile-packed implant kits

Sterile Implants and Instruments

Single-use implants and instruments used in the Lapiplasty Procedure and ancillary procedures

Biplanar Plating

Provides biomechanically-tested biplanar stability, which are designed to allow rapid return to weight-bearing in a walking boot

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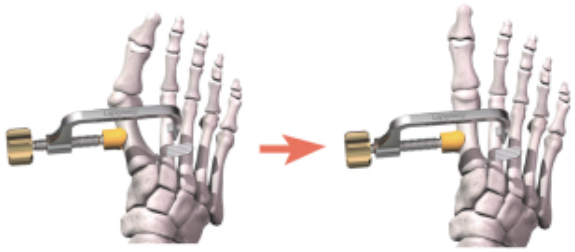
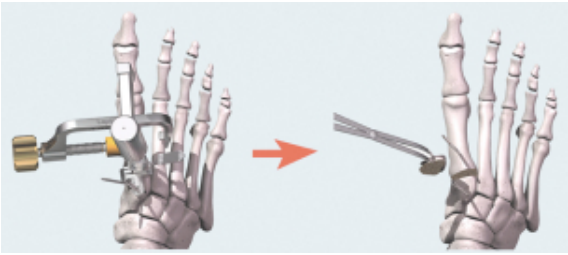
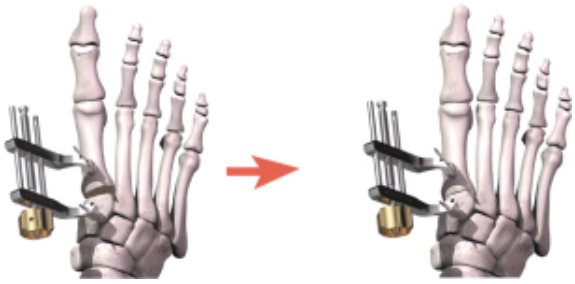
The following table illustrates our patented Lapiplasty System, with procedural instrumentation and implants used in each step of our proprietary Lapiplasty Procedure:

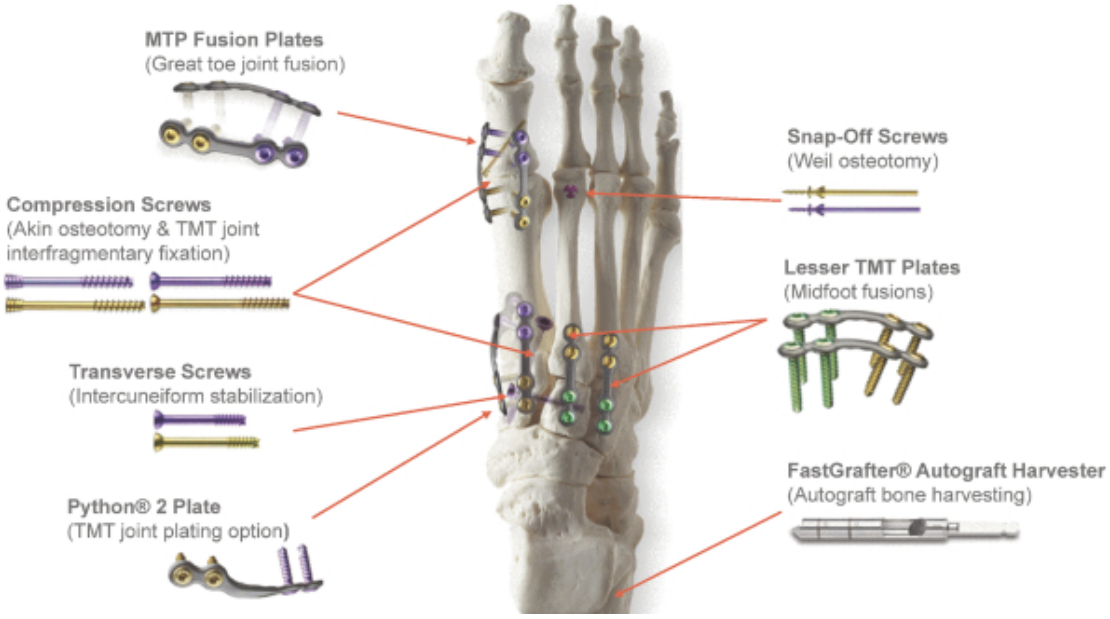
Lapiplasty System	
Correct. Make the correction *before* the cut Using the **Lapiplasty Positioner**, the entire metatarsal bone is returned to normal 3D alignment.	
Cut. Perform precision cuts with confidence Using the **Lapiplasty Cut Guide**, the unstable joint surfaces are cut in the corrected position.	
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 New Lapiplasty Mini-Incision System

Expanding our Lapiplasty offerings, we recently 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.

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 and 2nd cuneiforms), lesser TMT joint fusions and autograft bone harvesting, as well as for MTP (big toe joint) fusion, an option for bunion patients with arthritic big toe joints. 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:



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 is cited in 15 peer-reviewed journal publications as of December 2020.

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 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. In comparison, 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, and suggest its superiority relative to traditional approaches to bunion surgery. 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.

The table below summarizes the key advantages of the Lapiplasty System relative to traditional bunion surgical approaches:

	Lapiplasty® 3D Bunion Correction™	Traditional 2D Osteotomy	Traditional Lapidus Fusion
Consistent 3D deformity correction	✓	✗	✗
Addresses root cause of deformity	✓	✗	✓
Ease of procedure / reproducibility	✓	✓	✗
Time to weight-bearing	✓	✓	✗
Consistently slimmer foot	✓	✗	✓
Low rate of recurrence	✓	✗	✓

Our Clinical Data

We have generated, and are dedicated to continuing to develop, clinical evidence to support the safety and effectiveness of the Lapiplasty System. Clinical evidence is an important component of many physicians' decision to use, health care facilities' decision to purchase and payors' decision to reimburse a medical device. We believe that the data from our clinical studies will strengthen our ability to continue accelerated adoption of the Lapiplasty Procedure and advance the standard of care for bunion surgery. We are in the process of enrolling patients for our ALIGN3D post-market clinical study. As described in greater detail below, ALIGN3D is a prospective, multicenter, unblinded clinical study designed to evaluate the ability of the Lapiplasty Procedure to consistently and reliably correct all three dimensions of the bunion deformity and maintain the correction over an extended period of time (with a primary end point of 24 months after surgery and radiographic follow-up to five years).

Peer-Reviewed Publications

The safety, effectiveness and clinical advantages of the Lapiplasty Procedure have been observed in our robust portfolio of clinical data. The Lapiplasty Procedure is cited in 15 peer-reviewed journal publications as of December 2020, including multiple clinical studies which collectively evaluated hundreds of patients across multiple centers in the United States. These publications demonstrate the Lapiplasty Procedure consistently corrects the bunion deformity in all three dimensions and allows the patient to quickly and safely return to weight-bearing (in a post-operative boot).

Below are selected summaries of peer-reviewed journal publications addressing the Lapiplasty Procedure:

- A biomechanical study published in *The Journal of Foot & Ankle Surgery* in 2016 compared Lapiplasty Biplanar Plating to a commonly-used Lapidus anatomic plate and screw construct, demonstrating significant improvements in biomechanical performance under laboratory loading tests designed to simulate post-operative weight-bearing.
- A multicenter, retrospective clinical study in *The Journal of Foot & Ankle Surgery* in 2019 evaluated bone healing with accelerated weight-bearing protocol in patients undergoing the Lapiplasty Procedure or MTP Fusion with the Lapiplasty implants. 195 patients were included with mean follow up of 9.5 months. Patients were allowed to begin weight-bearing in a walking boot approximately five days after the operation. The results demonstrated that 97.4% of patients had successful fusion and 98.9% maintained a stable joint position over the course of the study.
- A multicenter, retrospective clinical study in *Foot & Ankle International* in 2019 evaluated 57 bunion patients (62 feet) treated with the Lapiplasty Procedure and early return to weight-bearing (average 10.9 days post-operation). At average follow-up of 13.5 months, the results demonstrated that 96.8% of study patients maintained their 3D bunion correction, and 1.6% experienced a symptomatic non-union complication.
- A retrospective clinical study in *The Journal of Foot & Ankle Surgery* in 2020 evaluated radiographic outcomes from 108 bunion patients (109 feet) that underwent 3-dimensional first TMT correction using biplanar plating Lapiplasty Procedure and began weight-bearing as tolerated within the first week after surgery. At an average follow up of 17.4 months, the results demonstrated all patients achieved successful fusion of the joint, with 99.1% of patients maintaining their 3D bunion correction (0.9% recurrence rate) and no hardware failures reported.
- A multicenter, retrospective clinical study in *Foot & Ankle Orthopaedics* in 2020 evaluated 144 bunion patients (148 feet) who underwent the Lapiplasty Procedure. All patients demonstrated a decrease in foot width after surgery. Bony width decreased by 10.4 mm (10.8%) post-operatively, whereas soft tissue width decreased 7.3 mm (6.8%) post-operatively.

ALIGN3D Prospective Clinical Study

The ALIGN3D post-market clinical study is a prospective, multicenter, unblinded study to evaluate Lapiplasty Procedure patient outcomes. The ALIGN3D study is designed to evaluate the ability of the Lapiplasty Procedure to:

1. Consistently and reliably correct all three dimensions of the bunion deformity.
2. Maintain the correction following accelerated return to weight-bearing.
3. Quantify improvement in patient quality of life.

We initiated patient enrollment for the ALIGN3D clinical study in November 2018 and are actively enrolling patients. The ALIGN3D study will enroll up to 200 patients. As of January 29, 2021, 162 patients have been enrolled and have undergone the Lapiplasty procedure. The mean age of currently-enrolled patients is 41 years, with an age range of 14 to 58.

The ALIGN3D study will involve seven clinical sites and will follow patients for 24 months after surgery with radiographic follow-ups for 5 years The Primary Endpoint of the ALIGN3D study is whether the 3D correction is maintained at 24 months follow up. The Secondary Endpoints of the ALIGN3D study will track the time to start of weight-bearing (in a post-operative boot or shoe), maintenance of 3D correction (over 5 years), fusion rate, quality of life (as measured by VAS pain scores, the MoXFQ and PROMIS-29 quality of life scales) and range of motion of the great toe joint.

We presented interim results from the ALIGN3D study at the American Orthopedic Foot & Ankle Society conference in September 2020. Specifically, the interim results indicated that the average number of days for patients to be able to bear weight in a boot was eight days, the average number of days for a patient to return to work was 19 days (full work at approximately 41 days) and the average number of days to return to unrestricted activity was approximately 115 days, in each case, post-Lapiplasty Procedure. In addition, we reported that the interim results indicated dramatic improvements in reported outcome scores and a low complication rate. These interim data were based on results from 74 patients at six weeks, 62 patients at six months and 26 patients at 12 months. We intend to present updated data at the American College of Foot & Ankle Surgeons in May 2021.

Commercial Strategy

We currently market and sell the Lapiplasty System through a combination of a direct employee sales force and independent sales agents across 98 territories in the United States. As of December 31, 2020, we had 34 direct sales representatives, eight regional sales vice presidents who are responsible for managing the sales representatives and 59 independent sales agents. In 2020, employee sales representatives generated approximately 35% of revenues while approximately 65% of revenues came through independent sales agents.

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:

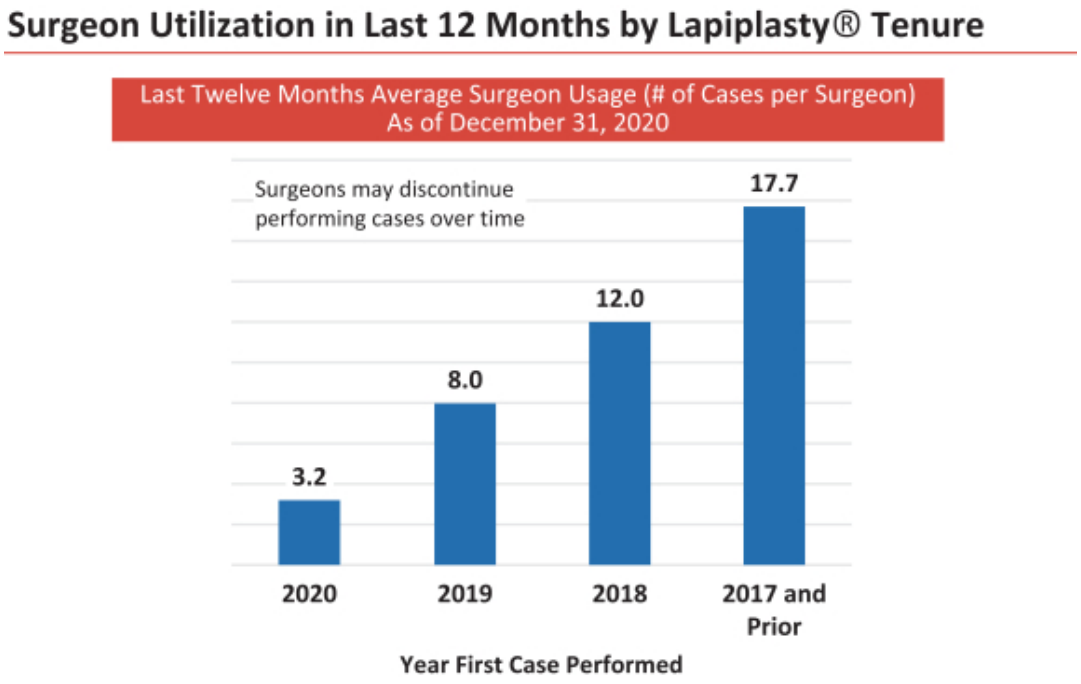
- accelerate growth and better penetrate the market with our products;
- further align incentives and allow for improved coordination of our sales team; and
- improve profitability with better operating leverage in the longer term.

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 seven 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.

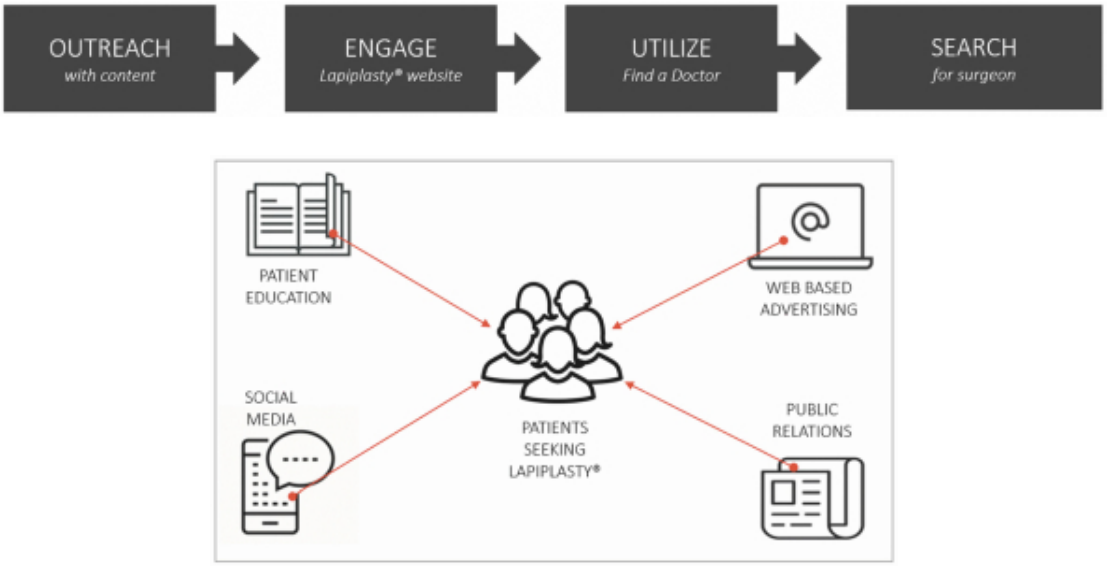
Surgeon users typically increase usage of the Lapiplasty Procedure over time as they see improved clinical outcomes for their patients relative to traditional bunion surgery approaches. The bar chart below shows the average number of procedures performed by surgeons in 2020 based on the year in which the surgeons performed their first case.



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 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, 2019 and 2020, our research, development and clinical expenses were $5.1 million and $5.8 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 surgeries, including the Lapiplasty Procedure.

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

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, 2020, our patent portfolio included 21 owned patents and one licensed patent. All of these patents are U.S. utility patents. The 21 owned patents cover core Lapiplasty-related hardware and surgical techniques as well as other associated innovations. For example, of the 21 owned patents, five relate to the main surgical techniques used by the Lapiplasty Procedure and seven other patents relate to 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, 2020 we had 50 pending patent applications globally, including 27 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™” 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 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, please see “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, 2020, 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 $1.7 million and $2.4 million for the years ended December 31, 2019 and 2020, respectively, resulting in an aggregate royalty rate of 4.3% and 4.1% for the years ended December 31, 2019 and 2020, 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 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.
- 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. and Paragon 28, Inc. 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 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 approval of a 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 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 II devices subject to 510(k) clearance, and we are in the process of pursuing approval of one of our product candidates under a PMA.

510(k) Clearance Marketing Pathway

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 legally marketed 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, FDA collects user fees for certain medical device submissions and annual fees for medical device establishments. For fiscal year 2021, the standard user fee for a 510(k) premarket notification application is $12,432.

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 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 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 2021 includes a standard application fee of $365,657.

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, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

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. As a manufacturer, we 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 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. By way of example, in 2017, the Tax Cuts and Jobs Act was signed into law, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health

coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs 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 the U.S. Supreme Court ruling, other such litigation, and the health care reform measures of the Biden administration will impact the ACA.

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, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. 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.

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 other health care providers beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives. 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.

Employees and Human Capital Resources

As of December 31, 2020, we had 133 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 additional 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 March 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.

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.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information, as of March 30, 2021, regarding our executive officers and directors.

Name	Age	Title
Executive Officers and Employee Director		
John T. Treace	49	Chief Executive Officer, Founder and Director
Mark L. Hair	51	Chief Financial Officer
Joe W. Ferguson	52	Senior Vice President, Research & Development
Jaime A. Frias	59	Chief Legal & Compliance Officer, Secretary
Daniel E. Owens	49	Chief Human Resources Officer
Dipak A. Rajhansa	51	Senior Vice President, Sales
Sean F. Scanlan	39	Senior Vice President, Marketing & Medical Education
Non-Employee Directors		
James T. Treace (3)	75	Chairman and Director
John K. Bakewell (1)(3)	59	Director
F. Barry Bays (2)	74	Director
Lawrence W. Hamilton (1)(2)	63	Director
Richard W. Mott (3)	62	Director
Thomas E. Timbie (1)(2)	63	Director
John R. Treace	76	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating, compliance and governance committee.

Executive Officers and Employee Director

John T. Treace founded Treace Medical Concepts in 2014 and has served as our Chief Executive Officer and a member of our board of directors since our inception. Before that, Mr. Treace served as Senior Vice President of U.S. Sales and Global Marketing from January 2010 to January 2013, as Vice President, Biologics and Extremities, from January 2003 to December 2009, Senior Director of Biologics Marketing from July 2001 to June 2003 and as Senior Directors of Sales Administration from November 2000 to June 2001 for Wright Medical Group, Inc., a medical device company, which was acquired by Stryker Corporation (NYSE: SYK) in November 2020. Before that, Mr. Treace held positions Xomed Surgical Products, Inc., including as Director of Marketing from June 1998 to September 2000 and as Senior Product Manager from April 1996 to June 1998. From July 2010 to July 2013, Mr. Treace served on the board of directors of ENTrigue Surgical, which was acquired by Arthrocare Corporation. Mr. Treace holds a BS in Finance from Seattle University. We believe Mr. Treace is qualified to serve on our board due to his extensive knowledge as our company's founder and Chief Executive Officer, his prior commercial and general management experience with a market-leading, publicly-traded foot and ankle medical device company and his prior experience as a board member for ENTrigue Surgical.

Mark L. Hair has served as our Chief Financial Officer since September 2020. Before that, from January 2018 to February 2020, Mr. Hair served as the Chief Financial Officer of Restoration Robotics, Inc., a medical device company. From May 2016 to August 2017, Mr. Hair served as the Vice President and Chief Accounting Officer of Zeltiq Aesthetics, Inc., a medical device company, including through its acquisition by Allergan plc in

April 2017. Prior to that, from September 2014 to January 2016, Mr. Hair served as the Vice President and Corporate Controller of Thoratec Corporation, a medical device company, including through its acquisition by St. Jude Medical in October 2015. Mr. Hair has also served as Senior Vice President, Finance and Corporate Controller at Diamond Foods, Inc., and also held positions at StoneTurn Group, LLP, and Deloitte, LLP. Mr. Hair holds a BS in Accounting and a Masters of Accountancy from Brigham Young University.

Joe W. Ferguson has served as our Senior Vice President, Research & Development since March 2021 and before that as our Chief Operating Officer since July 2014. Before that, from January 2011 to July 2014, Mr. Ferguson served in various senior management roles at IMDS, a medical device and instrument product development contractor, most recently as General Manager of the Florida Co-Innovation Group, including during its acquisition by Coors-Tek Medical in October 2013. Before that, from September 2007 to January 2011, Mr. Ferguson served as Senior Management of Development – Foot and Ankle at Wright Medical Group, Inc., which was acquired by Stryker Corporation (NYSE: SYK) in November 2020. Mr. Ferguson has also served at Medtronic plc (NYSE: MDT), Spinal Dynamics and DePuy Orthopaedics, now part of Johnson & Johnson (NYSE: JNJ). Mr. Ferguson holds a BS in Microbiology from Auburn University and an MS in Biomedical Engineering from the University of Memphis.

Jaime A. Frias has served as our Chief Legal & Compliance Officer since March 2021 and before that as our Executive Vice President, General Counsel and Chief Compliance Officer since July 2017. Mr. Frias has also served as our Secretary since June 2017. Before that, from November 2013 to June 2017, Mr. Frias served as the managing partner of Frias Legal PA, where he provided us with legal services starting in 2014. Before that, from November 1999 to October 2013, Mr. Frias served in various roles at Medtronic plc (NYSE: MDT), most recently as the Vice President, Chief Legal Counsel for the Surgical Technologies division. Before that, from October 1998 until its acquisition of Medtronic plc in November 1999, Mr. Frias served as in-house counsel for Xomed Surgical Products, Inc. Mr. Frias holds a Bachelor of Music from the University of Florida and a JD from the University of Michigan Law School.

Daniel E. Owens has served as our Chief Human Resources Officer since February 2021. Before that, from February 2019 to May 2020, Mr. Owens served as Vice President of Human Resources at Jackson Hewitt Tax Service Inc. From August 2012 to February 2019, Mr. Owens served in various human resources roles at HSN, Inc., a direct to consumer retail business, which was acquired by Qurate Retail, Inc. (NASDAQ: QRTEA, QRTEB, QRTEP) in December 2017, most recently as Vice President of People Lead. Mr. Owens has also served in human resources roles at Nomura Securities (NYSE: NMR), Hartford Life Insurance (NYSE: HIG) and General Electric (NYSE: GE). Mr. Owens holds a BA in Economics from Michigan State University.

Dipak A. Rajhansa has served as our Senior Vice President, Sales since March 2021 and before that as our Chief Sales Officer since July 2017. Before that, from September 2012 to July 2017, Mr. Rajhansa served as Senior Vice President of Sales and Marketing for Skeletal Dynamics, LLC, a medical device company. Mr. Rajhansa has also served at ImaCor from April 2008 to August 2012, Magellan Consulting Group from July 2006 to April 2008 and Hand Innovations from May 2002 to April 2006 when the company was acquired by Johnson & Johnson (NYSE: JNJ). Mr. Rajhansa holds a BA in Political Science from Washington University and an MBA from New York University.

Sean F. Scanlan, Ph.D. has served as our Senior Vice President, Market & Medical Education since March 2021 and before that as our Vice President, Marketing & Medical Education since January 2018, after serving in various marketing roles of increasing responsibility since December 2014. Before that, from June 2011 to April 2014, Dr. Scanlan served as Product Development Engineer Advanced Surgical Devices at Smith & Nephew (NYSE: SNN), focusing on product development and early-stage technology assessment. Before that, from January 2006 to May 2011, Dr. Scanlan led an interdisciplinary clinical research study at Stanford University, focusing on orthopaedic surgery and engineering and, from October 2009 to May 2011, served as a consultant for Moximed Inc., an early-stage orthopaedics start-up company. Mr. Scanlan holds a BS in Engineering Science (Biomechanics) from University of Florida and an MS and PhD in Mechanical Engineering (Biomechanical Engineering division) from Stanford University.

Non-Employee Directors

James T. Treace has served as the chairman of our board of directors since June 2014. Mr. Treace has served as the Founder and President of J&A Group, LLC, a privately funded medical device investment and consulting company, since October 2000. Before that, from November 1999 to October 2000, Mr. Treace served as President of Medtronic Xomed, a subsidiary of Medtronic plc (NYSE: MDT). Prior to that, from April 1996 to November 1999, Mr. Treace served as Chief Executive Officer, President and Chairman of the board of directors Xomed Surgical Products, Inc. (NASDAQ: XOMD), until it was acquired by Medtronic plc. Before that, from July 1993 to April 1996, Mr. Treace co-founded and served as the Chief Executive Officer and Chairman of the Board at TreBay Medical Corp., an orthopaedic and microsurgical device company. From September 1981 to July 1990 he served as President and Chief Executive Officer of Concept, Inc. (NASDAQ: CCPT), now known as Conmed Linvatec (NYSE: CNMD) and from June 1966 to September 1981 as Executive Vice President of Richards Medical, now known as Smith & Nephew (NYSE: SNN). Mr. Treace previously served as Chairman of the Boards of Kyphon, Inc. (NASDAQ: KYPH), now part of Medtronic plc, Wright Medical Group, Inc. which was acquired by Stryker Corporation (NYSE: SYK) in November 2020 and American Medical Systems, Inc. (NASDAQ: AMMD, now part of Endo Pharmaceuticals (NASDAQ: ENDP). We believe that James T. Treace is qualified to serve on our board due to his experience as chief executive officer and chairman of the board of publicly-traded and privately-held medical device companies.

John K. Bakewell has served as a member of our board of directors since November 2020. Before that, from January 2016 to November 2016, Mr. Bakewell served as the Chief Financial Officer of Exact Sciences Corporation (NASDAQ: EXAS), a molecular diagnostics company. Before that, from June 2014 to December 2015, he served as Chief Financial Officer of Lantheus Holdings, Inc. (NASDAQ: LNTH), a diagnostic medical imaging company. Mr. Bakewell has also previously served at Interline Brands, Inc., RegionalCare Hospital Partners, Wright Medical Group, Inc., which was acquired by Stryker Corporation (NYSE: SYK) in November 2020, Cyberonics, Inc., now part of LivaNova PLC (NASDAQ:LIVN), Altra Energy Technologies, Inc. and ZEOS International, Ltd. Mr. Bakewell has served as a member of the board of directors of Neuronetics, Inc. (NASDAQ: STIM), a medical technology company, since May 2020, and Xtant Medical Holdings, Inc. (NYSE MKT: XTNT), a medical device company, since February 2018. Mr. Bakewell also previously served as a member of the board of directors of Entellus Medical, Inc., now part of Stryker Corporation (NYSE: SYK), ev3 Inc., now part of Medtronic plc (NYSE: MDT) and Corindus Vascular Robotics, Inc., now a Siemens Healthineers company. Mr. Bakewell holds a BA in Accounting from the University of Northern Iowa and is a certified public accountant (current status inactive). We believe that Mr. Bakewell is qualified to serve on our board due to his extensive financial and managerial experience as a senior executive of several publicly traded medical technology companies, as well as his experience serving on the board of directors of other companies.

F. Barry Bays has served as a member of our board of directors since June 2014. From January 2000 to June 2008, he served in various senior leadership roles with Wright Medical Group, Inc., which was acquired by Stryker Corporation (NYSE: SYK) in November 2020, including as Executive Chairman from June 2004 to October 2005, and again from April 2006 to June 2008 and as President and Chief Executive Officer from January 2000 to June 2004, and again from October 2005 to April 2006. Before that, from 1996 to 2000 Mr. Bays served as the Chief Operating Officer of Xomed Surgical Products, Inc., which was acquired by Medtronic plc (NYSE: MDT) in 1999. Mr. Bays has also served in leadership roles at TreBay Medical Corp., Concept, Inc., now known as Conmed Linvatec (NYSE: CNMD), and Richards Medical, now known as Smith & Nephew (NYSE: SNN). Mr. Bays holds a BS in Mechanical Engineering from Christian Brothers University. We believe that Mr. Bays is qualified to serve on our board due to his experience at leading publicly-traded and privately-held medical device companies, including as a chief executive officer.

Lawrence W. Hamilton has served as a member of our board of directors since November 2020. Mr. Hamilton has served as an Executive Coach and Adjunct Faculty with the Center for Creative Leadership at Eckerd College since September 2008. Before that, from July 1993 to July 2006, Mr. Hamilton served in various roles at Tech Data Corporation, most recently as Senior Vice President, Human Resources. Before that, from

1991 to 1993, Mr. Hamilton served as Vice President of Human Resources and Administration at Linvatec. Before that, from 1985 to 1991, Mr. Hamilton served in a variety of human resource management positions at Bristol-Myers Squibb Company (NYSE: BMY). Mr. Hamilton has also previously served as a member of the board of directors of Wright Medical Group, Inc., which was acquired by Stryker Corporation (NYSE: SYK) in November 2020, and HomeBanc Mortgage (NYSE: HBMC). Mr. Hamilton holds a BA in Political Sciences from Fisk University, an MPA (Labor) Policy from the University of Alabama and an Ed.S. in Human Resources Development from George Washington University. Mr. Hamilton is a certified Senior Professional in Human Resources and holds the Certified Compensation Professional designation from the American Compensation Association. We believe that Mr. Hamilton is qualified to serve on our board due to his experience in managing employees, establishing compensation policies and guidelines and serving in board committee roles.

Richard W. Mott has served as a member of our board of directors since March 2015. Mr. Mott has served as the Chairman and Interim CEO of Endologix, LLC, a medical device company, since October 2020. Additionally, Mr. Mott has served as the Principal of Walkabout Consulting LLC, a management consulting and private equity firm, since January 2009 and as a Director and Owner of VFD Technologies, a private equity firm that invests in high performance materials and medical devices manufacturing businesses, since March 2010. Before that, from September 2002 to November 2007, Mr. Mott served as President and CEO of Kyphon Inc., global medical device company, including through its acquisition by Medtronic plc (NYSE: MDT). Before that, from 1993 to 2002, Mr. Mott held various management positions at Wilson Greatbatch Technologies, Inc. and Bristol-Myers Squibb Co. (NYSE: BMY). From May 2008 to December 2017, Mr. Mott served as a member of the board of directors of Silk Road Medical Inc. (NASDAQ: SILK), a medical device company. Mr. Mott currently serves on the board of various private companies, including Conventus Orthopaedics Inc., a developer of fracture fixation technology. He holds a BS in Ceramic Engineering from Alfred University and is a graduate of Harvard University's Advanced Management Program. We believe that Mr. Mott is qualified to serve on our board due to his extensive experience leading medical device companies from the early stages of development to liquidity events.

Thomas E. Timbie has served as a member of our board of directors since June 2014 and served as our chief financial officer from July 2014 to October 2015. Before that, from January 2005 to June 2005, Mr. Timbie served as the interim Chief Financial Officer of ev3 Inc., a medical device company, now part of Covidien plc, where he helped lead ev3 through its initial public offering. Before that, from April 1996 until December 1999, Mr. Timbie served as the Chief Financial Officer of Xomed Surgical Products, Inc., including during its initial public offering in 1996, and continuing in that role until Xomed was acquired by Medtronic plc (NYSE: MDT) in 1999. Mr. Timbie has also previously served as a member of the board of directors of Wright Medical Group, Inc., which was acquired by Stryker Corporation (NYSE: SYK) in November 2020, ev3 Inc., until its acquisition by Covidien plc, and American Medical Systems, Inc., now part of Endo Pharmaceuticals (NASDAQ: ENDP). Mr. Timbie holds a BS in Accounting from University of Florida, an MBA from Stetson University and is a certified public accountant (current status inactive). We believe that Mr. Timbie is qualified to serve on our board due to his professional expertise as a Chief Financial Officer and audit committee chairman for several medical device companies, extensive knowledge of the medical device industry and prior experience in leading medical device companies through initial public offerings.

John R. Treace has served as a member of our board of directors since June 2014. Mr. Treace has served as the Founder and Chief Executive Officer of JR Treace & Associates, a sales and marketing consulting firm, since September 2011. Before that, Mr. Treace served in various senior management roles at Wright Medical Group, Inc., which was acquired by Stryker Corporation (NYSE: SYK) in November 2020, including as Vice President, US Sales from September 2000 to May 2004, Executive Vice President of North American Sales from October 2005 to March 2007 and as Special Assistant to the President from April 2007 through December 2007. Mr. Treace held various management positions at Medtronic Xomed, a subsidiary of Medtronic plc (NYSE: MDT), TreBay Medical Corp. and Richards Medical, now known as Smith & Nephew (NYSE: SNN). Mr. Treace holds a BS in Psychology from University of Memphis. We believe that John R. Treace is qualified to serve on our board due to his experience leading the sales and marketing functions of publicly-traded and privately-held medical device companies.

Family Relationships

Three members of our board of directors, including our Chief Executive Officer, have a family relationship. John T. Treace, our Chief Executive Officer, is the son of our director John R. Treace and the nephew of our director James T. Treace. There are no family relationships among any of our executive officers. Each of our executive officers serves at the discretion of our board of directors and holds office until his or her successor is duly elected and qualified or until his or her earlier resignation or removal.

Board Composition

Director Independence

Our board of directors currently consists of eight members. Pursuant to the Nasdaq Global Market listing requirements, independent directors must comprise a majority of a listed company's board of directors within a specified period of time after listing on the Nasdaq Stock Market. The Nasdaq Global Market's independence definition includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us.

As required by the Nasdaq Global Market rules, our board of directors has made a subjective determination as to the independence of each director and determined that Messrs. Bakewell, Bays, Hamilton, Mott and Timbie, representing five of our eight directors, are independent directors under the rules of the Nasdaq Global Market. James T. Treace is the uncle of our Chief Executive Officer and John R. Treace is the father of our Chief Executive Officer. Our board of directors will review the independence of each director at least annually. During these reviews, the board of directors will consider transactions and relationships between each director, and his or her immediate family and affiliates, and our company and its management to determine whether any such transactions or relationships are inconsistent with a determination that the director is independent. This review will be based primarily on responses of the directors to questions in a directors' and officers' questionnaire regarding employment, business, familial, compensation and other relationships with our company including its management.

We believe that a majority of our directors and the composition of our board of directors meets the requirements for independence under the current requirements of the SEC and the Nasdaq Stock Market. As required by the Nasdaq Stock Market, we anticipate that our independent directors will meet in regularly scheduled executive sessions at which only independent directors are present. We intend to comply with future governance requirements to the extent they become applicable to us.

Classified Board of Directors

In accordance with our amended and restated certificate of incorporation to be in effect immediately before the completion of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election or until their earlier death, resignation or removal. Effective upon the completion of this offering, we expect that our directors will be divided among the three classes as follows:

- Our class I directors will be Lawrence W. Hamilton and John R. Treace, and their terms will expire at our annual meeting of stockholders to be held in 2022;
- Our class II directors will be Thomas E. Timbie, James T. Treace and F. Barry Bays, and their terms will expire at our annual meeting of stockholders to be held in 2023; and
- Our class III directors will be John K. Bakewell, Richard W. Mott and John T. Treace, and their terms will expire at our annual meeting of stockholders to be held in 2024.

Our amended and restated certificate of incorporation and amended and restated bylaws to be in effect immediately prior to the completion of this offering will provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms, together with the requirement that stockholders may remove our directors only for cause with a two-thirds vote and the inability of stockholders to call special meetings, may have the effect of delaying or preventing a change in control or management.

Board Committees

Our board of directors has established a standing audit committee, a compensation committee and a nominating committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee intends to adopt a written charter that satisfies the applicable rules and regulations of the SEC and Nasdaq Listing Rules, which we will post on our website at www.treace.com upon the completion of this offering. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Audit Committee

Effective upon the consummation of this offering, the members of our audit committee will be John K. Bakewell, Lawrence W. Hamilton, and Thomas E. Timbie, and Mr. Bakewell will serve as the chair of the audit committee. Our board of directors has determined that each member of the audit committee meet the heightened independence and experience requirements applicable to audit committee members under the applicable rules and regulations of the Nasdaq Global Market and the SEC and that Mr. Bakewell and Mr. Timbie are both an “audit committee financial expert” as defined under applicable rules of the SEC. Our board of directors has assessed whether all members of the audit committee meet the composition requirements of the Nasdaq Global Market, including the requirements regarding financial literacy and financial sophistication. Our board of directors found that each of the members of the audit committee have met the financial literacy and financial sophistication requirements under SEC and the Nasdaq Stock Market rules. The audit committee will operate under a written charter that satisfies the applicable standards of the SEC and the Nasdaq Global Market.

Our audit committee oversees our corporate accounting and financial reporting process and, as such, its primary responsibilities include:

- appointing, determining the engagement, approving the compensation of and assessing the qualifications and independence of our independent registered public accounting firm;
- monitoring the rotation of partners of the independent registered public accounting firm on our engagement team in accordance with requirements established by the SEC;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- preapproving the audit and non-audit fees due to and services to be performed by our independent registered public accounting firm;
- reviewing our financial statements and our management’s discussion and analysis of financial condition and results of operations to be included in our annual and quarterly reports to be filed with the SEC;
- monitoring annually our internal control over financial reporting, disclosure controls and procedures and treasury functions including cash management procedure;

- reviewing and approving all related party transactions on an ongoing basis;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting internal account controls or auditing matters;
- reviewing our policies with respect to risk assessment and risk management;
- consulting with management to establish procedures and internal controls relating to information technology management, information systems and cybersecurity;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management;
- investigating any reports received through the ethics helpline and reports to the board of directors periodically with respect to accounting, internal accounting controls or auditing matters;
- monitoring compliance with the code of business conduct and ethics with respect to accounting, internal accounting controls or auditing matters and establishing procedures for the confidential and anonymous submission of complaints regarding questionable accounting or auditing matters; and
- reviewing the audit committee charter and the audit committee's performance on an annual basis.

Compensation Committee

Effective upon the consummation of this offering, the members of our compensation committee will be Lawrence W. Hamilton, F. Barry Bays and Thomas E. Timbie, and Mr. Hamilton will serve as chair of the compensation committee. Each of the members of our compensation committee will be independent under the applicable rules and regulations of the Nasdaq Global Market, will be a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act and will be an "outside director" as that term is defined in Section 162(m) of the Code (Section 162(m)). The compensation committee will operate under a written charter that satisfies the applicable standards of the SEC and the Nasdaq Global Market.

The compensation committee's responsibilities include:

- annually reviewing and approving corporate goals and objectives relevant to compensation of our chief executive officer and our other executive officers;
- annually reviewing and making recommendations to our board of directors with respect to the compensation of our chief executive officer and determining the compensation for our other executive officers;
- reviewing and making recommendations to our board of directors with respect to director compensation; and
- overseeing and administering our equity incentive plans.

From time to time, our compensation committee may use outside compensation consultants to assist it in analyzing our compensation programs and in determining appropriate levels of compensation and benefits. For example, in the fourth quarter of 2020, we engaged Compensia, Inc., a compensation consulting firm to compensation committees, to advise us on compensation philosophy as we transition towards becoming a publicly-traded company, selection of a group of peer companies to use for compensation benchmarking purposes and cash and equity compensation levels for our directors, executives and other employees based on current market practices. The compensation committee will review and evaluate, at least annually, the performance of the compensation committee and its members, including compliance by the compensation committee with its charter.

Nominating, Compliance and Governance Committee

Effective upon the consummation of this offering, the members of our nominating, compliance and governance committee will be Richard W. Mott, John K. Bakewell, and James T. Treace, and Mr. Mott will serve as the chair of this committee. Messrs. Mott and Bakewell meet the independence requirements of under the applicable rules and regulations of the Nasdaq Global Market relating to nominating, compliance and governance committee independence. The nominating, compliance and governance committee will operate under a written charter that satisfies the applicable standards of the SEC and the Nasdaq Global Market.

The nominating, compliance and governance committee's responsibilities include:

- identifying individuals qualified to become board members and recommending directors;
- nominating board members for committee membership;
- monitoring compliance with the code of business conduct and ethics;
- overseeing our policies and programs related to compliance with laws and regulations;
- reviewing hotline reports and compliance investigations (other than reports related to accounting, internal accounting controls, fraud or auditing matters), "whistleblower" reporting and non-retaliation policies;
- receiving information about current and emerging risks and regulatory and enforcement trends, governing inquiries or third-party claims;
- developing and recommending to our board corporate governance guidelines; and
- overseeing the evaluation of our board of directors and its committees and management.

Role of the Board in Risk Oversight

While our board of directors does not have a standing risk management committee, our audit committee is responsible for overseeing our risk management and risk assessment processes on behalf of the board of directors and our nominating, compliance and governance committee is responsible for overseeing compliance programs related to legal and regulatory risks. Going forward, we expect that the audit committee will receive reports from management on at least a quarterly basis regarding our assessment of risks and risk management policies, including investment policies, insurance programs and cybersecurity. We expect the nominating, compliance and governance committee will receive periodic reports from management about current and emerging risks and regulatory and enforcement trends, governmental inquiries or third-party claims. In addition, the audit committee and nominating, compliance and governance committee both report regularly to the board of directors, which also considers our risk profile. Our audit committee, nominating, compliance and governance committee and board focus on the most significant risks we face and our general risk management strategies. While the board of directors oversees our risk management, management is responsible for day-to-day risk management processes. Our board of directors expects management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the audit committee, nominating, compliance and governance and the board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that our board of directors' leadership structure, which also emphasizes the independence of the board of directors in its oversight of its business and affairs, supports this approach.

Code of Business Conduct and Ethics

Our board of directors has adopted a written code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Following the completion of this offering, our code of business conduct and ethics will be available on our website at

www.treace.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements. The reference to our website address in this prospectus does not incorporate by reference into this prospectus the information on or accessible through our website, and you should not consider it to be a part of this prospectus. The inclusion of our website address in this prospectus is an inactive textual reference only.

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation and our amended and restated bylaws, both of which will become effective immediately prior to the completion of this offering will contain provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware General Corporation Law (DGCL). The DGCL provides that directors of a corporation will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for any:

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

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or recession.

Our amended and restated certificate of incorporation and amended and restated bylaws requires us to indemnify our directors and officers, in each case to the fullest extent permitted by DGCL. Our amended and restated bylaws also provide that we are obligated to advance expenses (including attorney's fees and disbursements) incurred by any indemnified person in advance of the final disposition of any action or proceeding, and permits us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law.

We have entered, and expect to continue to enter, into separate agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons under the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers.

We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers. However, the limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damages.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serve as a member of the board of directors (other than John T. Treace, our Chief Executive Officer) or as a member of the compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or its compensation committee. None of the current members of the compensation committee of our board of directors has been one of our employees within the past five years.

Board Diversity

Upon consummation of this offering, our nominating, compliance and governance committee will be responsible for reviewing with our board of directors, on an annual basis, the appropriate characteristics, skills and experience required for our board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members), the nominating, compliance and governance committee, in recommending candidates for election, and our board of directors, in approving (and, in the case of vacancies, appointing) such candidates, may take into account many factors, including but not limited to the following:

- personal and professional integrity;
- ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly held company;
- experience in the industries in which we compete;
- experience as a board member or executive officer of another publicly held company;
- diversity of expertise and experience in substantive matters pertaining to our business relative to other board members;
- conflicts of interest; and
- practical and mature business judgment.

Currently, our board of directors evaluates, and following the consummation of this offering will evaluate, each individual in the context of our board of directors as a whole, with the objective of assembling a group that can best maximize the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

Director Compensation

Before November 2020, non-employee members of our board of directors did not receive any cash compensation for service on our board of directors or committees, including attending board and committee meetings. However, we did reimburse our non-employee directors for travel, lodging and other reasonable expenses incurred in attending board, committee and other company related meetings. In November 2020, Messrs. Bakewell and Hamilton joined the board. In appointing Messrs. Bakewell and Hamilton and preparing for this offering, the board adopted the director compensation policies described below and began paying these fees to Messrs. Bakewell and Hamilton. Pursuant to their respective offer letters, Messrs. Bakewell and Hamilton are entitled to annual cash compensation consisting of $40,000, as well as additional retainers for service as a Chairperson or member of one or more committees of the board. The additional annual retainers for committee

service are as follows: (i) audit committee (Chair: $20,000; member: $10,000); (ii) compensation committee (Chair: $15,000; member: $7,000) and (iii) nominating, compliance and governance committee (Chair: $10,000; member: $5,000). All annual retainers are paid on a quarterly basis (in arrears) and pro-rated for partial year service. Since they did not start until November 2020, no cash compensation was paid to Messrs. Bakewell and Hamilton in 2020. In connection with their initial appointment to the board in November 2020, we granted each of Messrs. Bakewell and Hamilton an option to purchase 85,366 shares of our common stock. Each option will vest with respect to 1/36th of the shares subject to the option on each monthly anniversary of November 17, 2020 and will fully vest if the company experiences a merger or change in control, subject to the applicable holder's continued service through the vesting date.

The following table sets forth information for 2020 regarding the compensation awarded to, earned by or paid to our non-employee directors. Directors who are also our employees receive no additional compensation for their service as directors. During 2020, John T. Treace, who is one of our directors, was also an employee of our company. See "Executive Compensation—Summary Compensation Table" for additional information about the compensation for Mr. John T. Treace for his service as an employee.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
John K. Bakewell	—	175,000	175,000
F. Barry Bays	—	—	—
Lawrence W. Hamilton	—	175,000	175,000
Richard W. Mott	—	—	—
Thomas E. Timbie	—	—	—
James T. Treace	—	—	—
John R. Treace	—	—	—

(1) Amounts shown represents the grant date fair value of options granted during fiscal year 2020 as calculated in accordance with ASC Topic 718. See Note 2 of the financial statements included elsewhere in this prospectus for the assumptions used in calculating this amount. These amounts do not correspond to the actual value that may be recognized by the director upon exercise of the applicable awards or sale of the underlying shares of stock. As of December 31, 2020, Messrs. Bakewell and Hamilton each held options to purchase 85,366 shares of our common stock, and none of the other non-employee directors hold any options.

Outside Director Compensation Policy

After the completion of this offering, all of our non-employee director will be eligible to receive compensation for his or her service consisting of annual cash retainers and equity awards pursuant to our director compensation program. Our board of directors will have the discretion to revise non-employee director compensation as it deems necessary or appropriate.

Cash Compensation.

All non-employee directors will be entitled to receive the following cash compensation for their services following the completion of this offering:

- $40,000 per year for services as a board member;
- $35,000 per year additionally for service as chairman of the board of directors;
- $20,000 per year additionally for service as chairman of the audit committee;
- $10,000 per year additionally for service as an audit committee member;
- $15,000 per year additionally for service as chairman of the compensation committee;
- $7,000 per year additionally for service as a compensation committee member;

- $10,000 per year additionally for service as chairman of the nominating, compliance and governance committee; and
- $5,000 per year additionally for service as a nominating, compliance and governance committee member.

Each annual cash retainer and additional annual fee will be paid quarterly in arrears on a prorated basis.

Equity Compensation.

Non-employee directors will be entitled to receive all types of awards (except incentive stock options) under the 2021 Plan (or the applicable equity plan in place at the time of grant), including discretionary awards not covered under the outside director compensation policy. Following the completion of this offering, nondiscretionary, automatic grants of stock options will be made to our non-employee directors as follows:

- Initial option grant. Each person who first becomes a non-employee director after the completion of this offering will be granted an award of stock options with a value of $175,000.
- Annual option grant. Each non-employee director will be granted an award of stock options with a value of $120,000 on the date of each annual meeting of stockholders, beginning with the 2022 annual meeting.

The "value" for the options described above means the grant date fair value calculated in accordance with the Black-Scholes option valuation methodology, or such other methodology our board of directors or compensation committee may determine. The term of each option described above will be ten years from the date of grant, subject to earlier termination as provided in the 2021 Plan. The exercise price per share of each option will equal 100% of the fair market value of one share of our common stock on the date of grant.

Subject to the applicable provisions of the 2021 Plan as further described under the section titled "Equity Compensation Plans," each (1) initial option grant will be scheduled to vest over a three year period from the date of grant with one-36th of the shares subject to such option grant vesting each month and (2) the annual option grant will be scheduled to vest over a twelve month period from the date of grant with one-12th of the shares subject to such option grant vesting each month, in each case vesting is subject to the non-employee director continuing to provide services to our company on the applicable vesting date.

EXECUTIVE COMPENSATION

This discussion contains forward looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

We seek to ensure that the total compensation paid to our executive officers is reasonable and competitive. Compensation of our executives is structured around the achievement of individual performance and near-term corporate targets as well as long-term business objectives.

Our named executive officers (NEOs) for fiscal year 2020 were as follows:

- John T. Treace, our Chief Executive Officer, Director and Founder;
- Mark L. Hair, our Chief Financial Officer;
- Jaime A. Frias, our Chief Legal & Compliance Officer and Secretary; and
- Robert P. Jordheim, our former Chief Financial Officer.

Mr. Jordheim ceased to serve as our Chief Financial Officer in July 2020, but provided advisory services to us through December 2020. Following Mr. Jordheim's departure, Mr. Hair joined us as our Chief Financial Officer in September 2020.

2020 Summary Compensation Table

The following table sets forth total compensation paid to our NEOs for the fiscal year ending on December 31, 2020.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation ($)(3)	All Other Compensation ($)(4)	Total ($)
John T. Treace	2020	294,615	—	—	76,246	—	370,861
Chief Executive Officer, Director and Founder							
Mark L. Hair(5)	2020	75,000	10,000	820,000	19,410	—	924,410
Chief Financial Officer							
Jaime A. Frias	2020	210,550	5,000	37,800	55,490	—	308,840
Chief Legal & Compliance Officer and Secretary							
Robert P. Jordheim(6)	2020	128,845		37,800	—	287,300	453,945
Former Chief Financial Officer							

(1) Amounts reflect (i) for Mr. Frias, a one-time discretionary bonus paid to him in connection with his annual performance bonus and (ii) a signing bonus paid in September 2020 when Mr. Hair joined our company.

(2) The amounts reported represent the aggregate grant-date fair value of the stock options awarded to the NEOs in 2020, calculated in accordance with ASC Topic 718. The assumptions used in calculating the grant-date fair value of the options reported in this column are set forth in Note 10 of the financial statements included elsewhere in this prospectus.

(3) Annual cash incentive amounts for all NEOs were paid in February 2021, under our 2020 Bonus Plan, as described in the section below titled "Executive Compensation—Non-Equity Incentive Plan Compensation." The amount for Mr. Hair was pro-rated for his partial employment starting in September 2020.

(4) The amount reported for Mr. Jordheim consists of $279,823 paid by us for his cash severance plus $7,477 to cover COBRA premiums. Please see the description set forth below titled "Separation Agreement for Robert P. Jordheim" for further details on Mr. Jordheim's payments.

(5) Mr. Hair joined our company in September 2020.
(6) Mr. Jordheim left our company in July 2020, but provided advisory services to us through December 2020.

Narrative to Summary Compensation Table

2020 Salaries

Our NEOs each receive a base salary to compensate them for services rendered to our company. The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. For fiscal year 2020, effective as of February 5, 2020, Mr. Treace's base salary was $320,000, Mr. Frias' base salary was $221,048 and Mr. Jordheim's base salary was $226,883. Mr. Hair's base salary was $300,000, pro-rated for his partial employment commencing in September 2020. Our board of directors and compensation committee may adjust base salaries from time to time in their discretion. In February 2021, our board approved increasing Messrs. Treace, Hair and Frias' base salaries to $380,000, $303,000 and $270,000, respectively, with such increases being effective upon approval. In March 2021, our board of directors approved increasing Messrs. Treace and Hair's base salaries to $400,000 and $320,000, respectively, contingent and effective upon the effectiveness of the registration statement to which this prospectus relates.

Non-Equity Incentive Payments for 2020

Each of our NEOs participates in our annual cash incentive plan. Our annual cash incentive plan for 2020 (2020 Bonus Plan) provided for cash incentive compensation based upon achievement of our revenue and adjusted EBITDA performance goals for 2020. For the 2020 Bonus Plan, the target bonus for each of our NEOs is 40% of the NEO's base salary paid (not earned) from the start of the plan year to the end of the plan year. The 2020 Bonus Plan was amended in July 2020 to adjust revenue and EBITDA targets due to the COVID-19 pandemic and the associated temporary suspension of elective surgeries. After a review of our revenue and EBITDA goals against targets, based on the formula in the 2020 Bonus Plan, we paid bonuses at 64.7% of the target amount. Mr. Hair's payment under the 2020 Bonus Plan was pro-rated for his partial service commencing in September 2020. Mr. Frias also received an additional one-time cash bonus of $5,000 on top of his annual performance bonus for his individual performance in 2020. In March 2021, our board of directors approved changing the 2021 bonus targets for each of Messrs. Treace, Hair and Frias to 75%, 50% and 50%, respectively, of their base salary, in each case, contingent and effective upon the effectiveness of the registration statement to which this prospectus relates.

Equity-Based Compensation

In fiscal year 2020, we made equity award grants to each of our NEOs, except for Mr. Treace. In January 2020, we granted Messrs. Frias and Jordheim each an option to purchase 31,500 shares of our common stock. In September 2020, in connection with his commencement of employment, we granted Mr. Hair an option to purchase 240,000 shares of our common stock. In addition, in October 2020, Mr. Hair received another option to purchase 160,000 shares of our common stock. Each of Mr. Hair's options vests as to 25% of the shares on each anniversary of September 21, 2020, subject to his continuing to provide services to us through such vesting date.

We intend to adopt a 2021 Incentive Award Plan, referred to below as the 2021 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our NEOs) and consultants of our company and certain of its affiliates and to enable us to obtain and retain services of these individuals, which is essential to our long-term success. We expect that the 2021 Plan will be effective on the date on which it is adopted by our board of directors, subject to approval of such plan by our stockholders. For additional information about the 2021 Plan, please see the section titled "2021 Incentive Award Plan" below.

Other Elements of Compensation

Retirement Savings and Health and Welfare Benefits

Effective as of January 2021, we adopted a 401(k) profit sharing plan for our employees, including our NEOs, who satisfy certain eligibility requirements. Our NEOs are eligible to participate in the 401(k) plan on the same terms as other full-time employees. We match 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 us on a one to six year graded vesting schedule. We believe that providing a vehicle for tax-deferred retirement savings through our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our NEOs, in accordance with our compensation policies. All of our full-time employees, including our NEOs, are eligible to participate in our health and welfare plans.

Perquisites and Other Personal Benefits

We determine perquisites on a case-by-case basis and will provide a perquisite to an NEO when we believe it is necessary to attract or retain the NEO. For fiscal year 2020, no NEO received any additional perks. In connection with his commencement of employment with us and his travel to our offices in the Jacksonville area, we agreed to reimburse Mr. Hair for his temporary housing and travel before his full-time relocation that is anticipated to occur in 2021 and related tax gross-up payment for the relocation, housing and commuting expenses. No such payments or reimbursements were paid to Mr. Hair in 2020.

Outstanding Equity Awards at 2020 Fiscal Year-End

The following table sets forth information regarding outstanding stock options and stock awards held by our NEOs as of December 31, 2020. Mr. Treace has not been granted any stock options. In connection with Mr. Jordheim's departure in July 2020, any unvested equity awards were terminated as of the date of termination and Mr. Jordheim exercised all of his outstanding vested equity awards that remained outstanding during his advisory services before December 31, 2020.

	Option Awards				
Name	Vesting Commencement Date[1]	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)	Option Expiration Date
Mark L. Hair	9/21/2020	—	240,000	7.81	9/21/2030
	9/21/2020	—	160,000	7.81	9/21/2030
Jaime A. Frias	7/1/2014[2]	50,000	—	0.13	7/1/2024
	7/28/2015[2]	50,000	—	0.96	7/28/2025
	1/26/2016[2]	20,000	—	0.96	1/26/2026
	1/30/2017[2]	18,000	—	1.40	1/30/2027
	7/24/2017	224,999	75,001	1.40	7/24/2027
	1/23/2018	10,000	10,000	1.40	1/23/2028
	1/22/2019	10,000	30,000	2.10	1/22/2029
	1/21/2020	—	31,500	5.38	1/21/2030

(1) Each of the outstanding equity awards was granted under our 2014 Stock Plan and the individual option agreements provide that each option will accelerate upon a change in control (as defined in the 2014 Stock Plan), subject to the NEO's continued service through immediately prior such change in control. Unless otherwise indicated, the options generally vest over four years from the grant date in 25% annual installments on the first four anniversaries of the vesting commencement date, subject to the applicable NEO's continued service through each such vesting date.

(2) The option vests over three years from the grant date in one-third annual installments on the first three anniversaries of the vesting commencement date, subject to Mr. Frias' continued service through each such vesting date.

Executive Compensation Arrangements

NEO Change in Control and Severance Agreements

In October 2020, we entered into change of control agreements with each of our NEOs other than Mr. Treace. Under each of these agreements, if, within the period 18 months after a "change of control" (such period, the change in control period), we terminate the employment of the applicable NEO without "cause" (excluding by reason of the employee's death or "disability,") or the NEO resigns for "good reason" (as such terms are defined in the NEO's change of control and severance agreement) and the NEO executes a separation agreement and release of claims that becomes effective and irrevocable within 60 days following the NEO's termination and provides a written attestation that his or her confidentiality agreement is in effect and enforceable, the NEO is entitled to receive (i) continued payment of the NEO's annual base salary for 12 months, (ii) payment over a 12 month period equal to 100% of the NEO's annual target bonus for the year in which the termination occurs, (iii) reimbursement of COBRA premiums for 18 months, and (iv) up to $10,000 in outplacement services.

In addition, pursuant to individual option agreements under the 2014 Stock Plan, each NEO's outstanding stock options will accelerate in full upon a change in control (as defined in the 2014 Stock Plan), subject to the NEO's continued service through immediately prior such change in control.

Under each of these agreements, in the event any payment to the applicable employee under his or her change of control and severance agreement would be subject to the excise tax imposed by Section 4999 of the Code (as a result of a payment being classified as a parachute payment under Section 280G of the Code), the employee will receive 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 the NEO's projected marginal income tax rates) on such lump sum payment.

Under the severance agreement with Mr. Hair, we also agreed to pay Mr. Hair severance benefits equal to those payable upon a change of control as described above if Mr. Hair's employment is terminated without cause or he resigns for good reason if such termination occurs on or before September 21, 2022, regardless of whether such termination occurs before or after a change in control.

Offer Letter Agreement for Mark Hair

In connection with Mr. Hair's commencement of employment with us in September 2020, we entered into an offer letter agreement under which he was entitled to an annual base salary, target annual bonus, eligibility to participate in our benefit plans and an option as described above. Mr. Hair's annual salary under the offer letter agreement is $300,000. Mr. Hair was also eligible to receive a sign-on bonus of $10,000, payable in connection with his commencement of employment with us in September 2020 and a stock option grant equal to 0.6% of our fully diluted shares. Accordingly, we granted him an option to purchase 240,000 shares, which shall vest with respect to 25% of the shares on each anniversary of September 21, 2020, subject to Mr. Hair's continued service through the applicable vesting date. We also agreed to pay Mr. Hair a special event bonus of $150,000 at completion of the earlier of (i) the closing of a fully underwritten, firm commitment public offering with proceeds exceeding $50 million, or (ii) the sale of our company which results in a change of control. Mr. Hair was also eligible to receive an additional option grant equal to 0.4% of our fully diluted shares if by May 1, 2021, no change of control of our company has occurred and Mr. Hair is still employed by us. We granted him this option in October 2020 to purchase 160,000 shares. The additional option shall vest with respect to 25% of the shares on each anniversary of September 21, 2020, subject to Mr. Hair's continued service through the applicable vesting date. In connection with Mr. Hair's relocation to the Jacksonville area from California anticipated to occur in 2021, the offer letter agreement and a subsequent understanding between Mr. Hair and us provide that (1) he will receive temporary housing reimbursements up to $3,000 per month through August 2021, (2) reimbursement of reasonable round trip travel to our offices in Jacksonville from Mr. Hair's home office in California up to once every two weeks and (3) a tax gross-up payment for any taxes owed by Mr. Hair related to the reimbursements by us for the temporary housing and travel expenses.

Offer Letter Agreement for Jaime A. Frias

In connection with Mr. Frias' commencement of employment with us in July 2017, we entered into an offer letter agreement under which he was entitled to an annual base salary, target annual bonus and an initial stock option grant and is eligible to participate in our benefit plans.

Separation Agreement for Robert P. Jordheim

Effective as of July 2020, Mr. Jordheim ceased to serve as our Chief Financial Officer, but continued to provide advisory services to us through December 2020. In connection with Mr. Jordheim's separation, we entered into a release agreement where we provided to Mr. Jordheim (i) an aggregate separation payment of $279,823 (representing 12 months of base salary and pro-rated annual performance bonus assuming target achievement through his termination date) and (ii) payment of continued health, dental and vision insurance premiums for himself and any covered dependents for 12 months. In addition, all of Mr. Jordheim's unvested shares subject to his options as of his separation date were terminated for no consideration in accordance with their terms, and his vested shares subject to his options remained outstanding while he provided advisory services to us. The separation benefits set forth in Mr. Jordheim's separation agreement are in full satisfaction of his separation benefits under his change in control severance agreement and were in exchange of a general release of claims against us and our affiliates and continued compliance with his confidentiality, non-competition, non-solicitation and inventions assignment agreement.

Equity Compensation Plans

The following summarizes the material terms of the long-term incentive compensation plan in which our NEOs will be eligible to participate following the consummation of this offering and our 2014 Stock Plan, under which we have previously made periodic grants of equity and equity-based awards to our named executive officers and other key employees.

2021 Incentive Award Plan

We intend to adopt the 2021 Plan, which will be effective on the day before the first public trading date of our common stock. The principal purpose of the 2021 Plan is to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards. The material terms of the 2021 Plan, as it is currently contemplated, are summarized below.

Share Reserve. Under the 2021 Plan, shares of our common stock will be initially reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights (SARs), 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 an annual increase on the first day of each fiscal year beginning in 2022 and ending in 2031, equal to the lesser of (i) % 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 shares of stock may be issued upon the exercise of incentive stock options.

The following counting provisions will be in effect for the share reserve under the 2021 Plan:

- to the extent that an award terminates, expires or lapses for any reason or an award 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;
- 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 2021 Plan, such tendered or withheld shares will be available for future grants under the 2021 Plan;

- to the extent shares subject to SARs are not issued in connection with the stock settlement of SARs on exercise thereof, such shares will be available for future grants under the 2021 Plan;
- to the extent that shares of our common stock are repurchased by us prior to vesting so that shares are returned to us, such shares will be available for future grants under the 2021 Plan;
- the payment of dividend equivalents in cash in conjunction with any outstanding awards will not be counted against the shares available for issuance under the 2021 Plan; and
- to the extent permitted by applicable law or any exchange rule, shares issued in assumption of, or in substitution for, any outstanding awards of any entity acquired in any form of combination by us or any of our subsidiaries will not be counted against the shares available for issuance under the 2021 Plan.

Administration. The compensation committee of our board of directors is expected to administer the 2021 Plan unless our board of directors assumes authority for administration. The compensation committee must consist of at least three members of our board of directors, each of whom is intended to qualify as a "non-employee director" for purposes of Rule 16b-3 under the Exchange Act and an "independent director" within the meaning of the rules of the applicable stock exchange, or other principal securities market on which shares of our common stock are traded. The 2021 Plan provides that the board or compensation committee may delegate its authority to grant awards to employees other than our executive officers and certain senior executives to a committee consisting of one or more members of our board of directors or one or more of our officers, other than awards made to our non-employee directors, which must be approved by our full board of directors.

Subject to the terms and conditions of the 2021 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the number of shares to be subject to awards and the terms and conditions of awards, and to make all other determinations and to take all other actions necessary or advisable for the administration of the 2021 Plan. The administrator is also authorized to adopt, amend or rescind rules relating to administration of the 2021 Plan. Our board of directors may at any time remove the compensation committee as the administrator and revest in itself the authority to administer the 2021 Plan. The full board of directors will administer the 2021 Plan with respect to awards to non-employee directors.

Eligibility. Options, SARs, restricted stock and all other stock-based and cash-based awards under the 2021 Plan may be granted to individuals who are then our officers, employees or consultants or are the officers, employees or consultants of certain of our subsidiaries. Such awards also may be granted to our directors. Only employees of our company or certain of our subsidiaries may be granted incentive stock options.

Awards. The 2021 Plan provides that the administrator may grant or issue stock options, SARs, restricted stock, restricted stock units, other stock- or cash-based awards and dividend equivalents, or any combination thereof. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

- *Nonstatutory Stock Options* (NSOs), will provide for the right to purchase shares of our common stock at a specified price which may not be less than fair market value on the date of grant, and usually will become exercisable (at the discretion of the administrator) in one or more installments after the grant date, subject to the participant's continued employment or service with us and/or subject to the satisfaction of corporate performance targets and individual performance targets established by the administrator. NSOs may be granted for any term specified by the administrator that does not exceed ten years.
- *Incentive Stock Options* (ISOs), will be designed in a manner intended to comply with the provisions of Section 422 of the Code and will be subject to specified restrictions contained in the Code. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, and must not be exercisable after a period of ten years measured from the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) at least 10% of the total combined voting power of all

classes of our capital stock, the 2021 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must not be exercisable after a period of five years measured from the date of grant.

- *Restricted Stock* may be granted to any eligible individual and made subject to such restrictions as may be determined by the administrator. Restricted stock, typically, may be forfeited for no consideration or repurchased by us at the original purchase price if the conditions or restrictions on vesting are not met. In general, restricted stock may not be sold or otherwise transferred until restrictions are removed or expire. Purchasers of restricted stock, unlike recipients of options, will have voting rights and will have the right to receive dividends, if any, before the time when the restrictions lapse, however, extraordinary dividends will generally be placed in escrow, and will not be released until restrictions are removed or expire.
- *Restricted Stock Units* may be awarded to any eligible individual, typically without payment of consideration, but subject to vesting conditions based on continued employment or service or on performance criteria established by the administrator. Like restricted stock, restricted stock units may not be sold, or otherwise transferred or hypothecated, until vesting conditions are removed or expire. Unlike restricted stock, stock underlying restricted stock units will not be issued until the restricted stock units have vested, and recipients of restricted stock units generally will have no voting or dividend rights before the time when vesting conditions are satisfied.
- *SARs* may be granted in connection with stock options or other awards, or separately. SARs granted in connection with stock options or other awards typically will provide for payments to the holder based upon increases in the price of our common stock over a set exercise price. The exercise price of any SAR granted under the 2021 Plan must be at least 100% of the fair market value of a share of our common stock on the date of grant. SARs under the 2021 Plan will be settled in cash or shares of our common stock, or in a combination of both, at the election of the administrator.
- *Other Stock or Cash Based Awards* are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock or cash based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards. The plan administrator will determine the terms and conditions of other stock or cash based awards, which may include vesting conditions based on continued service, performance and/or other conditions.
- *Dividend Equivalents* represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards other than stock options or SARs. Dividend equivalents are credited as of dividend payments dates during the period between a specified date and the date such award terminates or expires, as determined by the plan administrator. In addition, dividend equivalents with respect to shares covered by a performance award will only be paid to the participant at the same time or times and to the same extent that the vesting conditions, if any, are subsequently satisfied and the performance award vests with respect to such shares.

Any award may be granted as a performance award, meaning that the award will be subject to vesting and/or payment based on the attainment of specified performance goals.

Change in Control. In the event of a change in control, unless the plan administrator elects to terminate an award in exchange for cash, rights or other property, or cause an award to accelerate in full before the change in control, such award will continue in effect or be assumed or substituted by the acquirer, provided that any performance-based portion of the award will be subject to the terms and conditions of the applicable award agreement. In the event the acquirer refuses to assume or replace awards granted, before the consummation of such transaction, awards issued under the 2021 Plan will be subject to accelerated vesting such that 100% of such

awards will become vested and exercisable or payable, as applicable. The administrator may also make appropriate adjustments to awards under the 2021 Plan and is authorized to provide for the acceleration, cash-out, termination, assumption, substitution or conversion of such awards in the event of a change in control or certain other unusual or nonrecurring events or transactions.

Adjustments of Awards. In the event of any stock dividend or other distribution, stock split, reverse stock split, reorganization, combination or exchange of shares, merger, consolidation, split-up, spin-off, recapitalization, repurchase or any other corporate event affecting the number of outstanding shares of our common stock or the share price of our common stock that would require adjustments to the 2021 Plan or any awards under the 2021 Plan in order to prevent the dilution or enlargement of the potential benefits intended to be made available thereunder, the administrator will make appropriate, proportionate adjustments to: (i) the aggregate number and type of shares subject to the 2021 Plan; (ii) the number and kind of shares subject to outstanding awards and terms and conditions of outstanding awards (including, without limitation, any applicable performance targets or criteria with respect to such awards); and (iii) the grant or exercise price per share of any outstanding awards under the 2021 Plan.

Amendment and Termination. The administrator may terminate, amend or modify the 2021 Plan at any time and from time to time. However, we must generally obtain stockholder approval to the extent required by applicable law, rule or regulation (including any applicable stock exchange rule). Notwithstanding the foregoing, an option may be amended to reduce the per share exercise price below the per share exercise price of such option on the grant date and options may be granted in exchange for, or in connection with, the cancellation or surrender of options having a higher per share exercise price without receiving additional stockholder approval.

No incentive stock options may be granted pursuant to the 2021 Plan after the tenth anniversary of the effective date of the 2021 Plan, and no additional annual share increases to the 2021 Plan's aggregate share limit will occur from and after such anniversary. Any award that is outstanding on the termination date of the 2021 Plan will remain in force according to the terms of the 2021 Plan and the applicable award agreement.

2021 Employee Stock Purchase Plan

We intend to adopt and ask our stockholders to approve the 2021 Employee Stock Purchase Plan, which we refer to as our ESPP, which will be effective upon the day prior to the effectiveness of the registration statement to which this prospectus relates. The ESPP is designed to allow our eligible employees to purchase shares of our common stock, at semi-annual intervals, with their accumulated payroll deductions. The ESPP is intended to qualify under Section 423 of the Code. The material terms of the ESPP, as it is currently contemplated, are summarized below.

Administration. Subject to the terms and conditions of the ESPP, our compensation committee will administer the ESPP. Our compensation committee can delegate administrative tasks under the ESPP to the services of an agent and/or employees to assist in the administration of the ESPP. The administrator will have the discretionary authority to administer and interpret the ESPP. Interpretations and constructions of the administrator of any provision of the ESPP or of any rights thereunder will be conclusive and binding on all persons. We will bear all expenses and liabilities incurred by the ESPP administrator.

Share Reserve. The maximum number of shares of our common stock which will be authorized for sale under the ESPP is equal to the sum of (i) shares of common stock and (ii) an annual increase on the first day of each year beginning in 2022 and ending in 2031, equal to the lesser of (1) 1% of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (2) such number of shares of common stock as determined by our board of directors; provided, however, no more than shares of our common stock may be issued under the ESPP. The shares reserved for issuance under the ESPP may be authorized but unissued shares or reacquired shares.

Eligibility. Employees eligible to participate in the ESPP for a given offering period generally include employees who are employed by us or one of our subsidiaries on the first day of the offering period, or the enrollment date. Our employees (and, if applicable, any employees of our subsidiaries) who customarily work less than five months in a calendar year or are customarily scheduled to work less than 20 hours per week will not be eligible to participate in the ESPP. Finally, an employee who owns (or is deemed to own through attribution) 5% or more of the combined voting power or value of all our classes of stock or of one of our subsidiaries will not be allowed to participate in the ESPP.

Participation. Employees will enroll under the ESPP by completing a payroll deduction form permitting the deduction from their compensation of at least 1% of their compensation but not more than the lesser of 15% of their compensation or $50,000. Such payroll deductions may be expressed as either a whole number percentage or a fixed dollar amount, and the accumulated deductions will be applied to the purchase of shares on each purchase date. However, a participant may not purchase more than 15,000 shares in each offering period and may not subscribe for more than $25,000 in fair market value of shares of our common stock (determined at the time the option is granted) during any calendar year. The ESPP administrator has the authority to change these limitations for any subsequent offering period.

Offering. Under the ESPP, participants are offered the option to purchase shares of our common stock at a discount during a series of successive offering periods, the duration and timing of which will be determined by the ESPP administrator. However, in no event may an offering period be longer than 27 months in length.

The option purchase price will be the lower of 85% of the closing trading price per share of our common stock on the first trading date of an offering period in which a participant is enrolled or 85% of the closing trading price per share on the purchase date, which will occur on the last trading day of each offering period.

Unless a participant has previously canceled his or her participation in the ESPP before the purchase date, the participant will be deemed to have exercised his or her option in full as of each purchase date. Upon exercise, the participant will purchase the number of whole shares that his or her accumulated payroll deductions will buy at the option purchase price, subject to the participation limitations listed above.

A participant may cancel his or her payroll deduction authorization at any time before the end of the offering period. Upon cancellation, the participant will have the option to either (i) receive a refund of the participant's account balance in cash without interest or (ii) exercise the participant's option for the current offering period for the maximum number of shares of common stock on the applicable purchase date, with the remaining account balance refunded in cash without interest. Following at least one payroll deduction, a participant may also decrease (but not increase) his or her payroll deduction authorization once during any offering period. If a participant wants to increase or decrease the rate of payroll withholding, he or she may do so effective for the next offering period by submitting a new form before the offering period for which such change is to be effective.

A participant may not assign, transfer, pledge or otherwise dispose of (other than by will or the laws of descent and distribution) payroll deductions credited to a participant's account or any rights to exercise an option or to receive shares of our common stock under the ESPP, and during a participant's lifetime, options in the ESPP shall be exercisable only by such participant. Any such attempt at assignment, transfer, pledge or other disposition will not be given effect.

Adjustments upon Changes in Recapitalization, Dissolution, Liquidation, Merger or Asset Sale. In the event of any increase or decrease in the number of issued shares of our common stock resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the common stock, or any other increase or decrease in the number of shares of common stock effected without receipt of consideration by us, we will proportionately adjust the aggregate number of shares of our common stock offered under the ESPP, the number and price of shares which any participant has elected to purchase under the ESPP and the maximum number of

shares which a participant may elect to purchase in any single offering period. If there is a proposal to dissolve or liquidate us, then the ESPP will terminate immediately before the consummation of such proposed dissolution or liquidation, and any offering period then in progress will be shortened by setting a new purchase date to take place before the date of our dissolution or liquidation. We will notify each participant of such change in writing at least ten business days before the new exercise date. If we undergo a merger with or into another corporation or sell all or substantially all of our assets, each outstanding option will be assumed or an equivalent option substituted by the successor corporation or the parent or subsidiary of the successor corporation. If the successor corporation refuses to assume the outstanding options or substitute equivalent options, then any offering period then in progress will be shortened by setting a new purchase date to take place before the date of our proposed sale or merger. We will notify each participant of such change in writing at least ten business days before the new exercise date.

Amendment and Termination. Our board of directors may amend, suspend or terminate the ESPP at any time. However, the board of directors may not amend the ESPP without obtaining stockholder approval within 12 months before or after such amendment to the extent required by applicable laws.

2014 Stock Plan, as Amended

2014 Stock Plan. Our board of directors adopted, and our stockholders approved, our 2014 Stock Plan (2014 Plan) in July 2014. Our 2014 Plan was most recently amended in November 2020. Our 2014 Plan allows for the grant of incentive stock options, within the meaning of Section 422 of the Code, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options and stock purchase rights to our employees, directors and consultants and our parent and subsidiary corporations' employees, directors and consultants.

Authorized Shares. Our 2014 Plan will be terminated in connection with this offering, and accordingly, no shares will be available for issuance under the 2014 Plan following the completion of this offering. Our 2014 Plan will continue to govern outstanding awards granted thereunder. As of December 31, 2020, options to purchase 6,042,544 shares of our common stock remained outstanding under our 2014 Plan. In the event that an outstanding option or other right for any reason expires or is canceled, the shares allocable to the unexercised portion of such option or other right shall be added to the number of shares then available for issuance under the 2021 Plan once adopted by our board of directors and our stockholders.

Plan Administration. Our board of directors or a committee of our board (the administrator) administers our 2014 Plan. Subject to the provisions of the 2014 Plan, the administrator has the full authority and discretion to take any actions it deems necessary or advisable for the administration of the 2014 Plan. All decisions, interpretations and other actions of the administrator are final and binding on all participants in the 2014 Plan.

Options. Stock options may be granted under our 2014 Plan. The exercise price per share of all incentive stock options must equal at least 100% of the fair market value per share of our common stock on the date of grant, as determined by the administrator. The term of a stock option may not exceed 10 years. With respect to any participant who owns 10% of the voting power of all classes of our outstanding stock as of the grant date, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price per share of such incentive stock option must equal at least 110% of the fair market value per share of our common stock on the date of grant, as determined by the administrator. The 2014 Plan administrator determines the terms and conditions of options.

After an employee, director or consultant ceases to be a "service provider" (as defined in the 2014 Plan), he or she may exercise his or her option for the period of time as specified in the applicable option agreement. If termination is due to death or disability, the option generally will remain exercisable for at least six months. In all other cases, the option will generally remain exercisable for at least 30 days. However, an option generally may not be exercised later than the expiration of its term.

Stock Purchase Rights. Stock purchase rights may be granted under our 2014 Plan as a purchasable award. The administrator will determine the purchase price, the number of shares granted to the award recipient and the time within which the person must accept the offer.

Transferability of Awards. Unless our administrator provides otherwise, our 2014 Plan generally does not allow for the transfer or assignment of options or stock purchase rights, except by will or by the laws of descent and distribution. Shares issued upon exercise of an option will be subject to such terms and conditions as the administrator may determine, including rights of first refusal and other transfer restrictions.

Certain Adjustments. In the event of a dividend or other distribution, recapitalization, stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of our common stock or other securities, or other change in our corporate structure affecting the common stock, the administrator has discretion to adjust the number and class of shares that may be delivered under the 2014 Plan and/or the number, class, and price of shares covered by each outstanding option or stock purchase right.

Merger or Change in Control. Our 2014 Plan provides that, in the event that we are a party to a merger or change in control, outstanding options and stock purchase rights shall be assumed or substituted by the successor corporation or a parent or subsidiary thereof. In the event the successor corporation refuses to assume or substitute for the option or stock purchase right, then the vesting of such awards will be fully accelerated and the administrator will notify the holder in writing or electronically that such awards will be fully exercisable and vested for a period of at least 15 days as determined by the administrator, and such awards will terminate upon expiration of such period. Notwithstanding the foregoing, our individual stock option agreements under the 2014 Plan all provide that, immediately upon a merger or a change in control of our company, the options shall fully vest and the option-holder will have the right to exercise all of the subject shares as of the date of such event.

Amendment; Termination. Our board of directors may amend, suspend or terminate our 2014 Plan at any time, provided that such action does not impair a participant's rights under outstanding awards without such participant's written consent. As noted above, upon completion of this offering, our 2014 Plan will be terminated and no further awards will be granted thereunder. All outstanding awards will continue to be governed by their existing terms.

CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS

Other than compensation arrangements, we describe below those transactions and series of similar transactions, since January 1, 2017, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000; and
- any of our directors, executive officers, or holders of more than 5% of our common stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Compensation arrangements for our directors and NEOs are described elsewhere in this prospectus.

Certain Transactions with Related Persons

Convertible Promissory Note Financing

On January 30, 2017, certain of our directors and officers collectively invested an aggregate of $2.1 million in our 8% convertible notes (the Convertible Notes). The aggregate principal amount and accrued interest on the Convertible Notes converted into shares of our Series A convertible preferred stock at a conversion price of $1.60 per share upon the initial closing of the initial tranche of our Series A convertible preferred stock financing in March 2017.

The following table summarizes the Convertible Notes purchased by our officers and directors and their affiliated entities or immediate family members.

Investor	Convertible Notes Purchased
F. Barry Bays	$ 446,000
Jaime A. Frias	$ 50,000
Richard W. Mott	$ 467,000
Thomas E. Timbie	$ 200,000
John R. Treace	$ 300,000
John T. Treace	$ 150,000
James T. Treace	$ 467,000

Series A Convertible Preferred Stock Financing

On May 1, 2017, we issued to certain of our directors and officers 3,040,625 shares of our Series A convertible preferred stock in exchange for a total of $4.865 million, including the $2.1 million from the Convertible Notes and an additional $2.765 million committed in the offering.

The following table summarizes the Series A convertible preferred stock originally purchased by our officers and directors and their affiliated entities or immediate family members. Each share of Series A convertible preferred stock will automatically convert into one share of our common stock upon the completion of this offering.

Investor	Shares of Series A Convertible Preferred Stock Purchased
F. Barry Bays	603,705
Jaime A. Frias	93,750
John K. Bakewell	250,000
Joe W. Ferguson	62,500
Richard W. Mott	510,625
Robert P. Jordheim	62,500
Thomas E. Timbie	218,750
John R. Treace	312,500
John T. Treace	218,750
James T. Treace	707,500

Stockholders Agreement

Certain of our stockholders, including James T. Treace, John. R. Treace, F. Barry Bays, Richard W. Mott and Thomas E. Timbie, and our NEOs, have entered into an amended and restated stockholders agreement, which will be terminated in connection with this offering by an agreement among the parties thereto.

Employment of Immediate Family

In October 2017, we hired Tori Dapas, the brother-in-law of John T. Treace and the son-in-law of John R. Treace, as a Regional Sales Manager. For 2020, Tori Dapas was paid a total of $0.2 million in salary.

Directed Share Program

At our request, the underwriters have reserved up to % of the shares offered by this prospectus for sale at the initial public offering price to certain individuals through a directed share program, including our directors, officers and certain other individuals identified by our officers or management. See the section titled “Underwriting” for additional information.

Indemnification Agreements and Directors’ and Officers’ Liability Insurance

We have entered into indemnification agreements with each of our directors and executive officers. These agreements will require us to, among other things, indemnify each of our directors and certain executive officers to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys’ fees, judgments, penalties, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person’s services as a director or executive officer. We have obtained an insurance policy that insures our directors and officers against certain liabilities, including liabilities arising under applicable securities laws. For additional information see the section titled. “Management—Limitations on Liability and Indemnification Matters.”

Policies and Procedures for Related Party Transactions

Our board of directors has adopted a written related person transaction policy, to be effective upon the consummation of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, a related person had or will have a direct or indirect material interest, including without limitation purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including but not limited to whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction with an unrelated third party and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy. However, all of the transactions described above were entered into after presentation, consideration and approval by our board of directors.

PRINCIPAL AND SELLING STOCKHOLDERS

The following table provides information concerning beneficial ownership of our common stock as of March 1, 2021, by:

- each person, or group of affiliated person, known by us to beneficially own more than 5% of our outstanding common stock;
- each of our directors;
- each of our named executive officers;
- all of our executive officers and directors as a group; and
- the selling stockholders, which are indicated by the stockholder shown as having shares listed in the column "Shares Being Offered" below.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days after December 31, 2020 through the exercise of any stock option, warrants or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of our common stock held by that person.

The percentage of shares beneficially owned is computed on the basis of 32,937,859 shares of our common stock outstanding as of December 31, 2020, which reflects the automatic conversion of all 5,000,000 of our outstanding shares of Series A convertible preferred stock into an equivalent number of shares of our common stock. Shares of our common stock that a person has the right to acquire within 60 days after December 31, 2020 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Percentage ownership of our common stock after the offering assumes the sale of shares by us and shares by the selling stockholders in this offering and no shares purchased by such parties in this offering.

Except as indicated in the footnotes to this table, (i) the persons or entities named have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them, and (ii) the address for each beneficial owner is c/o Treace Medical Concepts, Inc., 203 Fort Wade Rd., Suite 150, Ponte Vedra, Florida 32081.

When we refer to the "selling stockholder" in this prospectus, we mean the stockholder listed in the table below as offering shares, as well as the pledgees, donees, assignees, transferees, successors and others who may hold any of the selling stockholder's interests.

We have granted the underwriters an option exercisable for 30 days after the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price less estimated underwriting discounts and commissions. Such option is not reflected in the table below.

The table below excludes any purchases that may be made through our directed share program and any potential purchases in this offering by the beneficial owners identified in the table below.

For further information regarding material transactions between us and certain of our stockholders, see "Certain Relationships and Related Party Transactions."

	Shares Beneficially Owned Prior to the Offering					Shares Beneficially Owned After the Offering	
Name of Beneficial Owner	Number of Shares Outstanding	Number of Shares Exercisable Within 60 Days	Number of Shares Beneficially Owned	Percentage	Number of Shares Being Offered	Number of Shares Beneficially Owned	Percentage
John T. Treace(1)	8,347,255	—	12,022,255	35.9%			
John R. Treace(2)	2,017,159	—	2,842,159	8.5%			
Thomas E. Timbie(3)	2,103,409	—	2,103,409	6.3%			
James T. Treace(4)	1,641,875	—	2,737,783	8.2%			
Richard W. Mott(5)	1,257,215	—	1,557,215	4.7%			
F. Barry Bays(6)	1,285,028	—	1,285,028	3.8%			
Jaime A. Frias(7)	444,563	405,876	850,439	2.5%			
Robert P. Jordheim(8)	486,104	—	486,104	1.5%			
John K. Bakewell(9)	250,000	11,856	261,856	*			
Lawrence W. Hamilton(10)	—	11,856	11,856	*			
Mark L. Hair	—	—	—	*			
All executive officers and directors as a group (14 persons)(11)	17,895,108	1,904,089	25,695,105	72.7%			

* Indicates beneficial ownership of less than 1% of our total outstanding common stock.

(1) Consists of (i) 8,128,505 shares of our common stock, (ii) 218,750 shares of our Series A convertible preferred stock (which amount does not include any accrued but unpaid dividends that may be paid in kind as common stock in the future), (iii) 1,200,000 shares of our common stock held by Mr. Treace's wife, (iv) 1,375,000 shares of our common stock, held by Mr. Treace as trustee of a trust and (v) 1,100,000 shares of our common stock held by Mr. Treace's wife as co-trustee of a trust for Mr. Treace's descendants. Mr. Treace disclaims beneficial ownership of shares held by his wife directly or in trusts for which his wife serves as trustee or co-trustee.

(2) Consists of (i) 1,704,659 shares of our common stock, held jointly by Mr. Treace and Mr. Treace's wife, (ii) 312,500 shares of Series A convertible preferred stock (which amount does not include any accrued but unpaid dividends that may be paid in kind as common stock in the future), held jointly by Mr. Treace and Mr. Treace's wife, (iii) 400,000 shares of our common stock held by Mr. Treace as co-trustee of a trust and (iv) 425,000 shares of our common stock held by Mr. Treace as co-trustee of a trust. John R. Treace disclaims beneficial ownership of shares held in trusts for which he is a co-trustee.

(3) Consists of (i) 1,884,659 shares of our common stock and (ii) 218,750 shares of our Series A convertible preferred stock (which amount does not include any accrued but unpaid dividends that may be paid in kind as common stock in the future).

(4) Consists of (i) 1,350,000 shares of our common stock, (ii) 291,875 shares of our Series A convertible preferred stock (which amount does not include any accrued but unpaid dividends that may be paid in kind as common stock in the future) and (iii) 680,283 shares of common stock and 415,625 shares of our Series A Convertible Preferred Stock beneficially owned by J&A Group, LLC, a Florida limited liability company of which James T. Treace and his spouse are the managing members.

(5) Consists of (i) 746,590 shares of our common stock, (ii) 510,625 shares of our Series A convertible preferred stock (which amount does not include any accrued but unpaid dividends that may be paid in kind as common stock in the future) and (iii) 300,000 shares of our common stock owned by Mr. Mott's three children for which Mr. Mott has voting and dispositive power.

(6) Consists of (i) 983,153 shares of our common stock and (ii) 301,875 shares of our Series A convertible preferred stock (which amount does not include any accrued but unpaid dividends that may be paid in kind as common stock in the future).

(7) Consists of (i) 350,813 shares of our common stock, (ii) 93,750 shares of our Series A convertible preferred stock (which amount does not include any accrued but unpaid dividends that may be paid in kind as common stock in the future) and (iii) 405,876 shares of our common stock that may be acquired pursuant to the exercise of stock options within 60 days of March 1, 2021.

(8) Consists of (i) 423,604 shares of our common stock and (ii) 62,500 shares of our Series A convertible preferred stock (which amount does not include any accrued but unpaid dividends that may be paid in kind as common stock in the future).

(9) Consists of (i) 250,000 shares of our Series A convertible preferred stock (which amount does not include any accrued but unpaid dividends that may be paid in kind as common stock in the future) and (ii) 11,856 shares of our common stock that may be acquired pursuant to the exercise of stock options within 60 days of March 1, 2021.

(10) Consists of 11,856 shares of our common stock that may be acquired pursuant to the exercise of stock options within 60 days of March 1, 2021.

(11) Includes (i) 62,500 shares of our Series A convertible preferred stock (which amount does not include any accrued but unpaid dividends that may be paid in kind as common stock in the future) and (ii) 1,904,089 shares of our common stock that may be acquired pursuant to the exercise of stock options within 60 days of March 1, 2021.

DESCRIPTION OF CAPITAL 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, which will become effective immediately prior to the completion of this offering and of the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws, copies of which have been filed as exhibits to the prospectus of which this prospectus is part.

General

Upon the completion of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of shares of common stock, par value $0.001 per share, and shares of preferred stock, par value $0.001 per share. As of December 31, 2020, there were outstanding shares of common stock, on an as-converted basis, held of record by stockholders. In addition, shares of our common stock were issuable upon exercise of outstanding options granted under the 2014 Stock Plan. No shares of preferred stock will be issued or outstanding immediately after the offering contemplated by this prospectus. Unless our board of directors determines otherwise, we will issue all shares of our capital stock in uncertificated form.

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 will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of 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, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Preferred Stock

Immediately before the completion of this offering, all outstanding shares of our Series A convertible preferred stock will be converted into shares of our common stock. Upon the completion of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 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 our 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. Immediately after completion of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Options

As of December 31, 2020, we had outstanding options to purchase an aggregate of 6,042,544 shares of our common stock, with a weighted-average exercise price of $2.43 per share. For additional information regarding terms of our equity incentive plans, see the section titled “Executive and Director Compensation—Equity Compensation Plans.”

Warrants

The following table sets forth information about outstanding warrants to purchase shares of our stock as of December 31, 2020.

The warrants to purchase shares of our common stock will expire upon the earlier of the expiration date set forth in each warrant, which is December 29, 2029, our acquisition, a sale of all or substantially all our assets, or any sale or other transfer by our stockholders of shares representing at least a majority of our then-total outstanding combined voting power.

Class of Stock Underlying Warrants	Number of Shares of Stock Exercisable Prior to this Offering	Number of Shares of Common Stock Underlying Warrants on an As-Converted Basis	Exercise Price Per Share Prior to this Offering	Exercise Price Per Share on an As-Converted Basis
Common stock, par value $0.001			$	$

Dividends

The DGCL permits a corporation to declare and pay dividends out of “surplus” or, if there is no “surplus,” out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year. “Surplus” is defined as the excess of the net assets of the corporation over the amount determined to be the capital of the corporation by the board of directors. The capital of the corporation is typically calculated to be (and cannot be less than) the aggregate par value of all issued shares of capital stock. Net assets equal the fair value of the total assets minus total liabilities. The DGCL also provides that dividends may not be paid out of net profits if, after the payment of the dividend, remaining capital would be less than the capital represented by the outstanding stock of all classes having a preference upon the distribution of assets.

The declaration, amount and payment of any future dividends will be at the sole discretion of our board of directors. Our board of directors may take into account general and economic conditions, our financial condition and results of operations, our available cash and current and anticipated cash needs, capital requirements, contractual, legal, tax and regulatory restrictions and implications on the payment of dividends by us to our stockholders, including restrictions under any existing credit facilities and other indebtedness we may incur, and such other factors as our board of directors may deem relevant.

We currently expect to retain all future earnings for use in the operation and expansion of our business and have no current plans to pay dividends.

Annual Stockholder Meetings

Our amended and restated bylaws will 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 that will be in effect before the completion of this offering contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that 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 establishes 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 specifies 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 eliminates 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 authorizes 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.

Upon the completion of this offering, our board of directors will be divided into three classes. The directors in each class will 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 will be 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. For more information on the classified board, see the section titled "Management—Board of Directors." 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 will provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be 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 will also provide that the federal district courts of the Unites States 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 ay other professional or entity who has prepared or certified any part of this prospectus. 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.

Limitations on Liability and Indemnification Matters

For a discussion of liability and indemnification, see the section titled “Management—Limitation on Liability and Indemnification Matters.”

Exchange Listing

We have applied to list our common stock on the Nasdaq Global Market under the symbol “TMCI.”

Transfer Agent

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

SHARES ELIGIBLE FOR FUTURE RESALE

Before the completion of this offering, there has been no public market for our common stock, and we cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Future sales of our common stock in the public market, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future. As described below, only a limited number of shares will be available for sale for a period of several months after consummation of this offering due to contractual and legal restrictions on resale as described below. Nevertheless, sales of our common stock in the public market either before (to the extent permitted) or after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Sale of Restricted Shares

Based on the number of shares of our common stock outstanding as of December 31, 2020 and assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, upon the consummation of this offering and assuming the automatic conversion of all of our outstanding shares of Series A convertible preferred stock, we will have outstanding an aggregate of approximately shares of our common stock. Of these outstanding shares, all the shares of common stock to be sold in this offering, and any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our "affiliates" as such term is defined in Rule 144 of the Securities Act.

The remaining outstanding shares of our common stock will be deemed "restricted securities" as defined in Rule 144. Restricted securities may be sold in the public market only if they are registered or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, which rules are summarized below. In addition, holders of all or substantially all of our equity securities have entered into or will enter into lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions, not to sell any of our stock for at least 180 days following the date of this prospectus, as described below.

As a result of these agreements, based on the number of shares of our capital stock outstanding as of December 31, 2020, subject to the provisions of Rule 144 or Rule 701, these restricted securities will be available for sale in the public market as follows:

- beginning on the date of this prospectus, all shares of common stock sold in this offering will be immediately available for sale in the public market; and
- beginning 181 days after the date of this prospectus, additional shares of common stock will become eligible for sale in the public market, of which shares will be held by affiliates and will be subject to the volume and other restrictions of Rule 144, as described below.

Lock-Up Agreements

Our executive officers, directors, the selling stockholders and substantially all of our securityholders, including the selling stockholders, have entered into lock-up agreements with the underwriters of this offering under which they have agreed that, among other things and subject to certain exceptions, without the prior written consent of J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC, they will not dispose of or hedge any shares or any securities convertible into or exchangeable for shares of common stock for a period of 180 days from the date of this prospectus. See the section titled "Underwriting" for additional information. J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC, may, in their discretion, release any of the securities subject to these lock-up agreements at any time without notice. Following the expiration of the lock-up period, and

assuming that the representatives of the underwriters do not release any parties from these agreements, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market subject to the limitations of Rule 144 under the Securities Act.

Prior to the completion of the offering, certain of our employees, including our executive officers, and/or directors may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

Following the lock-up periods set forth in the agreements described above, and assuming that the representatives of the underwriters do not release any parties from these agreements, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell those shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then that person would be entitled to sell those shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, and upon expiration of the lock-up agreements described above, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell within any three-month period, a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering, assuming no exercise by the underwriters' option to purchase additional shares; or
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale;

provided, in each case, that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701.

Stock and Option Plans

Following the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register shares of our common stock issued or reserved for issuance under our 2014 Stock Plan and 2021 Incentive Award Plan (collectively, the Plans). The registration statement on Form S-8 will become effective immediately upon filing, and shares covered by such registration statement will thereupon be eligible for sale in the public markets, subject to vesting restrictions, the lock-up agreements described above and Rule 144 limitations applicable to affiliates. See the section titled “Executive Compensation—Equity Compensation Plans” for additional information.

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

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

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

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Internal Revenue Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Internal Revenue Code and entities all of the interests of which are held by qualified foreign pension funds.

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

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION

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

Definition of a Non-U.S. Holder

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

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

Distributions

As described in the section titled "Dividend Policy," we have never declared or paid, and do not anticipate declaring or paying, cash dividends on our common stock. We do not anticipate paying any dividends in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described under the subsection titled "—Sale or Other Taxable Disposition" below.

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

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

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

Sale or Other Taxable Disposition

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

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

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

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

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

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

Information Reporting and Backup Withholding

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

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

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

Additional Withholding Tax on Payments Made to Foreign Accounts

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

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

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

UNDERWRITING

We and the selling stockholders are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC are acting as joint book-running managers of the offering and as representatives of the underwriters. We and the selling stockholders have entered into an underwriting agreement with the representatives. Subject to the terms and conditions of the underwriting agreement, we and the selling stockholders have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of Shares
J.P. Morgan Securities LLC	
Morgan Stanley & Co. LLC	
SVB Leerink LLC	
Stifel, Nicolaus & Company, Incorporated	
Total	

The underwriters are committed to purchase all the shares of common stock offered by us and the selling stockholders if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $ per share. After the initial offering of the shares to the public, if all of the shares of common stock are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is $ per share. The following table shows the per share and total underwriting discounts and commissions to be paid by us and the selling stockholders to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares from us.

	Paid by the Company without Option to Purchase Additional Shares Exercise	Paid by the Company with Full Option to Purchase Additional Shares Exercise	Paid by the Selling Stockholders
Per Share	$	$	$
Total	$	$	$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be

approximately $ million. We have also agreed to reimburse the underwriters for expenses relating to the clearance of this offering with the Financial Industry Regulatory Authority, Inc. in an amount up to $.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not, subject to certain exceptions, (i) offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, hedge, lend, or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exercisable or exchangeable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, hedge, loan, disposition or filing, or (ii) enter into any swap, hedging, or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC for a period of 180 days after the date of this prospectus, other than the shares of our common stock to be sold in this offering.

The restrictions on our actions, as described above, do not apply to certain transactions, including (i) the issuance of shares of common stock or securities convertible into or exercisable for shares of common stock pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options (including net exercise) or the settlement of RSUs (including net settlement), in each case outstanding on the date of the underwriting agreement and described in this prospectus; (ii) grants of stock options, stock awards, restricted stock, RSUs, or other equity awards and the issuance of shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock (whether upon the exercise of stock options or otherwise) to our employees, officers, directors, advisors, or consultants pursuant to the terms of an equity compensation plan in effect as of the closing of this offering and described in this prospectus, provided that such recipients enter into a lock-up agreement with the underwriters; (iii) the issuance of up to 5% of the outstanding shares of our common stock, or securities convertible into, exercisable for, or which are otherwise exchangeable for, our common stock, immediately following the closing of this offering, in acquisitions or other similar strategic transactions, provided that such recipients enter into a lockup agreement with the underwriters; or (iv) our filing of any registration statement on Form S-8 relating to securities granted or to be granted pursuant to any plan in effect on the date of the underwriting agreement and described in this prospectus or any assumed benefit plan pursuant to an acquisition or similar strategic transaction.

Our directors and executive officers, the selling stockholders and substantially all of our securityholders (such persons, the “lock-up parties”) have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 180 days after the date of this prospectus (such period, the “restricted period”), may not and may not cause any of their direct or indirect affiliates to, without the prior written consent of J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC, (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such lock-up parties in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant) (collectively with the common stock, the “lock-up securities”), (2) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether

any such transaction described in clause (1) or (2) above is to be settled by delivery of lock-up securities, in cash or otherwise, (3) make any demand for or exercise any right with respect to the registration of any lock-up securities, or (4) publicly disclose the intention to do any of the foregoing. Such persons or entities have further acknowledged that these undertakings preclude them from engaging in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer (by any person or entity, whether or not a signatory to such agreement) of any economic consequences of ownership, in whole or in part, directly or indirectly, of any lock-up securities, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of lock-up securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including:

(a) the transfer, distribution, disposition or surrender (as the case may be) of, the lock-up party's lock-up securities:

- (i) as a bona fide gift or gifts, or for bona fide estate planning purposes,
- (ii) by will, testamentary document or intestacy,
- (iii) (1) to any trust for the direct or indirect benefit of the lock-up party or the immediate family of the lock-up party, or if the lock-up party is a trust, to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust (for purposes of the lock-up agreements, "immediate family" shall mean any relationship by blood, current or former marriage, domestic partnership or adoption, not more remote than first cousin) or (2) to any immediate family member,
- (iv) to a corporation, partnership, limited liability company or other entity of which the lock-up party and its immediate family are the legal and beneficial owner of all of the outstanding equity securities or similar interests,
- (v) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (iv) above,
- (vi) if the lock-up party is a corporation, partnership, limited liability company, trust or other business entity, (1) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of the lock-up party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the lock-up party or its affiliates (including, for the avoidance of doubt, where the lock-up party is a partnership, to its general partner or a successor partnership or fund, or any other funds managed by such partnership), or (2) as part of a distribution to partners, members or shareholders of the lock-up party,
- (vii) by operation of law, such as pursuant to a qualified domestic order, divorce settlement, divorce decree or separation agreement, provided that such transferee shall execute and deliver to the representatives a lock-up letter in the form of the lock-up agreements described herein,
- (viii) to us from an employee upon death, disability or termination of employment, in each case, of such employee,
- (ix) as part of a sale of lock-up securities acquired in open market transactions after the completion of this offering,
- (x) to us (1) pursuant to a right of first refusal described herein with respect to transfers of lock-up securities and (2) in connection with the vesting, settlement, or exercise of restricted stock units,

options, warrants or other rights to purchase shares of our common stock (including, in each case, by way of "net" or "cashless" exercise), including for the payment of exercise price and tax and remittance payments due as a result of the vesting, settlement, or exercise of such restricted stock units, options, warrants or rights, provided that any such shares of our common stock received upon such exercise, vesting or settlement shall be subject to the terms of the lock-up agreements, and provided further that any such restricted stock units, options, warrants or rights are held by the lock-up party pursuant to an agreement or equity awards granted under a stock incentive plan or other equity award plan, each such agreement or plan which is described herein, or

(xi) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction that is approved by our board of directors and made to all of our shareholders involving a change of control; provided that in the event that such transaction is not completed, all such lock-up securities shall remain subject to the restrictions in the immediately preceding paragraph;

provided that (A) in the case of any transfer or distribution pursuant to clause (a)(i), (ii), (iii), (iv), (v) and (vi), such transfer shall not involve a disposition for value and each donee, devisee, transferee or distributee shall execute and deliver to the representatives a lock-up letter in the form of the lock-up agreements described herein, (B) in the case of any transfer or distribution pursuant to clause (a) (i), (ii), (iii), (iv), (v), (vi) and (ix), no filing by any party (donor, donee, devisee, transferor, transferee, distributer or distributee) under Section 16 of the Exchange Act, or other public announcement shall be required or shall be made voluntarily in connection with such transfer or distribution (other than a filing on a Form 5 made after the expiration of the restricted period referred to above) and (C) in the case of any transfer or distribution pursuant to clause (a)(vii), (viii) and (x) it shall be a condition to such transfer that no public filing, report or announcement shall be voluntarily made and if any filing under Section 16(a) of the Exchange Act, or other public filing, report or announcement reporting a reduction in beneficial ownership of shares of our common stock in connection with such transfer or distribution shall be legally required during the restricted period, such filing, report or announcement shall clearly indicate in the footnotes thereto the nature and conditions of such transfer;

(b) exercise of the outstanding options, settlement of restricted stock units or other equity awards or the exercise of warrants granted pursuant to plans described in this prospectus; provided that any lock-up securities received upon such exercise, vesting or settlement would be subject to restrictions similar to those in the immediately preceding paragraph;

(c) the conversion of outstanding preferred stock, warrants to acquire preferred stock or convertible securities into shares of our common stock or warrants to acquire shares of our common stock; provided that any such shares of common stock or warrants received upon such conversion would be subject to restrictions similar to those in the immediately preceding paragraph;

(d) the establishment by lock-up parties of trading plans under Rule 10b5-1 under the Exchange Act; provided that (i) such plans do not provide for the transfer of lock-up securities during the restricted period and (ii) no filing by any party under Section 16 of the Exchange Act or other public announcement shall be required or made voluntarily in connection with such trading plan; and

(e) the sale of the securities by the lock-up party pursuant to the terms of the underwriting agreement.

J.P. Morgan Securities LLC and Morgan Stanley & Co. LLC, in their sole discretion, may release the securities subject to any of the lock-up agreements with the underwriters described above, in whole or in part at any time.

We and the selling stockholders have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

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

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be "covered" shorts, which are short positions in an amount not greater than the underwriters' option to purchase additional shares referred to above, or may be "naked" shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq Global Stock Market, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for shares of our common stock, or that the shares will trade in the public market at or above the initial public offering price.

Directed Share Program

At our request, the underwriters have reserved up to % of the shares offered by this prospectus for sale at the initial public offering price to certain individuals through a directed share program, including our directors,

officers and certain other individuals identified by our officers or management. The sales will be made at our direction by J.P. Morgan Securities LLC and its affiliates through a directed share program. The number of shares of our common stock available for sale to the general public in this offering will be reduced to the extent that such persons purchase such reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of common stock offered by this prospectus. We have agreed to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act, in connection with the sales of the shares reserved for the directed share program.

Other Relationships

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates, and the selling stockholders, and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates, and such selling stockholders, in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future. For example, certain of the underwriters or their respective affiliates serve as lenders under our term loan agreements. In addition, certain of the underwriters or their respective affiliates also served as lenders under our PPP Loan, which was repaid in March 2021.

Selling Restrictions

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area (each a “Relevant State”), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant State at any time:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to Prospective Investors in the United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(iii) in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards

for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

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

Notice to Prospective Investors in the Dubai International Financial Centre

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority (DFSA). This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Notice to Prospective Investors in the United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

Notice to Prospective Investors in Australia

This prospectus:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the Corporations Act);
- has not been, and will not be, lodged with the Australian Securities and Investments Commission (ASIC), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act (Exempt Investors).

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any “resident” of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (i) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the SFO, of Hong Kong and any rules made thereunder; or (ii) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, or the CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made thereunder.

Notice to Prospective Investors in Singapore

Each representative has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each representative has represented and agreed that it has not offered or sold any shares or caused the shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares or cause the shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, whether directly or indirectly, to any person in Singapore other than:

(i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA;

(ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or

(iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

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

(i) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(ii) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(b) where no consideration is or will be given for the transfer;

(c) where the transfer is by operation of law;

(d) as specified in Section 276(7) of the SFA; or

(e) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Singapore SFA Product Classification—In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of the shares, the company has determined, and hereby notifies all relevant persons (as defined in Section 309A(1) of the SFA), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Notice to Prospective Investors in Bermuda

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

Notice to Prospective Investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority, or CMA, pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended. The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

Notice to Prospective Investors in the British Virgin Islands

The shares are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of the company. The shares may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), or BVI Companies, but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

Notice to Prospective Investors in China

This prospectus will not be circulated or distributed in the PRC and the shares will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

Notice to Prospective Investors in Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder, or the FSCMA, and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder, or the FETL. The shares have not been listed on any of the securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

Notice to Prospective Investors in Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares has been or will be registered with the Securities Commission of Malaysia, or Commission, for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services License; (iii) a person who acquires the shares, as principal, if the offer is on terms that the shares may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding

categories (i) to (xi), the distribution of the shares is made by a holder of a Capital Markets Services License who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Notice to Prospective Investors in Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

Notice to Prospective Investors in South Africa

Due to restrictions under the securities laws of South Africa, no "*offer to the public*" (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted), or the South African Companies Act) is being made in connection with the issue of the shares in South Africa. Accordingly, this document does not, nor is it intended to, constitute a "*registered prospectus*" (as that term is defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. The shares are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions stipulated in section 96 (1) applies:

Section 96 (1) (a) the offer, transfer, sale, renunciation or delivery is to:

(i) persons whose ordinary business, or part of whose ordinary business, is to deal in securities, as principal or agent,

(ii) the South African Public Investment Corporation,

(iii) persons or entities regulated by the Reserve Bank of South Africa,

(iv) authorised financial service providers under South African law,

(v) financial institutions recognised as such under South African law,

(vi) a wholly-owned subsidiary of any person or entity contemplated in (c), (d) or (e), acting as agent in the capacity of an authorized portfolio manager for a pension fund, or as manager for a collective investment scheme (in each case duly registered as such under South African law), or

(vii) any combination of the person in (i) to (vi); or

Section 96 (1) (b) the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000 or such higher amount as may be promulgated by notice in the Government Gazette of South Africa pursuant to section 96(2)(a) of the South African Companies Act.

Information made available in this prospectus should not be considered as "advice" as defined in the South African Financial Advisory and Intermediary Services Act, 2002.

LEGAL MATTERS

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Latham & Watkins LLP, Menlo Park, California. Cooley LLP, San Diego, California, is acting as counsel for the underwriters in connection with this offering.

EXPERTS

The financial statements included in this registration statement have been so included in reliance upon the reports of Grant Thornton LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to Treace Medical Concepts, Inc. and the common stock offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address is www.sec.gov.

You may read our SEC filings, including this registration statement, over the Internet at the SEC's website at www.sec.gov. Upon the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for review at the SEC's website referred to above. We also maintain a website at www.treace.com, at which, following the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus or the registration statement of which it forms a part, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Treace Medical Concepts, Inc.
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Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
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, 2020 and 2019, the related statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years ended December 31, 2020 and 2019, and the related notes to the financial statements (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, 2020 and 2019, and the results of its operations and its cash flows for the years ended December 31, 2020 and 2019, 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 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 include 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 30, 2021

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

	December 31,	
	2019	2020
Assets		
Current assets		
Cash and cash equivalents	$ 12,139	$ 18,079
Accounts receivable, net of allowance for doubtful accounts of $249 and $446 as of December 31, 2019 and 2020, respectively	10,411	14,486
Inventories	5,562	7,820
Prepaid expenses and other current assets	458	594
Total current assets	28,570	40,978
Property and equipment, net	1,146	829
Total assets	$ 29,716	$ 41,807
Liabilities, and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 931	$ 2,265
Accrued liabilities	1,294	1,848
Accrued commissions	2,572	3,513
Accrued compensation	2,535	2,183
Short-term debt	—	1,788
Total current liabilities	7,332	11,598
Derivative liability on term loan	—	245
Long-term debt, net of discount of $777 and $811 as of December 31, 2019 and 2020, respectively	19,223	29,189
Total liabilities	26,555	41,031
Commitments and contingencies (Note 7)	—	—
Stockholders' equity		
Series A preferred stock, $0.001 par value, 5,000,000 shares and 5,000,000 authorized, issued and outstanding as of December 31, 2019 and 2020, respectively; liquidation value of $8,000 and $8,000 as of December 31, 2019 and 2020, respectively	7,935	7,935
Common stock Series A, $0.001 par value, 50,000,000 shares and 50,000,000 shares authorized as of December 31, 2019 and 2020, respectively; 27,687,373 shares and 27,937,859 issued and outstanding as of December 31, 2019 and 2020, respectively	28	28
Common stock Series B, $0.001 par value, 1,000,000 shares and 1,000,000 shares authorized as of December 31, 2019 and 2020, respectively; no shares issued and outstanding as of December 31, 2019 and 2020	—	—
Additional paid-in capital	12,884	14,166
Accumulated deficit	(17,686)	(21,353)
Total stockholders' equity	3,161	776
Total liabilities, and stockholders' equity	$ 29,716	$ 41,807

The accompanying notes are an integral part of these financial statements

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

	Year Ended December 31,	
	2019	2020
Revenue	$ 39,416	$ 57,365
Cost of goods sold	7,631	12,470
Gross profit	31,785	44,895
Operating expenses:		
Sales and marketing	25,786	31,654
Research and development	5,070	5,847
General and administrative	4,464	6,539
Total operating expenses	35,320	44,040
(Loss) income from operations	(3,535)	855
Interest and other income (expense), net	111	(1,746)
Interest expense	(841)	(2,777)
Other income (expense), net	(730)	(4,523)
Net loss and comprehensive loss	(4,265)	(3,668)
Convertible preferred stock cumulative and undeclared dividends	(640)	(640)
Net loss attributable to common stockholders	$ (4,905)	$ (4,308)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.18)	$ (0.16)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	27,597,463	27,715,129

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balances at January 1, 2019	5,000,000	$ 7,935	27,492,873	$ 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	—	—	194,500	1	67	—	—	68
Share-based compensation expense	—	—	—	—	815	—	—	815
Net loss attributable to common shareholders	—	—	—	—	—	—	(4,265)	(4,265)
Balances at December 31, 2019	5,000,000	$ 7,935	27,687,373	$ 28	$ 12,884	$ —	$ (17,686)	$ 3,161
Common stock issued upon exercise of stock options	—	—	250,486	—	364	—	—	364
Share-based compensation expense	—	—	—	—	919	—	—	919
Net loss attributable to common shareholders	—	—	—	—	—	—	(3,668)	(3,668)
Balances at December 31, 2020	5,000,000	$ 7,935	27,937,859	$ 28	$ 14,167	$ —	$ (21,353)	$ 776

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,	
	2019	2020
Cash flows from operating activities		
Net loss attributable to common shareholders	$ (4,265)	$ (3,668)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	793	1,210
Allowance for doubtful accounts	145	216
Share-based compensation expense	815	919
Amortization of debt issuance costs	147	220
Impairment of capitalized surgical instruments	—	144
Provision for inventory obsolescence	—	1,144
Loss on early settlement of debt	—	639
Net changes in operating assets and liabilities:		
Accounts Receivable	(6,022)	(4,291)
Inventory	(2,813)	(3,402)
Prepaid expenses and other assets	(94)	(103)
Accounts payable	(236)	1,334
Accrued liabilities	3,857	1,143
Net cash used in operating activities	(7,673)	(4,494)
Cash flows from investing activities		
Purchases of property and equipment	(1,211)	(1,069)
Net cash used in investing activities	(1,211)	(1,069)
Cash flows from financing activities		
Proceeds from interest bearing debt	20,000	29,530
Payments on interest bearing debt	—	(20,000)
Proceeds from SBA Loan	—	1,788
Debt issuance costs	(329)	(179)
Proceeds from exercise of employee stock options	68	364
Net cash provided by financing activities	19,739	11,503
Net increase in cash and cash equivalents	10,855	5,940
Cash and cash equivalents at beginning of year	1,284	12,139
Cash and cash equivalents at end of year	$ 12,139	$ 18,079
Supplemental disclosure of cash flow information		
Cash paid for interest	739	1,146
Non-cash financing activities		
Issuance of warrants for Class A common stock in connection with the Company's Credit Facility	594	—
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. Effective July 1, 2014, the entity converted to a C Corporation and changed its name to Treace Medical Concepts, Inc. (the "Company"). The Company is a commercial-stage orthopaedic medical device company driving a paradigm shift in the surgical treatment of *Hallux Valgus* (commonly known as bunions). The Company has pioneered the proprietary Lapiplasty 3D Bunion Correction System – a combination of novel 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 operates from its corporate headquarters located in Ponte Vedra, Florida.

The Company received 510(k) clearance for the Lapiplasty System in March 2015 and began selling its surgical medical devices in September 2015.

Liquidity and Capital Resources

The Company has incurred operating losses to date and has an accumulated deficit of $21.4 million as of December 31, 2020. During the year ended December 31, 2020, the Company used $4.5 million of cash in its operating activities. As of December 31, 2020, the Company had cash and cash equivalents of $18.1 million. Additional financing, including the completion of the proposed initial public offering, will be required to sustain further growth of the Company's revenues and operations.

Coronavirus Pandemic

The Company's operations were impacted by the coronavirus ("COVID-19") pandemic 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. 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. While the Company has experienced revenue growth during the pandemic, the Company reduced its revenue growth forecast to reflect a lower number of surgical procedures.

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").

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 reporting periods. 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.

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. 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 maturity of three months or less at the time of purchase to be cash equivalents, which include money market funds.

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. Sales of the Lapiplasty System and ancillary products accounted for the Company's revenue for the year ended December 31, 2020. The Company's accounts receivable are 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 agents. At December 31, 2019 and December 31, 2020, no customer accounted for more than 10% of accounts receivable or revenue.

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 estimated losses resulting from a customer's inability to make required payments. 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 the Company deems individual balances are no longer collectible. As of December 31, 2019 and December 31, 2020, accounts receivable is presented net of an allowance for doubtful accounts of $0.3 million and $0.4 million respectively. For the years ended December 31, 2019 and December 31, 2020, the Company recorded provision for bad debts of $0.1 million and $0.2 million, respectively.

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, 2019 and December 31, 2020, the Company recorded a provision of $0.1 million and $1.1 million for obsolete inventory to cost of goods sold.

Patents

Costs related to filing patent applications are expensed as incurred. Expenses related to patent application filings and licensing were approximately $0.6 million and $0.7 million for the years ended December 31, 2019 and December 31, 2020, are included in research and development expenses in the statement of operations. No patent costs had been capitalized at December 31, 2019 and December 31, 2020.

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 of the related assets as follows:

	Years
Furniture, fixtures and equipment	7
Machinery and equipment	3
Capitalized surgical instruments . .	1.5
Computer equipment .	3
Leasehold improvements	5 or lease term, whichever is shorter
Software	3

Long-lived assets are evaluated whenever a change in circumstances indicate 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 and $0.1 million for the years ended December 31, 2019 and December 31, 2020, respectively.

Deferred Rent

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 recognition of 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 patented Lapiplasty System and ancillary products. The Lapiplasty System is comprised of single-use implant kits and reusable instrument trays. The implant kit and ancillary products are sold in the United States through a combination of a direct employee sales force and independent sales agents. The Company invoices hospitals and ambulatory surgery centers for the implant kits and pays commissions to the sales representatives and independent sales agents. 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 Accounting Standards Codification ("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, 2019 and December 31, 2020 and there were no product returns during the years ended December 31, 2019 and December 31, 2020.

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 agents 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 agents or internal sales representatives.

Cost of Goods Sold

Cost of goods sold consists primarily of costs for the purchase of the Company's Lapiplasty System 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, rent and information technology, 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, patent costs, 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. Additionally, R&D expenses include costs associated with our clinical studies, including clinical trial design, clinical trial site initiation and study costs, data management, related travel expenses and the cost of products used for clinical trials, internal and external costs associated with the Company's regulatory compliance and quality assurance functions and allocated overhead costs. Research and development expenses for the years ended December 31, 2019 and December 31, 2020 were $5.1 million and $5.8 million respectively.

Shipping and Handling

The Company bills customers for shipping and handling costs. Amounts billed for shipping and handling are included in sales. 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 costs totaled approximately $1.9 million and $3.1 million for the years ended December 31, 2019 and December 31, 2020.

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, 2019 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 determined the value of the Company using the income, asset based and market approaches. The value was allocated among the share classes based upon the Probability-Weighted Expected Return Method ("PWERM") and the option pricing model ("OPM"), estimating the probability-weighted value across multiple scenarios but using the option pricing model to estimate the allocation of value for those scenarios. The Company then determines the fair value of stock options on the date of grant using the Black-Scholes option pricing model. The Company's determination of the fair value of stock options is impacted by its common stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the anticipated timing of a potential liquidity event, expected common stock price volatility over the term of the option awards, risk-free interest rates and expected dividends. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop.

The fair value of time-based awards is recognized over the period during which an option holder is required to provide services in exchange for the option 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.

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, 2019 and December 31, 2020.

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, convertible preferred stock, and common stock options are considered to be potentially dilutive securities. Because the Company has reported a net loss for the year ended December 31, 2019 and December 31, 2020, diluted net losses per common share were the same as basic net losses per common share for the 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.

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") requires 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 month or less as leases in the scope of the new standard. ASC 842 supersedes the previous leases standard, ASC 840, *Leases*. 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 assessing the impact that this standard may have on its financial statements.

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.

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, 2019 and December 31, 2020:

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds(1)	$11,880	$ —	$ —	$11,880
Total	$11,880	$ —	$ —	$11,880

	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, 2019 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. There were no adjustments to the fair value of the derivative liability recognized in net loss for the year-ended December 31, 2020.

There were no assets or liabilities measured at fair value on a nonrecurring basis as of December 31, 2019 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,	
	2019	2020
Cash	$ 259	$ 502
Cash equivalents:		
Money market funds	11,880	17,577
Total cash and cash equivalents	$ 12,139	$ 18,079

Property and equipment, net

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

	December 31,	
	2019	2020
Furniture and fixtures, and equipment	$ 70	$ 131
Machinery and equipment	155	226
Capitalized surgical instruments	2,190	2,652
Computer equipment	150	150
Leasehold improvements	84	168
Software	138	138
Total property and equipment	2,787	3,465
Less: accumulated depreciation and amortization	(1,641)	(2,636)
Property and equipment, net	$ 1,146	$ 829

Depreciation and amortization expense on property and equipment was $0.8 million and $1.2 million for the years ended December 31, 2019 and December 31, 2020.

Accrued liabilities

Accrued other liabilities consist of the following (in thousands):

	December 31,	
	2019	2020
Accrued royalty expenses	$ 741	$1,032
Accrued expenses	411	565
Other	142	251
Total prepaid expenses and other current assets	$1,294	$1,848

6. Long Term Debt

Silicon Valley Bank

On December 31, 2019, the Company entered into the Second Amendment to the Loan and Security Agreement (the "Second Amendment") with Silicon Valley Bank ("SVB"). The Second Amendment represents a modification to the First Amendment to the Loan and Security (the "First Amendment") dated February 14, 2019 and the Loan and Security Agreement (the "LSA") dated April 18, 2018. The LSA, First Amendment, and Second Amendment (collectively the "SVB Credit Facility") is secured by substantially all the assets of the Company (excluding intellectual property) and matures August 3, 2024.

The SVB Credit Facility provides for up to $25.0 million in term loans and up to $5.0 million in a revolving line of credit. The term loans are structured in three tranches. The Company received the proceeds from tranche 1 of $10.0 million upon execution of the First Amendment. The Company received the proceeds from tranche 2 of $10.0 million upon execution of the Second Amendment. Access to tranche 3 of remaining $5.0 million was subject to achievement of a revenue milestone prior to December 31, 2020. The term loans are interest only through August 1, 2021 with amortization of the principal balance beginning September 1, 2021 through the Maturity Date. The interest only period can be extended through February 1, 2022 based on achievement of the milestone and the funding of tranche 3.

The term loans accrue interest 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 2 and seven percent (7.0%) for tranche 3. Interest on the term loans is payable monthly in arrears. Under the terms of the SVB Credit Facility, the Company is subject to certain affirmative and negative covenants, including (but not limited to), covenants limiting the Company's ability to incur certain additional indebtedness, create certain liens, and make certain distributions and investments without the lender's consent.

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 1.00% above the prime rate as published from time to time in the money rates section of the Wall Street Journal.

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 gives the lender the right to purchase up to 533,332 shares of the Company's Class A common stock (see Note 9). The Company valued the warrants based upon the probability-weighted expected return method and option pricing model using the Black-Scholes option pricing model and accounted for the warrants as debt discount and additional paid in capital on the balance sheets. 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 are amortized over the term of the debt using the effective interest method and included within interest expense on the statement of operations.

On August 3, 2020, the Company entered into the Third Amendment to the LSA (the "Third Amendment") with SVB. The Third Amendment, which represents a modification to the Second Amendment, terminates tranche 3 of the term loans, increases the revolving line of credit from $5.0 million to $10.0 million, and extends the maturity date to August 3, 2024. In addition, the Third Amendment modifies the interest rate on the revolving line of credit 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 to be an amount of 1.00% of the revolving line of credit if the termination occurs before the second anniversary of the closing of the Third Amendment. Proceeds received from the CRG Term Loan Facility were used to repay the $20.0 million in term loans outstanding under the Second Amendment to the LSA (described below). As of December 31, 2020, 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.

As of December 31, 2019, the balance outstanding for term loans under the SVB Credit Facility was $20.0 million. The Company did not have any balances outstanding under the revolving line of credit as of December 31, 2019 and December 31, 2020.

CRG Term Loan Facility

On July 31, 2020, the Company 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 amounts totaling $30 million were borrowed through December 31, 2020 and are currently outstanding. The CRG Term Loan Facility matures on June 30, 2025, and the Company can 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. In an event of default occurs, interest under the CRG Term Loan Facility will increase by 4.00%. If the Company repays the CRG Term Loan Facility within one year of the borrowing date, the Company is required to pay a premium of 20.00% of the aggregated outstanding principal amount of the loans that is 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 CRG 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 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 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. Debt issuance costs and debt discount are amortized to interest expense using the effective interest method.

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

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, matures on April 22, 2022 and bears interest at a fixed rate of 1% per annum, payable monthly on the date that is the latter of (i) the date that is the 10th month after the end of the PPP Loan covered period and (ii) assuming the Company applied for forgiveness within the period described in clause (i), the date on which the Small Business Administration (the "SBA") remits the loan forgiveness amount on the loan to SVB (or notifies such lender that no loan forgiveness is allowed). Under the terms of the PPP Loan, the principal may be forgiven if the loan proceeds are used for qualifying expenses as described in the CARES Act, such as payroll costs, benefits, mortgage interest, rent, and utilities. While the details of the PPP continue to evolve regarding which companies are qualified to receive loans pursuant to the PPP and on what terms, the Company repaid $1.8 million borrowed under the PPP Loan in March 2021.

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

	December 31,	
	2019	2020
Revolving line of credit		
SVB Credit Facility	$ —	$ —
Term loans		
SVB Credit Facility	20,000	—
CRG Term Loan Facility	—	30,000
PPP Loan	—	1,788
Total term loans	20,000	31,788
Less: debt discount and issuance costs	(777)	(811)
Total debt	19,223	30,977
Short-term debt	—	1,788
Long-term debt	$19,223	$29,189

As of December 31, 2020, future payments under term loan, including interest only payments and the final payment, were as follows (in thousands):

Fiscal Year	
2021	$ 1,788
2022	—
2023	—
2024	—
2025	30,000
Total principal payments	31,788
Less: Unamortized debt discount and debt issuance costs	(811)
Total short-term and long-term debt	$30,977

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

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 2024. Lease payments comprise of the base rent stated in the lease plus operating costs which include taxes, insurance and common area maintenance.

In November of 2019 the Company amended the lease agreement to include additional space of the second floor of their existing building. The commencement date began May 1, 2020 and is reflected as such in the minimum rental obligation schedule below.

The future minimum rental obligations required under non-cancelable leases at December 31, 2020 were as follows (in thousands):

Fiscal Year	
2021	$ 518
2022	466
2023	278
2024	286
Total minimum lease payments	$1,548

Total rent expense was approximately $0.2 million and less than $0.1 million for the years ended December 31, 2019 and December 31, 2020, 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 royalty agreement if the member's contributions to the product are novel, significant and innovative.

As of December 31, 2019 and December 31, 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, 2019 and December 31, 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% of net sales for the particular product to which the surgeon contributed.

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

8. Income Taxes

The Company has not recorded an income tax provision for years ended December 31, 2019 and December 31, 2020 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,	
	2019	2020
Income tax at the statutory rate	(21%)	(21%)
Research and development credits	(3%)	(4%)
State taxes, net of federal benefit	(4%)	(4%)
Non-deductible items	1%	1%
Change in valuation allowance	27%	28%
	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,	
	2019	2020
Components of the deferred tax assets		
Net operating loss carryforwards	$ 2,904	$ 3,703
Research and development credits	358	475
Stock option compensation expense	473	672
Inventory	138	218
Property and equipment	68	45
Deferred lease payable	10	10
Allowance for doubtful accounts	71	113
Accrued bonus	584	244
Other	25	21
Total deferred tax assets	4,631	5,501
Deferred tax asset valuation allowance	(4,631)	(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 $4.6 million and $5.5 million as of December 31, 2019 and December 31, 2020, respectively. The Company's change in the deferred tax asset valuation allowance for years ended December 31, 2019 and December 31, 2020, were approximately $1.2 million and $0.9 million, respectively.

The Company had unused federal and state net operating loss carryforwards of approximately $11.5 million and $9.5 million, respectively as of December 31, 2019, 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 and research and development tax credit carryforwards of $0.4 million and $0.4 million as of December 31, 2019 and December 31, 2020, respectively, 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. Based on our analysis as of December 31, 2020, we have determined that we do not expect these limitations to impair our ability to use our NOLs prior to expiration.

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 2016.

9. Warrants for Class A Common Stock

During 2019, the Company issued warrants in connection with the SVB Credit Facility that give SVB the right to purchase up to 533,332 shares of the Company’s Class A common stock. The warrants have a 10-year expiration period with a strike price equal to $5.38. The estimated fair value of the warrants was $594,876 on the date of issuance and was allocated to 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	0%
Expected volatility	49.19%
Risk-free interest rate	2.30%
Expected warrant life	3 years

Under the terms of the SVB Credit Facility, the Company was required to issue an additional 66,668 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 66,668 common stock warrants.

10. Stockholders’ Equity

Convertible Preferred Stock

Under the Company’s Amended and Restated Certificate of Incorporation, the Company is authorized to issue up to 5,000,000 shares of Series A convertible preferred stock (the “Preferred Shares”), with 5,000,000 shares issued and outstanding as of December 31, 2019 and December 31, 2020.

Dividends—Dividends on the Preferred Shares accrue at the rate of 8% per annum on the original issue price and holders of the Preferred Shares have general preference rights with respect to dividends and distributions to holders of Common Stock. Accrued dividends may be paid in cash or, at the election of the Company’s Board of Directors, paid in kind by issuing Class A Common Stock at the then per share value as determined by an independent appraiser.

At December 31, 2019 and December 31, 2020, the Company had accrued and unpaid Preferred Shares dividend of $1.7 million and $2.3 million, respectively, which may be paid from available cash or in Class A Common Stock.

Voting Rights—Holders of the Preferred Shares are entitled to vote with holders of Class A Common Stock equal to the number of shares of Class A Common Stock into which the Preferred Shares are convertible.

Conversion—Each Preferred Share is convertible, at the option of the holder at any time after the date of issuance and upon a deemed liquidation event, as defined in the Certificate of Incorporation, into the number of fully paid and non-assessable shares of Class A Common Stock as determined by dividing the original issue price per share of the Preferred Shares by the conversion price per share in effect at the time of conversion. The original conversion price per Preferred Share is the original issue price of $1.60, and is subject to adjustment, as described in the Company's Amended and Restated Certificate of Incorporation.

In addition, upon conversion, the Company will pay all accrued and unpaid dividends on such converted Preferred Shares (i) in cash, or (ii) upon the election of the Company's Board of Directors or the holders of Preferred Shares to receive payment of the dividends in kind, by issuing the holder additional shares of Class A Common Stock equal to the quotient of the accrued and unpaid dividends on the Preferred Shares with respect to the converted shares, divided by the most recent per share value, as determined by an independent appraiser.

Common Stock

The Amended and Restated Certificate of Incorporation authorizes the Company to issue up to 50,000,000 Class A Common Stock voting shares and 1,000,000 Class B Common Stock non-voting shares.

Shares Reserved for Future Issuance

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

	December 31,	
	2019	2020
Series A convertible preferred stock outstanding	5,000,000	5,000,000
Warrants to purchase Class A common stock	533,332	533,332
Common stock options issued and outstanding	5,588,337	6,042,544
Estimated preferred share conversion	—	249,956
Class A common stock available for future grants	11,190,647	10,236,309
Class B common stock available for future grants	1,000,000	1,000,000
Total	23,312,316	23,062,141

Stock Option Plan

The Company has approved the 2014 Stock Plan (the "Stock Plan"), to allow for the issuance of stock purchase rights and to grant options to purchase Class A Common Stock to employees, directors and consultants. Stock options shall 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. At December 31, 2020, the Stock Plan is authorized to grant awards for up to 8,000,000 shares of Class A Common Stock which may include incentive stock options, non-statutory stock options, or stock purchase rights.

Activity under the Stock Plans is set forth below:

		Outstanding Options		
	Shares Available for Grant	Number of Shares	Weighted-Average Remaining Contractual Term (in years)	Weighted-Average Exercise Price
Balance, January 1, 2019	2,039,708	4,793,542		$ 1.40
Options granted	(1,272,920)	1,272,920		$ 3.50
Options exercised	—	(194,500)		$ 0.35
Options canceled	283,625	(283,625)		$ 2.49
Balance, December 31, 2019	1,050,413	5,588,337	7.66	$ 1.82
Shares authorized	1,000,000	—		
Options granted	(1,095,957)	1,095,957		$ 6.97
Options exercised	—	(250,486)		$ 1.45
Options canceled	391,264	(391,264)		$ 2.42
Balance, December 31, 2020	1,345,720	6,042,544	6.86	$ 2.43
Options vested and expected to vest at December 31, 2020		5,247,863	6.56	$ 2.03
Options vested and exercisable at December 31, 2020		3,432,718	5.70	$ 1.15

The aggregate intrinsic value of options exercised during the years ended December 31, 2019 and December 31, 2020 was $0.9 million and $1.9 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 $42.1 million, $38.7 million and $28.0 million as of December 31, 2020, respectively.

Stock-Based Compensation

During the year ended December 31, 2019 and December 31, 2020, the Company granted stock options to employees to purchase an aggregate of 1,272,920 and 1,095,957 shares respectively, of the Company's common stock. The weighted-average grant date fair value of the employee stock options granted during the years ended December 31, 2019 and December 31, 2020 were $1.25 and $3.02 per share, 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 weighted-average assumptions for options granted during 2019 and 2020 fiscal years:

	December 31,	
	2019	2020
Expected term (in years)	3.0 years	2.7 – 3.3 years
Expected volatility	49.19%	37.09% – 51.29%
Risk-free interest rate	2.30%	0.18% -1.53%
Expected dividend yield	0.00%	0.00%

Expected Term

The expected term represents the period that the stock options are expected to remain outstanding. The Company determined the expected term based upon the probabilities of the anticipated timing of potential liquidity events.

Expected Volatility

The expected volatility is derived from the historical stock volatilities of several comparable publicly listed peers over a period approximately equal to the expected term of the options as the Company has no trading history to determine the volatility of its common stock. In evaluating similarity, the Company considered factors such as industry, stage of life cycle and size.

Risk-Free Interest Rate

The risk-free interest rate assumption 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 does it anticipate paying any dividends on its common stock in the foreseeable future.

Fair Value of Common Stock

The fair value of the Company's common stock is determined by the Board of Directors with assistance from Management and, in part, on input from an independent third-party valuation firm. The Board of Directors determines the fair value of common stock by considering a number of objective and subjective factors, including valuations of comparable companies, sales of convertible preferred stock, operating and financial performance, probabilities of anticipated timing of potential liquidity events, the lack of liquidity of the Company's common stock and the general and industry-specific economic outlook.

Stock-Based Compensation Expense

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

	December 31,	
	2019	2020
Sales and marketing expenses	$404	$479
Research and development expenses	160	199
General and administrative expenses	250	241
Total	$814	$919

As of December 31, 2019 and December 31, 2020, there was $2.2 million and $4.1 million, respectively, of unrecognized stock-based compensation expense related to unvested common stock options, which the Company expects to recognize over a weighted-average period of 2.65 years and 3.01 years, respectively. The total grant date fair value of shares vested during the year ended December 31, 2019 and December 31, 2020 were $0.8 million and $0.9 million, respectively.

11. 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, 2019 and December 31, 2020, 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):

	December 31,	
	2019	2020
Numerator		
Net loss	$ (4,265)	$ (3,668)
Adjust: Convertible preferred stock cumulative and undeclared dividends	(640)	(640)
Net loss attributable to common stockholders	(4,905)	$ (4,308)
Denominator		
Weighted-average common stock outstanding, basic and diluted	27,597,463	27,715,129
Net loss per share attributable to common stockholders, basic and diluted	$ (0.18)	$ (0.16)

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,	
	2019	2020
Series A convertible preferred stock outstanding	5,000,000	5,000,000
Warrants to purchase Class A common stock	533,332	533,332
Common stock option issued and outstanding	5,588,337	6,042,544
Total	11,121,669	11,575,876

12. Subsequent Events

The Company evaluated subsequent events through March 30, 2021, the date on which the accompanying financial statements were issued.

Retirement Plan

Effective as of January 2021, the Company began sponsoring a 401(k) profits sharing plan trust for our employees who satisfy certain eligibility requirements. 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.

PPP Loan

In March 2021, the Company repaid the $1.8 million in borrowings outstanding from the PPP loan.

Lease for Headquarters

In March 2021, the Company amended the lease agreement for its corporate headquarters in Ponte Vedra to include additional space of the second floor of their existing building.

Option Grants

Since January 1, 2021, the Company has granted options to purchase 382,500 shares under the Stock Plan, options to purchase 516,300 shares have been exercised and options to purchase 3,875 shares have been forfeited.

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Shares

Common Stock

Prospectus

J.P. Morgan **Morgan Stanley**

SVB Leerink **Stifel**

, 2021

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered. All amounts are estimates except for the Securities and Exchange Commission (SEC) registration fee, the Financial Industry Regulatory Authority (FINRA) filing fee and the Nasdaq Global Market (Nasdaq) listing fee.

	Amount Paid or to Be Paid
SEC registration fee	$ 10,910
FINRA filing fee	15,500
Nasdaq listing fee	*
Transfer agent's fees and expenses	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Blue Sky fees and expenses	*
Miscellaneous	*
Total	$ *

* To be completed by amendment.

Item 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneys' fees), judgments, fines, and amounts paid in settlement actually and reasonably incurred by such person in connection with any threatened, pending, or completed actions, suits, or proceedings in which such person is made a party by reason of such person being or having been a director, officer, employee, or agent to the registrant. The Delaware General Corporation Law provides that Section 145 is not exclusive of other rights to which those seeking indemnification may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise. Article 9 of the registrant's amended and restated certificate of incorporation provides for indemnification by the registrant of its directors, officers, and employees to the fullest extent permitted by the Delaware General Corporation Law. The registrant has entered into indemnification agreements with each of its current directors, executive officers, and certain other officers to provide these directors and officers additional contractual assurances regarding the scope of the indemnification set forth in the registrant's amended and restated certificate of incorporation and amended and restated bylaws and to provide additional procedural protections. There is no pending litigation or proceeding involving a director or executive officer of the registrant for which indemnification is sought.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) for unlawful payments of dividends or unlawful stock repurchases, redemptions, or other distributions, or (iv) for any transaction from which the director derived an improper personal benefit. The registrant's amended and restated certificate of incorporation provides for such limitation of liability.

The registrant maintains standard policies of insurance under which coverage is provided (i) to its directors and officers against loss rising from claims made by reason of breach of duty or other wrongful act, and (ii) to the registrant with respect to payments that may be made by the registrant to such officers and directors pursuant to the above indemnification provision or otherwise as a matter of law.

The proposed form of underwriting agreement to be filed as Exhibit 1.1 to this registration statement provide for indemnification of directors and officers of the registrant by the underwriters against certain liabilities.

Item 15. Recent Sales of Unregistered Securities

Since January 1, 2018, the registrant has sold the following securities without registration under the Securities Act of 1933, as amended:

(a) Since January 1, 2018, we have granted to our directors, employees and consultants options to purchase 3,968,477 shares of our common stock with per share exercise prices ranging from $1.40 to $9.40 under our 2014 Stock Plan, as amended (the 2014 Plan) of which 870,964 shares have been canceled or forfeited and 978,036 shares have been exercised.

(b) Between February and December 2019, we issued warrants to purchase an aggregate of 533,332 shares of common stock with an exercise price of $5.38 to two accredited investors.

The offers, sales, and issuances of the securities described in Item 15(a) were exempt from registration under the Securities Act under either Rule 701, in that the transaction were under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act in that the transactions were between an issuer and members of its senior executive management and did not involve any public offering within the meaning of Section 4(a)(2). The recipients of such securities were our employees, directors or consultants. Appropriate legends were affixed to the securities issued in these transactions.

The offers, sales, and issuances of the securities described in Item 15(b) were exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving any public offering. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about our company.

Item 16. Exhibits and Financial Statement Schedules

See the Exhibit Index attached to this registration statement, which Exhibit Index is incorporated herein by reference.

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings

(a) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant

of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered hereunder, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(b) The undersigned registrant hereby undertakes that:

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

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

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
1.1*	Form of Underwriting Agreement.				
3.1	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.				X
3.2*	Amended and Restated Certificate of Incorporation of the Registrant, to be in effect upon the completion of this offering.				
3.3	Bylaws, as amended, of the Registrant, as currently in effect.				X
3.4*	Amended and Restated Bylaws of the Registrant, to be in effect upon the completion of this offering.				
4.1*	Reference is made to Exhibits 3.1 through 3.4				
4.2*	Specimen Common Stock Certificate of the Registrant.				
5.1*	Opinion of Latham & Watkins LLP.				
10.1*	Form of Indemnification Agreement for directors and executive officers, to be in effect upon the completion of this offering.				
10.2(a)+	2014 Stock Plan, as amended.				X
10.2(b)+	Form of Stock Option Agreement for Directors under 2014 Stock Plan.				X
10.2(c)+	Form of Stock Option Agreement for Employees under 2014 Stock Plan.				X
10.2(d)+	Form of Notice of Option Exercise under 2014 Stock Plan.				X
10.3*+	2021 Incentive Award Plan and related form agreements.				
10.4	Term Loan Agreement by and among the Registrant, the subsidiary guarantors from time to time party thereto, certain lenders, and CGR Servicing LLC, as administrative agent and collateral agent for the lenders, dated July 31, 2020.				X
10.5	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.				X
10.6+	Severance Agreement by and between the Registrant and Mark L. Hair, dated as of October 5, 2020.				X
10.7+	Change in Control Severance Agreement by and between the Registrant and Jaime A. Frias, dated as of October 5, 2020.				X
10.8+	Severance Agreement by and between the Registrant and Robert P. Jordheim, dated as of July 31, 2020.				X
10.9+	Offer Letter Agreement by and between the Registrant and Mark L. Hair, dated as of September 11, 2020.				X

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Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.10+	Offer Letter Agreement by and between the Registrant and Jaime A. Frias, dated as of June 8, 2017.				X
10.11*+	2021 Employee Stock Purchase Plan.				
10.12	Form of Product Development Royalty Agreement.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
23.2*	Consent of Latham & Watkins LLP (See Exhibit 5.1).				
24.1	Power of Attorney. Reference is made to the signature page to the Registration Statement.				

* To be filed by amendment.
\+ Indicates management contract or compensatory plan.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Ponte Vedra, State of Florida, on March 30, 2021.

Treace Medical Concepts, Inc.

By: /s/ John T. Treace
Name: John T. Treace
Title: Chief Executive Officer, Founder and Director

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John T. Treace and Mark L. Hair, and each of them, his or her true and lawful attorneys-in-fact and agents, 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 (including post-effective amendments) to this registration statement and any and all additional registration statements pursuant to Rule 462(b) of the Securities Act of 1933, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agents full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or either of them or their or his or her substitute or substitutes may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ John T. Treace John T. Treace	Chief Executive Officer, Founder and Director (Principal Executive Officer)	March 30, 2021
/s/ Mark Hair Mark L. Hair	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 30, 2021
/s/ James T. Treace James T. Treace	Chairman of the Board of Directors	March 30, 2021
/s/ John K. Bakewell John K. Bakewell	Director	March 30, 2021
/s/ F. Barry Bays F. Barry Bays	Director	March 30, 2021
/s/ Lawrence W. Hamilton Lawrence W. Hamilton	Director	March 30, 2021
/s/ Richard W. Mott Richard W. Mott	Director	March 30, 2021

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Signature	Title	Date
/s/ Thomas E. Timbie Thomas E. Timbie	Director	March 30, 2021
/s/ John R. Treace John R. Treace	Director	March 30, 2021