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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

Commission File Number 001-40587

SIGHT SCIENCES, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**80-0625749**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4040 Campbell Ave, Suite 100 Menlo Park, CA	**94025**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (877) 266-1144

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

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

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

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

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

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

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

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

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

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

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

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

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter, and therefore cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date.

The number of shares of Registrant's Common Stock outstanding as of March 18, 2022 was 47,586,682.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to its 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2021 are incorporated herein by reference in Part III of this Annual Report on Form 10-K.

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Forward-Looking Statements

Unless the context otherwise requires, references in this Annual Report on Form 10-K to the "Company," "Sight Sciences," "we," "us" and "our" refer to Sight Sciences, Inc.

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations or financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "hope," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these words or other similar terms or expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- estimates of our total addressable market, future revenue, expenses, capital requirements, and our needs for additional financing;
- our ability to enter into and compete in new markets;
- the impact of the COVID-19 pandemic on our business, our customers' and suppliers' businesses and the general economy;
- our ability to compete effectively with existing competitors and new market entrants;
- our ability to scale our infrastructure;
- our ability to manage and grow our business by expanding our sales to existing customers or introducing our products to new customers;
- our ability to establish and maintain intellectual property protection for our products or avoid claims of infringement;
- potential effects of extensive government regulation;
- our ability to obtain and maintain sufficient reimbursement for our products;
- our abilities to protect and scale our intellectual property portfolio;
- our ability to hire and retain key personnel;
- our ability to obtain financing in future offerings;
- the volatility of the trading price of our common stock;
- our expectation regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act (the "JOBS Act"); and
- our ability to maintain proper and effective internal controls.

Actual events or results may differ from those expressed in forward-looking statements. As such, you should not rely on forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this Annual Report on Form 10-K primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, operating results, prospects, strategy, and financial needs. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, assumptions, and other factors described in the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a highly competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report on Form 10-K. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements in this Annual Report on Form 10-K are based on information available to us as of the date of this Annual Report on Form 10-K. While we believe that such information provides a reasonable basis for these statements, such information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely on these statements.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed as exhibits to this Annual Report on Form 10-K with the understanding that our actual future results, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Annual Report on Form 10-K to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect new information, actual results, revised expectations, or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. “Risk Factors” in this Annual Report on Form 10-K. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- We have incurred significant losses since inception and expect to incur significant additional losses for the foreseeable future which may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability;
- Our business is highly dependent on the success of two current commercial products, and in particular OMNI. The development of TearCare for expanded indications depends upon positive clinical data, and the safety and efficacy of our products are not yet supported by long-term clinical data, which could delay or prevent clearance by regulatory authorities or limit sales if cleared, certified or approved;
- We may need additional funding in order to finance our planned operations. The inability to raise funds on acceptable terms, if at all, when needed, may force us to delay, reduce or eliminate our product development programs and commercialization efforts;
- The COVID-19 pandemic has impacted, and likely will continue to impact, our operations and financial results and may materially and adversely affect our business and financial results in the future;
- We are subject to extensive and costly government regulation on federal, state and foreign levels and we may not receive, or may be delayed in receiving, the necessary regulatory clearances, certifications or approvals for our future products or modifications to our current products;
- We may incur significant liability if it is determined that we are not complying with federal, state or foreign regulatory requirements, such as if it is determined that we are promoting off-label uses of our products;
- Changes in private and public health insurance coverage and reimbursement rates may affect the adoption of our products and our future revenue;
- Developments by competitors may render our products or technologies obsolete or noncompetitive and the development of new products, technologies, procedures, medications or other therapies could replace or reduce the importance of our products;
- We rely on third parties for the manufacture and supply of OMNI and TearCare;
- We depend on a limited number of single source suppliers for some of the components, accessories, and materials used in the manufacture and assembly of OMNI and TearCare and any shortfall in the supply chain may cause our business to materially suffer;
- If we are unable to obtain, protect, maintain, enforce and adequately protect our intellectual property rights with respect to our technology and current and future products, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and current and future products may be adversely affected;

- Litigation related to infringement and other intellectual property claims, with or without merit, is unpredictable, may be expensive and time-consuming and may divert management's attention from our core business. Our intellectual property has not been tested in litigation. Litigation that we initiate to protect our rights could result in invalidation of our patents, which may undermine our competitive position in our current or anticipated markets; and
- If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers or other significant personnel or experience increases in our compensation costs, our business may materially suffer.

PART I

Item 1. Business

Overview

Our mission is to transform ophthalmology and optometry through the development and commercialization of proprietary devices that target the underlying causes of the world's most prevalent eye diseases. We are passionate about improving patients' lives. Our business philosophy is grounded in the following principles: comprehensively understanding disease physiology; developing products that are intended to restore natural physiological functionality to diseased eyes; developing and marketing products that achieve superior effectiveness versus current treatment paradigms while minimizing complications or side effects; providing intuitive, patient friendly solutions to ophthalmologists and optometrists (together, eyecare professionals or ECPs); and delivering compelling economic value to all stakeholders, including patients, providers and third- party payors such as Medicare and commercial insurers. Our objective is to develop and market products for use in new treatment paradigms and to create an interventional mindset in eyecare whereby our products may be used in procedures which supplant conventional outdated approaches. We believe current eyecare treatment models rely heavily on prescription medications, symptom relief, or either flawed or highly invasive, later-stage procedural interventions, and often fail to adequately address the true underlying cause of disease.

We have focused our initial product development efforts on the treatment of two of the world's most prevalent and underserved eye diseases, glaucoma and dry eye disease, or DED. We estimate the annual addressable U.S. market opportunities for the products in our Surgical Glaucoma and Dry Eye segments are approximately $6 billion and approximately $10 billion, respectively, while 2020 U.S. manufacturer revenues in the surgical glaucoma and DED markets were approximately $350 million and $2.4 billion, respectively, demonstrating that currently available solutions have not addressed a large part of the market need.

Glaucoma, a group of chronic, often asymptomatic, diseases that damage the optic nerve, is the world's leading cause of irreversible blindness. Glaucoma does not have a cure and is a progressive disease; if left untreated or insufficiently treated, glaucoma can lead to irreversible disability and blindness. An estimated 102 million people worldwide suffer from glaucoma. Primary open-angle glaucoma, or POAG, is the most prevalent form of glaucoma and affects over 60 million people worldwide, including approximately 4.1 million people in the United States, of whom an estimated 3.4 million have been diagnosed. One of the greatest risk factors for POAG, and the only risk factor that can be controlled, is elevated intraocular pressure, or IOP. Elevated IOP is often caused by malfunctioning drainage pathways in the eye that provide abnormal resistance to the outflow of aqueous humor, a clear, watery fluid which bathes and nourishes the lens and maintains pressure within the eye.

Our OMNI Surgical System, or OMNI, is a handheld, single use, therapeutic device that allows ophthalmic surgeons to reduce IOP in adult glaucoma patients. OMNI allows the ophthalmic surgeon to sequentially complete two well-established but historically invasive *ab externo* glaucoma procedures, canaloplasty and trabeculotomy, in an efficient, minimally invasive manner using a single, bloodless and sutureless clear corneal microincision. OMNI allows ophthalmic surgeons to transform these two distinct, historically invasive *ab externo* glaucoma procedures into a sequential, *ab interno* minimally invasive glaucoma surgery, or MIGS, procedure. MIGS procedures are performed through a one to two millimeter clear corneal incision similar to those used in cataract surgery for intraocular access and have a strong demonstrated safety profile, characterized by minimal trauma to the eye and quick patient recovery times. The FDA has authorized the use of OMNI for reducing IOP in all adult POAG patients both by itself on a standalone basis, which we refer to as Standalone procedures, or in combination with cataract surgery, which we refer to as Combination Cataract procedures. Several competing MIGS devices, including the current market leaders, have only been authorized by the FDA for use in Combination Cataract procedures for adult patients with Mild-to-Moderate severity. We estimate that over 85% of the U.S. addressable market opportunity for POAG cannot be served with Combination Cataract procedures because less than 15% of POAG patients receive cataract surgery in any given year.

We believe that OMNI delivers the highest level of effectiveness of any available MIGS product, as it is the only device that provides access to 360 degrees of the diseased conventional outflow pathway and can address all three primary points of resistance in the conventional outflow pathway (trabecular meshwork, Schlemm's canal, and the distal collector channels), through a single clear corneal incision.

OMNI's indication for use, which we believe is among the most comprehensive in MIGS, was cleared by the FDA in March 2021 based upon the review of clinical data from ROMEO, our U.S. multi-center clinical study of OMNI in

Combination Cataract and Standalone procedures. OMNI has received 510(k) clearance from the FDA and a CE mark to be marketed in the U.S. and the European Union, or EU, respectively, for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce IOP in adult patients with POAG in the U.S. or with open-angle glaucoma, or OAG, in the EU. OMNI is cleared by the FDA to lower IOP in both Combination Cataract and Standalone cases for all adults with POAG. By comparison, trabecular bypass stents are indicated for use only in Combination Cataract procedures for patients with Mild-to-Moderate severity in the U.S. Trabecular bypass stents were the first MIGS implant devices to be authorized by the FDA. We believe the combination of their restricted indication for use and their market leadership position has unnaturally skewed the U.S. MIGS market towards Combination Cataract procedures. In November 2021, the FDA granted an Investigational Device Exemption, or IDE, authorizing us to conduct a clinical study, which we refer to as PRECISION, to assess the safety and effectiveness of a new, higher volume investigational OMNI device to perform canaloplasty alone to lower IOP in adults with POAG. We are conducting this canaloplasty alone IDE trial to support a premarket notification to the FDA seeking clearance for use to perform canaloplasty-alone procedures in adults with POAG.

Our goal is to establish OMNI as the standard of care for all POAG patients by continuing to grow its adoption and utilization in the existing Combination Cataract market segment, which we believe remains underpenetrated and estimate is capturing less than one-third of its current potential procedural volume, and by pioneering the development of the Standalone market segment (over 85% of the potential U.S. POAG market). We believe the consistent therapeutic outcomes OMNI delivers are important for patients and surgeons alike, especially those considering a Standalone MIGS procedure. For patients, we believe the anxiety that may accompany the need for ocular surgery can be tempered by driving education and awareness of these consistent outcomes. For surgeons, consistent outcomes simplify the treatment choice and the decision to perform a procedure. We believe delivering consistently effective results will be crucial to unlocking the Standalone market, as well as capitalizing on the full potential of the Combination Cataract market.

After receiving our initial FDA 510(k) clearance for OMNI in late 2017, we began the commercial sale of the device in February 2018. We primarily sell OMNI in the U.S. through our dedicated Surgical Glaucoma sales team. Our commercial strategy for OMNI centers on building confidence and conviction amongst the glaucoma community through continued execution of our clinical trials and publishing their results in peer- reviewed journals. In addition, our highly involved sales and training model serves to promote a world-class surgical experience and identify additional OMNI use cases within its cleared indication, including in additional Standalone procedures and across all addressable POAG severities. The procedure enabled by OMNI, canaloplasty followed by trabeculotomy, is covered and reimbursed by all Medicare Administrative Contractors, or MACs, and numerous private insurers, covering an estimated 74% of U.S. POAG sufferers. Designed for use in well-established clinical procedures, and with advantages that have been observed to promote safe, effective and highly consistent clinical outcomes, we believe that OMNI has the potential to establish a more proactive, interventional paradigm for IOP reduction in POAG. Our Surgical Glaucoma segment, which includes OMNI, represented 95% of our total revenues for the year ended December 31, 2021.

The TearCare System, or TearCare, is a unique open-eye heating and expression device designed to melt and remove meibomian gland obstructions. We believe TearCare has a compelling physiological profile to address obstruction from meibomian gland disease, or MGD, which is the primary cause of evaporative DED, a disease characterized by low quality tears that evaporate prematurely. Dry eye complaints are the most common reason for a patient visit to an eye doctor. There are an estimated 739 million people globally who suffer from DED. DED is the most common reason for a patient visit to an eye doctor, yet of the 38 million people with DED in the U.S., only an estimated 17 million have been diagnosed with DED. Dry eye symptoms have a significant impact on the quality of life and productivity of patients suffering from DED. If left untreated, DED can be extremely painful, leading to permanent cornea damage and vision impairment.

Studies have shown that evaporative DED resulting from MGD is associated with approximately 86% of all DED cases. In healthy eyes, there are 25-30 meibomian glands located within each of the upper and lower eyelids. These glands produce and secrete an oily substance called meibum which forms the outer layer of healthy tears, which is also known as the lipid layer. Meibum normally has an olive oil-like consistency and contributes a vital element of the tear film that prevents premature tear evaporation. In patients with MGD, meibum hardens within the glands causing obstructions that can partially or completely block the oily secretions from reaching the tear film. The resulting compromised outer surface of the tear leads to accelerated tear evaporation and DED. Third-party clinical studies have also demonstrated that treating MGD by liquefying and removing clogged meibum is the most effective method of eliminating obstructions and restoring a healthy tear film lipid layer, thereby preventing premature evaporation of tears.

TearCare is designed to enable ECPs to heat and liquefy meibomian gland blockages, followed promptly by manual, comprehensive clearing of these blockages with a separate clearance tool. We developed TearCare to serve as an elegant, compact, portable, and intuitive solution comprised of a reusable hardware controller, the SmartHub, and a breakthrough, wearable, software-controlled eyelid technology, the SmartLids. Applied adhesively and non-invasively to the outside of the eyelids, single-use SmartLids deliver a precise therapeutic level of heat into the meibomian glands. Engineering SmartLids to remain comfortably adhered to virtually all shapes and sizes of eyelids while allowing freedom to blink and delivering precise therapeutic heat is one of our most significant design accomplishments. This heating process follows clinically proven guidelines for temperature and duration required to melt obstructions in the glands and restore the production and secretion of healthy, clear meibum onto the tear surface. The proprietary, highly conformant, open-eye design of TearCare allows patients to blink naturally throughout the thermal portion of the procedure, which provides a comfortable patient experience. TearCare can be utilized by an ECP in a straightforward in-office procedure and can be accommodated during the course of a routine patient visit. Additionally, TearCare does not require a large capital equipment investment by ECPs, and we believe that it offers an attractive economic value proposition to providers, patients and third- party payors.

In OLYMPIA, our large multi-center, randomized control trial, or RCT, TearCare was associated with statistically significant clinical improvements in all assessed signs and symptoms of DED. This included tear breakup time, or TBUT, and meibomian gland secretion score, or MGSS, objective measurements of DED that were the trial's primary endpoints, as well as patient-reported symptoms surveys, including Ehlers Danlos syndrome, or EDS, ocular surface disease index, or OSDI, and symptom assessment in dry eye, or SANDE, at all time periods measured (both two weeks and four weeks post-treatment).

We believe the MGD market requires additional ECP and patient education, including clinical data to differentiate procedural and product alternatives, and enhanced patient access through the potential advancement of reimbursement coverage. Our goals with the development of TearCare are to fully transform the current outdated treatment paradigm based primarily on over-the-counter, or OTC, and prescription eyedrops which do not address obstruction of the meibomian glands, the primary root cause of MGD, and establish use of TearCare as the standard of care for the millions of patients suffering from evaporative DED caused by MGD. Revenues from our Dry Eye segment, which includes TearCare and related accessories, represented 5% of our total revenues for the year ended December 31, 2021

In December 2021, the FDA cleared TearCare for the application of localized heat therapy in adult patients with evaporative DED due to MGD, when used in conjunction with manual expression of the meibomian glands. We modified our commercial efforts to incorporate this expanded indication for use, which we believe will make TearCare more attractive to our customers and their patients.

We focus on continuous innovation and seek regular input from our network of expert employees (including several ophthalmologists on staff), advisors and customers to rapidly iterate our pre- and post-commercial product designs with the aim of better satisfying the needs of our customers and their patients, and increasing adoption and utilization of our solutions.

Our ability to continuously and rapidly innovate our products is a core competency of our company. Our product innovation has resulted in a comprehensive portfolio of 30 issued U.S. patents, 45 issued patents outside of the U.S. (including five issued European patents and their national validations), 19 pending U.S. non-provisional patent applications, 18 pending foreign patent applications and two pending Patent Cooperation Treaty patent applications as of December 31, 2021.

The overall success of our innovative approach to eyecare to date has been confirmed by the over 85,000 estimated uses of OMNI and its direct predicates in over 1,200 hospitals and ambulatory service centers, or ASCs, in the U.S. and EU, and over 15,000 estimated uses of TearCare in over 550 eyecare facilities in the U.S. through December 31, 2021. We have experienced significant growth and market adoption since launching OMNI and are executing a long-term plan for further development of the market for TearCare.

Our Solutions

We have designed OMNI and TearCare to be interventional ophthalmology devices. We believe that both glaucoma and DED are significantly underserved by current treatment offerings and that there are large market opportunities for effective solutions that restore the natural functionality of diseased eyes.

Our Product Development Approach

The past, current, and ongoing development of OMNI and TearCare follows our internal product development approach, which is governed by four fundamental requirements that we believe are critical to delivering the most effective, safe and consistent clinical outcomes for patients with eye disease.

- **Comprehensive Understanding of Disease Physiology.** We review and analyze all available clinical data, science, and literature that is relevant to a disease to achieve a sound understanding of its underlying cause(s), which guides the development of our products.
- **Treatment of Underlying Causes.** Healthy eyes are self-regulating marvels of evolution, biomechanics, chemistry and physiology. We believe that restoring the natural functionality of diseased eyes by comprehensively treating underlying cause(s) of disease provides the optimal combination of effectiveness and safety.
- **Intuitive Design.** Our products are designed to transform complex, impractical or invasive treatment approaches into intuitive, minimally invasive, user-friendly procedures. Our product development goals are focused on delivering a preferred "go to" treatment of choice for ophthalmologists and optometrists.
- **Patient Access.** We seek to maximize availability and accessibility of our products for as many patients as possible. We believe that our devices have the potential to offer differentiated clinical, experiential and economic value to all eyecare stakeholders. For conditions where patients lack optimal treatment access due to insurance coverage limitations or difficult patient-pay economics, we plan to demonstrate the value proposition of our solutions through data from rigorous clinical trial data and real-world results to improve access.

We aim and expect to be a clinical leader in every eyecare segment we enter and seek to achieve all four criteria in any of our product development projects. From device ideation to commercialization, we take into consideration the perspectives of patients, providers and third-party payors throughout our product development process. When possible, we seek to streamline our product commercialization process by judiciously designing our products to achieve the most efficient routes for FDA clearance or authorization for each applicable indication and reimbursement coverage by third-party payors.

OMNI Surgical System

OMNI is a handheld, single use, therapeutic device for minimally invasive glaucoma surgery, or MIGS. OMNI is designed to restore the eye's natural drainage system without compromising the structural integrity of the eye or leaving implants behind post-surgery.

We believe that OMNI is the first and only MIGS device that the FDA has indicated for *ab interno* procedures to lower IOP across all severities of POAG, including Standalone procedures. We further believe that OMNI is also the first and only multi-procedure MIGS device dually indicated for canaloplasty followed by trabeculotomy. Canaloplasty primarily addresses distal resistance (i.e., collapsed Schlemm's canal, blocked collector channel ostia) and has some presumed effects on the inner wall of Schlemm's canal and the trabecular meshwork due to dilation and stretching. In a trabeculotomy procedure, a surgeon unroofs Schlemm's canal by cutting the trabecular meshwork to provide aqueous humor with direct access to the drainage points in the conventional outflow pathway. Trabeculotomy addresses proximal resistance (i.e., outflow resistance in the trabecular meshwork and inner wall of Schlemm's canal). We believe that the sequential combination of canaloplasty followed by trabeculotomy is uniquely capable of treating all three primary points of resistance in the conventional outflow pathway of the eye. We believe treating all three primary points of resistance is critical to achieving the consistency and level of effectiveness in reducing IOP and medication requirements necessary to expand the use case for MIGS procedures to the Standalone market and to all disease severities among adult POAG patients.

We have applied our medical expertise, as well as specialized design and engineering capabilities, to create a complex device that is simple in appearance and intuitive to use. Each OMNI device consists of 29 separate precision-engineered parts that have been optimized for performance, effectiveness and usability. After inserting the cannula tip into the corneal microincision and accessing Schlemm's canal, the surgeon can advance and retract the catheter with a fingertip dial up to 180 degrees. Upon retraction of the catheter, OMNI delivers viscoelastic fluid to complete the viscodilation of Schlemm's canal. The surgeon can complete a full 360 degree canaloplasty by reinserting the catheter and advancing it in the opposite direction. To perform the trabeculotomy following the canaloplasty, the same microcatheter can be reinserted into Schlemm's canal and used to deroof the trabecular meshwork in a titratable manner (90, 180, 270 or 360 degrees). OMNI's versatility and titratable functionality, which we believe are unmatched by other MIGS products currently on the market, enable surgeons to perform sequential comprehensive outflow treatments that they can customize based on an individual patient's disease severity and eye anatomy in both Combination Cataract and Standalone settings.

TearCare System

In an effort to address the treatment of evaporative DED due to MGD, we custom designed TearCare to facilitate what we believe is the optimal method for clearing meibomian gland obstructions based on numerous clinical studies: warming the glands to a minimum of 41 degrees Celsius for 15 minutes to melt congealed meibum followed by manual, clinician customized and performed removal of the liquefied obstructions using forceps to help facilitate restoration of healthy meibum production to naturally fortify the tear's protective lipid layer. Tear film is a complex, continuously renewed solution that is necessary for maintaining a healthy cornea and optical clarity. Tears consist of three layers: an inner mucous layer that nourishes the cornea and helps stabilize and anchor the tear film; a middle aqueous layer that lubricates the eye, removes particles and prevents infection; and an outer lipid layer, or meibum, that prevents premature evaporation and maintains tear film stability. MGD occurs when meibum accumulates and hardens within the meibomian gland. Over time, the glands can become blocked or clogged, which prevents meibum from reaching the tear, fortifying the outermost tear lipid layer, and protecting the integrity of the tear. The goal of TearCare treatments is to restore the eyelid's natural ability to produce healthy lipid secretions and recover the integrity of the tear film.

Our TearCare System includes a pair of single-use SmartLids, the first wearable, highly conformant, precision heating device for the eyelids. SmartLids allow for eyes to be open and blink during the thermal portion of the process and are software-controlled, delivering precise heat to the tarsal plates of the eyelids directly overlying the meibomian glands while continuously monitoring temperature and communicating 144 times per second with the SmartHub, a compact, finely calibrated power source and control unit which can make instantaneous adjustments to ensure delivery of the desired amount of heat and therapeutic temperature level. Engineering SmartLids to remain comfortably adhered to virtually all shapes and sizes of eyelids while allowing freedom to blink and delivering precise therapeutic heat is one of our most significant design accomplishments. Following therapeutic heat application by TearCare, ECPs may use forceps to manually express melted meibum from each gland. ECPs can tailor the amount of pressure applied during expression to specific glands based on a desired full evacuation of the glands, thereby allowing the eyelids to resume the production and secretion of meibum to coat and protect tears.

According to patient and ECP feedback, treatments using TearCare are comfortable for patients since they can keep their eyes open during the thermal portion of the procedure and have the freedom to blink naturally. Additionally, TearCare was designed to be administered during the course of a routine office visit to an ECP, which makes it convenient for patients, and allows providers to maintain procedural throughput in their practices. We believe that these features of the patient and ECP experience with TearCare procedures offer a stark contrast to other available alternatives which we believe are burdened by ineffective and suboptimal product design, including awkward and uncomfortable patient experiences through closed eye solutions and/or manual solutions that require extremely close patient proximity to the ECP throughout the treatment.

Our Success Factors

Our mission is to transform eyecare by developing products that address the underlying causes of the world's most prevalent eye diseases. We design our products to enable ECPs to perform safe and effective interventional procedures that can transform treatment paradigms. We believe the following success factors will drive the growth of our company:

Large market opportunities in eyecare with flawed treatment paradigms. We estimate the total addressable annual market opportunities in the U.S. for OMNI and TearCare are approximately $6 billion and approximately $10 billion, respectively, yet combined 2020 U.S. manufacturer revenues in these markets implied less than 20% total

addressable market penetration. We believe the addressable market penetration in Standalone MIGS and in MGD procedures are less than 10% each. We believe that market leading MIGS alternatives do not consistently and comprehensively address the underlying causes of POAG and do not adequately treat a broad enough range of disease sufferers. In POAG, we estimate that over 85% of diagnosed sufferers can be treated only with Standalone procedures because they do not require cataract surgery. Similarly, we believe that the market leading DED products do not address the primary underlying cause of the disease, MGD, while those that do attempt to treat MGD lack user friendly design and do not provide broad patient access. Given the narrow historical product development focus on aqueous deficiency, DED patients are currently limited by a mismatched treatment set (typically prescription or OTC eyedrops) which do not address the root causes of MGD, the predominant underlying cause of the condition.

Continual development of innovative technologies. Our ability to transform treatment paradigms in large, underserved eyecare markets will depend on our ability to develop and commercialize products which are differentiated in how they treat underlying diseases, in their safety and effectiveness, in the breadth of their patient access and in their ease of use for the ECP. We believe our product development approach is a key differentiator of our team and our company. We design and iterate our products with continual input from our advisor network, an elite group of ECPs who prioritize efficiency, safety and effectiveness. Once our products are authorized by the FDA and launched, our customer feedback loop helps us further develop our products.

Consistent delivery of exceptional customer experience. One of the key drivers of our success will be fully developing the potential addressable markets for POAG and MGD by maximizing the breadth of patients that our products can serve. We believe developing our target markets requires a consistent, exceptional customer experience, which is best accomplished through a differentiated, highly involved commercial model. Our sales professionals provide ECPs with the necessary education, training and support to adopt and continue to use our products for their authorized uses. We devote significant resources to onboarding our sales professionals and to continuously augmenting their knowledge and capabilities. Our management team and commercial organization are highly experienced in developing primary markets and commercializing disruptive products designed to satisfy unmet patient needs.

Prioritization of clinical excellence and market education. We are deeply committed to a robust clinical trial program and are investing significant resources to generate additional scientific evidence regarding the safety and effectiveness of OMNI and TearCare through numerous clinical studies and the publication of our findings in leading peer-reviewed journals. We believe OMNI is growing rapidly in adoption because of its superior effectiveness and comparable safety compared to alternative MIGS devices and that patients, surgeons and other stakeholders will all benefit from our continued investment in clinical trials and our broader market education initiatives, which include actively engaging in scientific conventions, presenting at conferences, and conducting educational and promotional activities, including peer-to-peer events. We also believe that treatment decisions should be evidence-based and that rigorous clinical studies with high quality data are crucial to achieving and maintaining optimal patient access.

Focus on compelling economics and value creation for all eyecare stakeholders. We focus on developing products to generate substantial benefits for patients, providers and payors. We believe use of our devices will ultimately reduce the all-in cost of treating these diseases for payors. For the sequential procedures using OMNI, surgeons and facilities use the longstanding permanent Category I CPT code for canaloplasty, which is broadly covered by Medicare and private payors. TearCare can provide ECP practices with an attractive recurring revenue business model with only a modest initial investment. While there is a viable patient-pay market for TearCare, we believe that improving access to treatments using TearCare through insurance coverage by Medicare and private payors will be the most effective way to reach the largest number of patients. Leveraging the results from our OLYMPIA RCT, we received FDA clearance to expand TearCare's indication for use and plan to pursue further clearances for more robust indications for use as we build out our library of clinical trial and real-world data regarding the benefits of TearCare treatments. DED is the most common reason for patient visits to an ECP and has major negative effects on patient health and society. One study estimated the overall direct and indirect costs of DED in the U.S. to be $55.4 billion per year.

Scale culture built on community, passion, courage and perseverance. Our organization is designed to be nimble, innovative, adaptive and growth oriented. We have an entrepreneurial and creative foundation that is complemented with an experienced executive team, who provide deep relationships throughout the eyecare community. We share a passion for improving the lives of people suffering from eye diseases and our success has engendered significant esprit-de-corps at all levels of our organization. We believe that our focus on thought leadership, high performance and collaboration, as well as our hiring and recruiting processes, have enabled us to attract and retain a world class team that is prepared to transform eyecare for all stakeholders.

Our Growth Strategy

The fundamental objectives of our growth strategy are to establish robust clinical data to support the development of our target markets and the continued commercialization of our products and to deliver an exceptional customer experience to the ECPs and patients who utilize our products. Our current growth strategies include:

- **Establish OMNI as the standard of care for interventional glaucoma treatment among MIGS-trained surgeons.** We believe OMNI has the unique potential to transform the treatment paradigm for IOP reduction in adult POAG patients by greatly expanding the universe of patients who can be treated with MIGS treatment alternatives. We believe OMNI has distinct advantages with respect to effectiveness, safety and its broad indication for use to reduce IOP across all adult POAG patients in both Standalone and Combination Cataract procedures. High-volume cataract surgeons who are familiar with MIGS procedures are our highest priority customer acquisition targets and we have directed our initial commercial efforts towards them. We have successfully gained commercial traction with many of these surgeons, who typically first learn to use OMNI during Combination Cataract procedures.
- **Pioneer the $5 billion Standalone MIGS segment.** Based on our field research, we believe that after gaining experience using OMNI and confidence in its consistency and effectiveness in familiar Combination Cataract cases, surgeons will often expand the use case for OMNI to include more proactive and interventional POAG cases. We believe many of these cases will involve Mild-to-Moderate Standalone procedures for which we believe OMNI is the only MIGS device authorized by the FDA for lowering IOP via an *ab interno* approach. A year-end 2020 internal field study of our user base has indicated that Standalone procedures in 2020 constituted an estimated greater than 20% of our responding customers' total OMNI procedures. Given these strong initial results, we have continued to invest resources to execute our interventional POAG market development plan, which includes educating surgeons, Facility administrators, primary care ECP referral networks and patients on the clinical benefits of OMNI, particularly in Standalone procedures. Our ongoing and planned clinical studies feature Standalone and Combination Cataract trials, including head-to-head RCTs versus a leading trabecular bypass stent and a leading prescription OAG medication.
- **Develop the MGD treatment market through a patient access-led strategy.** We are executing a comprehensive long-term strategy to increase patient access to TearCare beyond its current patient-pay market. Our long-term goal is for TearCare procedures to achieve broad reimbursement from private payors and Medicare for effectively treating the signs and symptoms of DED due to MGD. We believe the MGD market is the most underserved in eyecare and that current treatment protocols either fail to directly address MGD's root cause, require cost-prohibitive capital equipment purchases, lack elegant and user-friendly design, and/or lack the compelling clinical data required to transform treatment paradigms and properly develop the market. Key components of our strategy include: pursuing clearance from the FDA to continue expanding TearCare's indications for use to treat DED due to MGD; execution of our SAHARA RCT, which will compare treatments using TearCare to the leading prescription eyedrop treatment and assess the durability of TearCare procedures over a 24 month period (SAHARA was designed specifically to provide key clinical data that could support potential reimbursement decisions by third-party payors); developing real-world prior authorization and reimbursement claims evidence to educate payors on the benefits of TearCare for its authorized uses, facilitated by our market access team; and converting our temporary Category III CPT code for TearCare to a permanent Category I CPT code.
- **Drive adoption and utilization of our products by leveraging additional clinical trials and market education.** We believe our existing clinical data demonstrates the compelling safety and effectiveness of OMNI for its cleared indication, and we plan to continue delivering additional clinical evidence regarding its safety and effectiveness. We have dedicated significant resources to further establish definitive clinical studies regarding the use of OMNI for IOP reduction and/or medication reduction in adult patients. We received clearance from the FDA for an expanded indication for use for TearCare in December 2021, supported by the effectiveness and safety data from our OLYMPIA RCT We have two additional ongoing and planned studies intended to evaluate the safety and effectiveness of TearCare. We believe the results of these studies will support potential clearances for expanded indications for use and our patient access development strategy.

- **Deepen and broaden our commercial organization**. We plan to continue investing resources to grow our commercial team, both in the U.S. and internationally. In addition to competing in the market for devices used for Combination Cataract MIGS procedures in adult POAG patients, we are investing significant resources in our Standalone market development plan, which includes a team of representatives focused on educating ECPs, ophthalmic surgeons and patients on the broad utility and use cases for OMNI and on Standalone treatment alternatives generally. Through December 31, 2021, we had sold OMNI and its predicate devices to over 1,200 facilities in the U.S. As of December 31, 2021, there were over 750 currently active (i.e., ordering with past 90 days) ordering facilities. There are over 10,000 ophthalmologists focused on performing cataract and glaucoma surgeries in the U.S. and over 3,000 are currently MIGS trained, a figure that is expected to grow as MIGS utilization increases, in part driven by the benefits offered by OMNI. As of December 31, 2021, approximately 1,500 surgeons have been trained to use OMNI. This customer base has seen very low churn levels, with strong retention of surgeons following a multi-month training and trial period. Our targeted and controlled launch of TearCare in the U.S. through a small, dedicated sales team has been successful in demonstrating that DED-experienced customers have strong reorder levels and in providing insights into the large patient-pay market. To help our customers secure appropriate reimbursement from payors for utilizing either OMNI or TearCare in treating their patients, our Market Access group added a dedicated field based Reimbursement Account Executive team that is now fully on board. We plan to grow our commercial organization over time by matching its growth to the achievement of key milestones in our long-term plan to develop our target markets.

- **Expand into international markets**. We believe there is a substantial market opportunity for clinically effective glaucoma and DED products such as OMNI and TearCare outside of the U.S., or OUS. Over the next several years, we intend to increase our OUS investment. The number of U.S. POAG and DED sufferers represents a small fraction of global sufferers — approximately 6% and 5%, respectively — yet the U.S. represents approximately 60% and approximately 40% of the global glaucoma surgical device and DED treatment markets, respectively. There are currently a number of developed OUS markets with ECPs who have relevant ophthalmologic and optometric experience and existing reimbursement for MIGS devices, particularly in the EU where OMNI has a broad CE mark to lower IOP for all adult OAG patients. Trabecular bypass stents have established significant markets in Europe and other geographies. We also believe that a number of OUS market fundamentals are attractive with respect to potential OMNI adoption throughout Europe and Asia:

    - Surgeons in certain OUS markets choose to intervene at a later stage of eye disease which places increased criticality on highly robust and dependable effectiveness;

    - Circumferential canal procedures are widely accepted and adopted in select large OUS markets. For add addexample, *ab externo* canaloplasty has been very successful in Germany and *ab externo* circumferential trabeculotomy has been a preferred glaucoma surgery for many years in Japan; and

    - Surgeons in certain OUS markets are typically salaried and less specialized than U.S. peers and while procedural efficiency and/or potential case volumes are still significant considerations for these OUS surgeons, clinical effectiveness is of increased relative importance.

    We believe that OUS markets can be particularly compelling for clinically differentiated products. Our OMNI clinical trial program includes head-to-head RCTs against competing treatments in European markets that are designed to address the needs of regulatory bodies and third-party payors in those markets. We believe the results of these trials will help OMNI penetrate and gain adoption in these geographies. We also plan to commercialize TearCare in OUS markets and believe MGD procedures have significant potential. We currently rely on a combination of direct sales personnel and independent distributors to sell our products in Europe. In 2021, we hired our first direct sales personnel in the U.K. and have continued to add to our U.K.-based sales teams. We plan to both deepen that team and expand through a combination of direct resources and distributor sales into other geographies in 2022 and beyond. We will also be expanding our Market Access capabilities as appropriate in 2022 to ensure that we secure optimal coverage and reimbursement for OMNI.

- **Continuously innovate premium product offerings throughout eyecare.** Over the course of our ten year operating history, we have successfully brought to market multiple iterations of OMNI, its predicate devices and TearCare. Our product development approach, which targets underserved eyecare

populations, and our ability to effectively navigate commercialization pathways, has enabled us to launch our products in a highly capital efficient manner, which we believe is distinctive relative to other medical device technology companies and allows us to retain financial flexibility to continue investing in further product enhancements or to explore other avenues of research and development for future pipeline products in eyecare, including drug therapies, sustained release drug delivery platforms and devices. Our internal and external advisor and customer networks provide us with ongoing real-world feedback, which we use to rapidly implement improvements and further develop our products. Our product development roadmap focuses on improving our current products, seeking required FDA authorizations, and disrupting other eyecare categories where stakeholders' needs remain unmet. We believe our product development capabilities and process provide us with a competitive advantage.

Clinical Data

We believe that treatment decisions should be evidence-based and hold ourselves to the highest clinical and ethical standards to build and maintain credibility in the medical community. We are deeply committed to conducting studies to evaluate the safety, effectiveness and durability of treatments using our products, and subjecting the results to the rigorous peer review process for publication in leading journals. Our robust and growing libraries of evidence to support OMNI and TearCare are helping to drive their awareness and adoption, and ultimately advancing patient care in ophthalmology and optometry.

We are currently conducting active and robust clinical trial programs in both POAG and MGD. Our completed, ongoing, and planned clinical trials include several head-to-head RCTs against market leading treatments. We also plan to continue supporting our investigator-initiated trial program.

OMNI Surgical System

OMNI Clinical Program Overview

Building on a solid foundation of completed and ongoing clinical trials, we are investing significant resources to further develop clinical data regarding the use of OMNI. Clinical trial designs for OMNI include both RCTs and retrospective real-world studies, based on our belief that each of these approaches has unique strengths. Since 2018, there have been 15 articles published in peer-reviewed journals for OMNI and its Sight Sciences predicate devices and procedures. Our robust clinical trial program for OMNI intends to include nearly 2,000 subjects across our trials. Our completed trials include ROMEO and GEMINI. ROMEO was used to support OMNI's indication for use expansion in the U.S. in March 2021 and resulted in two published articles in peer-reviewed journals. GEMINI was a prospective, multi-center, historical control, single-arm, U.S. study.

Table 2: Sight Sciences OMNI Ongoing and Planned Clinical Studies

Name	Description
TRIDENT	NCT04658095: A Prospective, Randomized, Multicenter Study To Compare The Safety And Effectiveness Of The OMNI® Surgical System And The iStent Inject In Pseudophakic Eyes With Open Angle Glaucoma. Three-armed RCT in Europe evaluating the safety and effectiveness of (1) canaloplasty alone using OMNI, (2) canaloplasty followed by trabeculotomy using OMNI and (3) trabecular bypass canal implants all as standalone intervention in pseudophakic eyes.
PRECISION	Three-armed RCT IDE evaluating the safety and effectiveness of (1) canaloplasty alone using new higher volume OMNI, (2) canaloplasty followed by trabeculotomy using new higher volume OMNI and (3) trabecular bypass canal implants, all in conjunction with cataract extraction. IDE could be used to support a canaloplasty alone indication for use for OMNI
JAEGER	Three-armed RCT IDE evaluating the safety and effectiveness of (1) canaloplasty alone using new higher volume OMNI, (2) canaloplasty followed by trabeculotomy using new higher volume OMNI and (3) hypotensive medication
TREY	Retrospective study evaluating the effectiveness of Standalone intervention using OMNI in eyes with uncontrolled IOP previously treated with trabecular bypass canal implants
ROMEO II	Multi-center study to evaluate longer term outcomes (18-24 months) from Elevated IOP cohort (>18 mmHg) in ROMEO study
GEMINI 2.0	NCT05044793: An Observational Multicenter Clinical Study To Assess The Long-Term Safety And Effectiveness Of The OMNI® Surgical System In Combination With Cataract Surgery In Eyes With Open Angle Glaucoma
ORION 2.0	NCT04872348: An Observational Multicenter Clinical Study To Assess The Safety And Effectiveness Of The OMNI® Surgical System In Pseudophakic Eyes With Primary Open Angle Glaucoma. Evaluate 24-month durability of effectiveness and safety for OMNI
AAO/IRIS® Registry	Evaluate historical data for OMNI and competing products from IRIS® Registry in the U.S.

ROMEO Study

The ROMEO study was a multi-center retrospective study conducted from February 2018 through April 2020 and designed to assess safety and effectiveness of OMNI in reducing IOP and hypotensive medication usage in Mild-to-Moderate OAG patients at 12 months post-operation. This study evaluated the clinical effect of *ab interno* canaloplasty and trabeculotomy performed using OMNI in both Standalone and Combination Cataract procedures, the use of ocular hypotensive medications and safety in patients with OAG. Clinical data from ROMEO supported our March 2021 FDA 510(k) clearance for an expanded indication for use of OMNI.

The study evaluated two different groups of patients based on baseline IOP with different treatment goals: The Elevated IOP Group had a preoperative IOP greater than 18 mmHg and its treatment goal was IOP reduction. The Controlled IOP Group had a preoperative IOP less than or equal to 18 mmHg, with a treatment goal of IOP maintenance and medication reduction. The primary endpoint was defined as the proportion of subjects at 12 months post-operation with IOP between 6 mmHg and 18 mmHg or with a 20% or greater reduction from preoperative baseline IOP, on the same or fewer number of ocular hypotensive medications compared to the preoperative baseline, and with no additional IOP-lowering surgery or laser treatment. IOP of 18 mmHg or below is a well-established benchmark by the clinical community for control of POAG progression and is based on the belief that maintenance of IOP control should be considered a "success" for patients already controlled on medication. For patients not controlled on medication, a 20% reduction in IOP is the recommended primary efficacy endpoint according to FDA guidance for implantable MIGS devices, which we have relied upon in designing our retrospective non-implantable device study. Safety endpoints included ocular adverse events, and efficacy endpoints included secondary surgical interventions. In ROMEO, 77.5% of all patients met the success criteria, including 80.2% of Combination Cataract patients and 72.9% of Standalone patients. There have been two articles published in peer-reviewed journals based on data from ROMEO.

GEMINI Study

The GEMINI study was a prospective, multi-center, single-arm, historic-controlled, interventional clinical trial designed to assess the safety and effectiveness of OMNI in Combination Cataract surgery in patients with Mild-to-Moderate OAG at 12 months postoperatively. The GEMINI study initiated in February 2019, completed enrollment in March 2020 (n=145) and completed final patient 12-month follow up by the end of April 2021. An article published in a peer-reviewed journal in the third quarter of 2021 based on results from GEMINI showed that Combination Cataract MIGS using OMNI resulted in a significant reduction in overall mean IOP from baseline, and in a post hoc analysis, a reduction in the variation and amplitude of mean IOP was observed at each diurnal time point evaluated. In the study, 95% of patients had a diminished peak IOP postoperatively when compared to preoperative measurements. The difference between "high"

and “low” IOP at 12 months reduced an average of 36% compared to preoperative measurements. We expect two additional articles based on data from GEMINI to be published in peer-reviewed journals in 2022.

TearCare System

TearCare Clinical Program Overview

We designed TearCare to comprehensively address meibomian gland disease, which we believe to be the primary underlying cause of evaporative DED. We have developed robust clinical data evaluating TearCare. We have completed one RCT for TearCare (OLYMPIA), have one RCT enrolling patients (SAHARA) and have one additional study in the planning stage (RESTORE). In our completed OLYMPIA RCT, we observed significant improvements in the signs and all symptoms of DED as assessed by an array of measures including both functional and biologic markers, and patient-reported symptoms surveys. We observed TearCare to be safe and well tolerated, with only minor adverse events that resolved without any further treatment. Data from OLYMPIA supported the FDA clearance of TearCare’s expanded indication for use in December 2021. Our two ongoing and planned studies are intended to evaluate the safety and effectiveness of TearCare in reducing signs and symptoms of DED due to MGD. We plan to leverage the results of these studies to support FDA clearances to further expand indications for use of TearCare and to support our patient access strategy.

Table 3: Sight Sciences TearCare Ongoing and Planned Clinical Studies

Name	Description
SAHARA	NCT04795752: Prospective, Randomized, Masked, Controlled Trial To Evaluate The Safety And Effectiveness Of The TearCare® System In The Treatment Of The Signs And Symptoms Of Dry Eye Disease. Control group will self-administer Restasis® for six months then receive one TearCare treatment
RESTORE	Evaluate the safety and effectiveness of TearCare® to treat the signs and symptoms of DED in patients previously treated with Restasis® or Xiidra®

Commercial Approach

We have built a world-class direct sales commercial organization that features professionals and executives with substantial leadership experience from leading ophthalmic product companies. In particular, we have recruited professionals with track records that include launching new technologies, growing primary demand, changing treatment paradigms and securing market access from payors. We believe this expertise is crucial to achieve our market development objectives for interventional Standalone MIGS and MGD treatment. Sales representatives typically have relevant experience across all facets of medical device and/or pharmaceutical sales focused on eyecare to ensure the development of a trusted consultative relationship with our ECPs. As we have continued to develop additional clinical data and brand recognition, we believe our team has differentiated our product offerings and gained commercial traction through exceptional, highly involved training, support and ongoing professional education. As of December 31, 2021, our overall commercial team consisted of over 100 professionals dedicated to sales, marketing, commercial support, training and professional relations.

We created distinct sales, marketing, and training teams to sell OMNI and TearCare because the products are predominantly sold to different types of customers and require specialized product specific sales expertise and ECP training to integrate our products into their practices. We sell OMNI to facilities where ophthalmic surgeons perform outpatient procedures, mainly ambulatory surgery centers, or ASCs and hospital outpatient departments, or HOPDs. We sell TearCare to optometry and ophthalmology practices.

Our marketing efforts are centered around increasing awareness of our products and presenting clinical study results through leading medical publications and at-large industry and scientific meetings, both directly and through our advisors. We have also partnered with early-adopting ECPs to speak to peers on our behalf through educational forums either in-person or via virtual meetings. Clinical data that demonstrate the benefits of OMNI and TearCare for their authorized uses

will continue to underpin our commercial efforts and we will continue to devote significant resources to conduct new clinical studies and publish articles in peer- reviewed journals.

OMNI

Since the commercial launch of OMNI in February 2018, we have pursued a three-part strategy to gain rapid commercial adoption and simultaneously expand its potential market:

(i) Target and train the over 3,000 high volume cataract surgeons who are already familiar with MIGS approaches (*ab interno* access techniques) and have a willingness to trial new technologies;

(ii) Leverage positive clinical experiences and outcomes to expand the utilization of OMNI among these MIGS-trained surgeons and drive adoption from additional surgeons and facilities; and

(iii) Educate ECPs on the clinical benefits of interventional Standalone treatments with OMNI for the larger population of adult POAG patients for whom other leading MIGS devices are not indicated.

The majority of our OMNI sales representatives cover dedicated geographic territories or specialized customer segments, such as academic or government institutions, across the U.S. These sales representatives establish new accounts, train new surgeons and operating room personnel and nurture the continuing use of OMNI at existing accounts. We have created a team of Strategic Account Managers, who focus on serving teaching institutions and government facilities, and a team of Glaucoma Clinical Consultants, whose goal is to educate primary care ECPs regarding the potential benefits of OMNI in interventional Standalone procedures in adult patients with POAG. The general ophthalmologists and optometrists who provide primary eyecare services are typically the first to diagnose POAG and deliver first line treatment. We aim to educate these primary care ECPs regarding the clinical benefits and use cases for OMNI as they often have referral relationships with ophthalmic surgeons for patients who require advanced treatment. We seek to increase usage of OMNI among the ophthalmic surgeons who have already been trained and convert those who are not.

We believe our initial commercial efforts for OMNI have been successful and we plan to accelerate growth with the expansion of our team to cover more geographic territories and provide increased support to accounts, as well as roll-out large-scale marketing programs for the interventional Standalone opportunity. Although the vast majority of our sales are in the U.S., we have also begun to sell OMNI in select European countries both on a direct basis and through distributors.

TearCare

We implemented a controlled launch of TearCare in the U.S. in April 2019 with a limited sales effort. We have assembled a proprietary list of over 5,000 practices that are prime targets for our device and, as of December 31, 2021, we had sold TearCare to over 550 eyecare facilities.

While the success of our initial launch has shown that a significant patient-pay market exists for TearCare, market research indicates that improving access to TearCare through Medicare and private payors will accelerate adoption of the product. Currently, no third-party payors have formal policies establishing coverage for procedures using TearCare, although we believe that some payors may agree to provide coverage outside of formal policy based on medical need. As an early step of a comprehensive long-term market development plan, our market access team assists key strategic accounts and their patients in the pursuit of prior authorization approvals and reimbursement claims for TearCare on a case-by-case basis. Simultaneously, we are also continuing to support our customers with patient-pay models, which remains a significant growth opportunity.

Our dedicated commercial team for TearCare consists of sales representatives and leaders, marketing professionals, dedicated trainers, and independent sales representatives. We intend to scale up this team to the extent we achieve key market development and patient access milestones, including completion of clinical trials and our pursuit of FDA clearances for more robust indications for use of TearCare. Our sales representatives collaborate with stakeholders across the practice to train doctors and staff, implement workflow processes and monitor operations to ensure proper integration. As we help customers incorporate the use of TearCare, we have gained insights that enable us to continually improve our selling model. We expect to add new accounts and increase utilization at existing accounts, as we methodically grow our commercial team dedicated to TearCare.

Reimbursement

There are three primary aspects of reimbursement in the United States: coding, coverage and payment. Each aspect is an important determinant of our customers' ability to obtain appropriate reimbursement.

- **Coding** refers to the availability of billing codes for use by healthcare providers to report the provision of medical procedures, and the use of supplies and resources for specific patients, to insurance providers and organizations that make payments for healthcare, commonly referred to as third-party payors. The Healthcare Common Procedure Coding System, or HCPCS, is a national, standardized code set used by providers to capture and report healthcare services and products. This code set consists of two subsystems: Level I, Current Procedural Terminology, or CPT, codes, representing procedures performed, and Level II, commonly referred to as HCPCS codes, representing healthcare products (e.g. devices, drugs, durable medical equipment), supplies and services not captured in the CPT code set. CPT codes are published by the American Medical Association, or AMA, and are used to report medical services and procedures performed in the outpatient setting of care by or under the direction of physicians. HCPCS codes are established and maintained by the Centers for Medicare and Medicaid Services, or CMS, and identify items used in the course of care delivery. Health plans pay outpatient facilities and physicians for services based on submission of a claim using one or more CPT and/or HCPCS codes. CPT codes fall into one of three categories.
    - Category I CPT codes have been approved by the AMA as permanent procedure codes based on a number of factors, including the level of published clinical evidence. They are identified with a five-digit number and official code description. Approved Category I CPT codes have typically been endorsed by relevant medical specialty societies, are consistent with contemporary medical practice, and represent procedures performed by many physicians in clinical practice in multiple locations. Category I codes are only available to procedures for which the technology (e.g., device, drug, test) has been FDA approved/cleared when such a regulatory requirement exists.
    - Category II CPT Codes are supplemental tracking codes used for performance measurement. They are intended to facilitate data collection about quality of care by coding certain services and/or test results that support performance measures and that have been agreed upon as contributing to good patient care. Some codes in this category may relate to compliance by health care professionals with state or federal law.
    - Category III CPT codes are a temporary set of tracking codes for new and emerging technologies. These codes are designed to facilitate data collection for the assessment of new procedures. Additionally, Category III codes provide a mechanism for payors to value a new procedure. Temporary codes are not automatically assigned Relative Value Units, or RVUs, or weights and, therefore, do not typically have a widely accepted payment rate methodology. To achieve Category III status, a new procedure is required to have either an approved protocol for a study of procedures being performed, support from the specialties that would use the procedure, availability of US peer-reviewed literature, or current clinical trials that outline the effectiveness of the procedure. Once granted, Category III CPT codes expire five years after the initial application was approved, although they can be extended beyond the five-year limit.
- Level II HCPCS codes are alpha-numeric codes governed by CMS that identify medical products and items or services that are not appropriately designated by another code set (e.g., CPT). Criteria must be met in order to qualify for an HCPCS code, including such requirements as regulatory approval (if necessary), national programmatic need, and a distinct difference from existing HCPCS codes.
- **Coverage** refers to decisions made by third-party payors as to whether there is sufficient published clinical evidence to support medical necessity, or to consider a healthcare item or service "reasonable and necessary" (as per Medicare guidelines). Coverage can be established by explicit medical policies that outline specific parameters covering procedures and/or technologies, and under what conditions coverage is permitted, including specific diagnoses, clinical indications and therapeutic prerequisites. Coverage can also be implicit, as when payors are "silent" on a procedure or technology (i.e., no formal policy is developed). In the absence of formal policy, coverage may be granted one of two ways: (1) with no required review, as with long-standing established healthcare items or services, or (2) on a case-by-case

basis via review of each patient's circumstance, as may be the case with newer procedures/technologies. Each payor can make its own decision as to which procedures or technologies warrant formal policy.

- **Payment** refers to the reimbursement rate for a healthcare item or service. The amount paid by third-party payors to providers, including facilities and doctors, for specific procedures and items (e.g., medical devices, drugs, ancillary supplies) is determined by each payor. Payments for professional services under CPT coding are generally determined by the RVUs of a specific billing code. These RVUs identify the time and intensity of the work required, the practice expense incurred and the level of risk related to the procedure. Payors can use their organization-specific formula or conversion factor to translate RVUs into payment rates, or may establish payment by reference to a national Medicare payment amount. Likewise, facility payments are weighted based on the resources (e.g., operating suite time, devices and supplies) needed for the procedure to be performed in the facility setting. Most payment rates are geographically adjusted, taking into account the cost of providing services in different wage index areas across the country. As with procedure payments, payments for healthcare items (e.g., products reported using HCPCS coding) are determined by individual health plans, often based on some form of manufacturer's invoice or billed charges based on the provider's mark-up methodology, or based on established fee schedule rates. It is important to recognize that not all reportable codes are separately payable. Some codes are bundled with related items or services and do not have a separate payment allowance.

For further information regarding reimbursement, see "Risk Factors—We may not be able to maintain adequate levels of third-party coverage and payment for procedures in which OMNI is used, and third parties may rescind or modify their coverage related to OMNI. We may not be able to secure any, or adequate levels of, third-party coverage and payment for procedures in which TearCare is used, and even if third parties provide coverage they may rescind or modify their coverage related to TearCare." Our commercial activities are substantially within the United States. We sell OMNI primarily to ASCs and HOPDs, who in turn bill various third-party payors, such as Medicare and private health insurance plans for the healthcare services and resources rendered to treat a patient. TearCare is not currently covered or paid by Medicare or private payors under any formal policy, although some payors may agree to provide case-based coverage outside of a formal policy. Our market access team facilitates patient access to the OMNI and TearCare systems by engaging payors on coverage, coding and payment matters, and by providing support to patients and our customers as they seek reimbursement from payors that do not have positive coverage or those that do not have formal policies in place regarding our products.

Reimbursement for Uses of the OMNI Surgical System

Surgeons are able to use OMNI to sequentially perform two well-established glaucoma procedures, canaloplasty followed by trabeculotomy.

Canaloplasty and trabeculotomy are covered by the Medicare Administrative Contractors, or MACs outside of formal policy, based on a claim-by-claim adjudication. Widespread coverage is important for commercial adoption. Based on POAG prevalence, we estimate that currently over 70% of patients who receive glaucoma treatment using OMNI are covered by Medicare, and that this percentage may decline modestly over time as usage of OMNI expands to include patients with a broader range of OAG progression. Private payor coverage policies for canaloplasty and trabeculotomy vary. Some private payors, including numerous Blue Cross Blue Shield plans, have published medical policies that consider canaloplasty medically necessary for the treatment of glaucoma, though specific criteria for coverage may vary depending on the payor. Additionally, as with many healthcare items and services, some health plans cover the procedures performed using the OMNI surgical system outside of a formal policy. Where coverage is less consistent or is limited, as is the case with certain private payors, our market access team works with payors directly and with customers to facilitate patient access to our solutions and verify that appropriate reimbursement can be obtained. We have established and continue to build a substantial library of clinical trial data and published articles to directly address the needs of payors. We believe that the results from our completed, in-progress and planned clinical trials and subsequent accompanying peer-reviewed articles will help to expand and solidify coverage of canaloplasty and the use of OMNI. We estimate that, as of December 31, 2021, approximately 75% of people with medical benefit coverage have access to the canaloplasty procedures and/or OMNI specifically. We continue to proactively engage with the remaining key national and regional payors currently not covering canaloplasty and/or OMNI to seek reversals of their current non-covered policies.

Virtually all sales of OMNI in the U.S. are to ASCs and HOPDs. Surgeons may use OMNI to perform canaloplasty and trabeculotomy sequentially, with CPT code 66174 used to report the procedure. Per Medicare and many private payor payment policies, when certain procedures are performed in the ASC setting, such as cataract surgery and canaloplasty,

multiple procedure payment reduction rules apply. Therefore, when a canaloplasty is performed with cataract surgery on the same patient on the same day, payment of the lower-cost procedure (most commonly the cataract procedure) is reduced by 50%. Multiple procedure payment reduction rules also typically apply to professional services. Physicians are likely to be paid at a reduced rate for lower valued procedures when performed concomitantly. In the HOPD setting, Medicare procedures performed using OMNI as well as cataract procedures, are paid under comprehensive ambulatory payment classifications, or C-APCs. In these circumstances, the highest valued code is paid at 100%, with payment for additional procedures performed during the same operative session bundled into the single highest payment rate. Many commercial payers use a similar payment methodology, but payment rules can vary across health plans, particularly across plan types (e.g., HMO, PPO, POS).

In the ASC setting, the 2022 Medicare national unadjusted average facility payment rate for CPT 66174 is $1,917.31. In the HOPD setting, the 2022 Medicare national unadjusted average facility payment rate for CPT 66174 is $3,999.59. These payments are classified as comprehensive C-APCs, therefore in the HOPD setting, the highest valued code will be paid and other C-APC classified procedures will be bundled into the highest paid procedure. Regardless of facility setting, the Medicare national unadjusted physician payment rate for CPT 66174 is $738.33. Based on customer feedback, we believe the rates for facility and physician reimbursement in both settings reflect attractive and reasonable payments to cover all of our customers' costs and economic needs related to glaucoma treatments using OMNI for both Standalone and Combination Cataract procedures.

While commercialization of OMNI has primarily been focused on the U.S., we have also begun international commercialization efforts. Outside the U.S., we have made the most progress in the United Kingdom, where we have hired a local commercial team to promote OMNI to health care professionals and are establishing a market access team as well. In Germany, we have established and trained an ophthalmic distributor with successful experience commercializing devices approved to perform canaloplasty procedures. Although Germany employs a single-payor health system and national MIGS procedure codes which include canaloplasty and trabeculotomy, coverage decisions are decentralized among Germany's 17 regions. To date, canaloplasty and trabeculotomy procedures are covered in all 17 regions and our distributor is working towards educating health care providers and hospital personnel across all regions on how to appropriately procure and submit claims for reimbursement from the German health insurance system via the decentralized Physician's Associations (*Kassenärztliche Vereinigung*) to facilitate access to OMNI for patients and ECPs. As we expand into other countries, we will establish reimbursement strategies that are appropriate for each local market. In the United Kingdom, we have secured access for OMNI at 12 hospitals to date and are continuing our efforts to obtain access at an additional 7 hospitals in 2022 across both the combination cataract and standalone procedures.

Reimbursement for Uses of the TearCare System

TearCare is not currently covered by Medicare or private payors via formal medical policy, although some payors may agree to provide coverage and payment outside of formal policy. We received FDA clearance for an expanded indication for the use of TearCare in December 2021. TearCare is now indicated for the application of localized heat therapy in adult patients with evaporative dry eye disease due to meibomian gland dysfunction, when used in conjunction with manual expression of the meibomian glands. We believe that the current standard of care (representing over 95% of the existing market), which primarily consists of over-the-counter artificial tears or lubricating eyedrops, and prescription eyedrops, does not treat the root cause of MGD. We believe TearCare, as cleared by the FDA for an expanded indication for use, has the potential to offer a better standard of care for evaporative dry eye patients and reduced overall costs for payors.

Despite the presence of a large and growing patient-pay market for TearCare as shown in our controlled launch, we believe that improving access to TearCare through positive coverage decisions by Medicare and private payors will help grow the market for the device. We are pursuing a vigorous market access development plan to obtain more favorable policies from Medicare and private payors for procedures using TearCare in the U.S.

Category III CPT code 0563T, which became effective January 1, 2020, describes the heating of meibomian glands using a wearable open-eye device and manual evacuation of meibomian glands. This code allows providers to pursue reimbursement claims and payors to establish payment rates for the procedure. Prior to formal coverage decisions or a permanent Category I code, third-party payors may cover procedures billed with temporary Category III codes on a case-by-case basis.

We have begun to generate clinical data to support positive coverage decisions from Medicare and private payors. In September 2021, an article discussing results from our OLYMPIA RCT was published in *Cornea The Journal of Cornea*

and External Disease. This randomized controlled trial compared treatment using TearCare to the leading alternative MGD treatment device on the market. In the study, we observed that a single use of TearCare was associated with improvement in each of the signs and symptoms of DED within two weeks of treatment in subjects with MGD. In a post-hoc analysis we also observed that a greater proportion of subjects in the TearCare group reported better symptomatic relief relative to the comparator group as assessed by patient reported outcomes.

Our comprehensive long-term strategy to improve patient access to TearCare includes the following key initiatives:

- **Demonstrate the effectiveness, safety and durability of TearCare with rigorous clinical data**. Building on supportive data from completed studies, our upcoming clinical program for TearCare, including the SAHARA and RESTORE studies, aims to advance the development of TearCare for the signs and symptoms of DED due to MGD with comparative trial designs established to evaluate the effectiveness and durability of treatment with TearCare, which our research suggests would be the primary criteria for payors to decide coverage determinations. SAHARA, which commenced in 2021, features a trial design directly informed by a masked panel of medical directors from eight payors. This study is an RCT evaluating TearCare versus the leading DED prescription eyedrop, and will compare effectiveness and safety, as well as assess durability of effect through a 24-month follow up period.
- **Augment library of published articles on TearCare**. We plan to facilitate publication of numerous articles describing the results of our studies of TearCare in peer-reviewed journals. We collaborate with our advisors to design and conduct our studies, and ensure findings undergo the rigorous peer review process for publication in leading ophthalmology and optometry journals, recognizing that third-party payors base coverage decisions on reviews of the published medical literature.
- **Support coverage applications**. Our market access team assists key strategic accounts in their submission of high quality reimbursement requests for uses of TearCare. Our market access team also works with customers and patients to navigate the reimbursement process with third-party payors, including prior authorization approvals and appeals for denial of coverage or low payment. As more claims for uses of TearCare are accepted, we will work with third-party payors to formalize coverage decisions to streamline the coverage and payment processes.
- **Convert to permanent Category I CPT code**. We plan to leverage our clinical studies, peer-reviewed publications, society and medical community support, and utilization / real world reimbursement claims data to support conversion of our Category III CPT code for TearCare to a permanent Category I CPT code. Although Medicare and private payors may cover Category III CPT codes that meet their coverage criteria, we believe AMA approval of a permanent Category I CPT code for uses of TearCare, along with potential enhanced indications for use, will bolster our efforts to gain positive coverage determinations combined with appropriate reimbursement from Medicare and private payors.

Competition

We believe our focus on developing and marketing intuitively designed products that are intended to restore the eye's natural physiological function by addressing underlying causes of eye disease will be an important factor in our future success. The medical device and pharmaceutical industries are intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete with medical device and pharmaceutical companies that develop and commercialize products for eye conditions. Notable competitors with approved MIGS products include Glaukos, Alcon/Ivantis and AbbVie/Allergan, while AbbVie/Allergan, Novartis, Johnson & Johnson, and Alcon have notable approved products to treat DED. Other competitors with approved ophthalmic products in glaucoma and DED include Aerie Pharmaceuticals, Bausch and Lomb, MST, New World Medical, Nova Eye, Kala Pharmaceuticals, Oyster Point and Sun Pharmaceutical Industries. Notable competitors seeking approval for new MIGS and sustained release glaucoma treatments include Glaukos, Ocular Therapeutix, and iSTARMedical, and in pharmaceutical DED treatments include, among others, Aldeyra Therapeutics, Bausch and Lomb, Ocular Therapeutix and Tarsus Pharmaceuticals. Some of our competitors are larger, well-capitalized companies with greater current market share and resources. Consequently, they can spend more on product development, marketing, sales and other product initiatives than we can. We also compete with several smaller medical device companies that have single products or a limited range of products. Some of our competitors have:

- Significantly greater name recognition;
- Broader or deeper relations with healthcare professionals, customers and third-party payors;
- More established distribution networks;
- Additional lines of products and the ability to offer rebates or bundle products to offer greater discounts or other incentives to attract adoption;
- Greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- Greater financial and human resources for product development, sales and marketing and patent and other intellectual property litigation.

We compete primarily on the basis that our medical devices are able to treat patients with prevalent eye diseases safely and effectively. Our continued success depends on our ability to:

- Develop innovative, proprietary technology and products that can cost-effectively address significant clinical needs;
- Obtain and maintain regulatory clearances or approvals for the use of our products;
- Obtain and maintain favorable reimbursement decisions relating to the use of our products;
- Demonstrate clinical safety and effectiveness in our sponsored and third-party trials and studies;
- Attract and retain skilled research and development and sales personnel; and
- Successfully market and sell products.

Manufacturing

On January 14, 2021, we entered into a Supply Agreement, or the Peter's Supply Agreement, with Peter's Technology (Suzhou) CO LTD., or PTCS, a Chinese subsidiary of Peter's Co., Ltd., a Taiwan-based contract manufacturer. In February 2021, PTCS began to produce commercially saleable OMNI units for us at its Suzhou City, China production facility. Currently Peter's is the sole contract manufacturer of OMNI production and we plan to have production availability with an additional high-volume contract manufacturer with U.S. production facilities by the end of the second quarter of 2022. The Peter's Supply Agreement governs the assembly and supply of OMNI by PTCS, pursuant to which PTCS purchases components from our approved suppliers for assembly and we make purchases from PTCS on a purchase order basis. The initial term of the three year Peter's Supply Agreement expires January 14, 2024. The Peter's Supply Agreement automatically renews for additional one year periods if neither party provides notification that they intend to terminate the agreement within 90 days of the term ending. We have the right to terminate the agreement without cause during its term by providing 180 days' advance written notice, or with 30 days' written notice with any material agreement default by PTCS.

For the production of TearCare, we currently have supply arrangements with separate medical device manufacturers. For the production of TearCare's SmartLids, we partner with Peter's Technology, and for TearCare's SmartHubs, we have a supply arrangement with Philips-Medisize Costa Mesa (California).

We directly engage with several third-party suppliers for key components used in our products. We believe that our approved third-party suppliers will be adequate to meet our current and anticipated manufacturing needs. We do not currently plan to manufacture our products or any related components ourselves.

Manufacturing facilities that produce medical devices or their component parts intended for distribution world-wide are subject to regulation and periodic unannounced inspection or audits by the FDA and other domestic and international regulatory agencies or notified bodies. In the United States, any products we sell are required to be manufactured in compliance with the FDA's Quality System Regulation, which covers the methods used in, and the facilities used for, the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products.

The distribution of our products is handled directly through a third-party logistics provider. Our finished goods are shipped from our contract manufacturers to a local gamma sterilization facility after which they are shipped to distribution facilities and, ultimately, to our customers.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our current and future products and product candidates, novel discoveries, product development technologies and know-how; to operate without infringing on the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, seeking to obtain or in-licensing U.S. and foreign patents and patent applications related to our proprietary technology that are important to the development and implementation of our business. We seek to obtain domestic and international patent protection, and endeavor to promptly file patent applications for new commercially valuable inventions. We file new patent applications as we conduct research and development, initiate new programs, and monitor the activities of others. We also rely on other approaches to protecting our proprietary position, such as trademarks, trade secrets, know-how, and/or continuing technological innovation to develop and maintain our proprietary position.

The patent positions of medical device companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent may be challenged in courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or at all, whether the claims of any patent applications, should they issue, will cover our products or product candidates, or whether the claims of any issued patents will provide sufficient protection from competitors or otherwise provide any competitive advantage.

We cannot be certain of the priority of inventions covered by our patents and pending patent applications, in part because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries and patent application filings. Accordingly, we may not have been the first to invent the subject matter disclosed in some of our patents and patent applications or the first to file patent applications covering such subject matter.

Patent Term

Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, U.S. patent term can be adjusted to recapture a portion of delay by the U.S. Patent & Trademark Office, or USPTO, in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. In some cases, the term of a U.S. patent may be shortened by terminal disclaimer, such that its term is reduced to end with that of an earlier-expiring patent.

Trade Secrets

In addition to patents, we rely on or may in the future rely on trade secrets and know-how to develop and maintain our competitive position. We typically rely on or may in the future rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. It is our policy to protect trade secrets and/or know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements provide that all confidential information developed or made known during the course of an individual or entity's relationship with us must be kept confidential during and after the relationship. These agreements also provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

Patents

As of December 31, 2021, we owned 30 issued U.S. patents, 45 issued patents outside the U.S. (which includes five issued European patents and their national validations), 19 pending U.S. non-provisional patent applications, 18 pending foreign patent applications and two pending Patent Cooperation Treaty patent applications. Our issued patents include claims directed to devices and methods for canaloplasty and/or trabeculotomy, ocular implants and related methods, the TearCare apparatus and methods of using the TearCare apparatus, components of the TearCare apparatus (including the SmartHub and SmartLids) and methods of their use, the TearCare apparatus in combination with an eyelid compression instrument and methods of their use, and methods of using the TearCare apparatus with patients wearing contact lenses.

Subject to payment of required maintenance fees, annuities, and other charges, our issued U.S. patents have expiration dates between 2027 and 2037, with six of our issued U.S. patents having expiration dates before 2030, 23 having expiration dates between 2031 and 2035, and the remaining one expiring in 2037, in each case exclusive of possible patent term extensions. Of our 19 pending U.S. non-provisional patent applications, one was filed in 2016, one was filed in 2018, three were filed in 2019, four were filed in 2020, and 10 were filed in 2021. Our pending U.S. non-provisional patent applications, if issued, have expected expiration dates between 2026 and 2041, exclusive of any possible patent term adjustments or patent term extensions.

The foreign jurisdictions where we own issued patents include: Australia, China, France, Germany, Italy, Japan, Spain, Switzerland, and the United Kingdom. Subject to payment of required annuities and other charges, these foreign patents have expiration dates between 2027 and 2035. We have pending patent applications in Australia, Brazil, Canada, China, Europe, Hong Kong, and Japan which, if issued, have expected expiration dates between 2032 and 2039.

As of December 31, 2021, we owned eight U.S. trademark registrations, one German trademark registration and one pending E.U. trademark application.

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

Government Regulation

Our products and our operations are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other federal, state, and local 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, or FDCA, and its implementing regulations.

United States Regulation

The FDA regulates, among other things, the development, design, non-clinical and clinical testing, manufacturing, safety, effectiveness, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export and post-marketing surveillance of medical devices in the United States 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 new or significantly modified medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, or approval of a premarket approval, or PMA, application. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy.

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 devices 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 FDA's current good manufacturing practices for devices, as reflected in the Quality System Regulation, or QSR, establishment registration and device listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the

FDA through the 510(k) premarket notification process described below. Most Class I devices are exempt from the premarket notification requirements.

Class II devices are subject to the FDA's general controls, and any other special controls deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, special labeling requirements, post-market surveillance, patient registries and FDA guidance documents.

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.

Class III devices include 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, requiring approval of a PMA. Due to the level of risk associated with Class III devices, the FDA's general controls and special controls alone are insufficient to assure their safety and effectiveness. Devices placed in Class III general require the submission of a PMA application demonstrating the safety and effectiveness of the device, which must be approved by the FDA prior to marketing, or the receipt of a 510(k) de novo classification, which provides for the reclassification of the device in Class I or II. The PMA approval process is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

If a new medical device does not qualify for the 510(k) premarket notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification process. This process allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk and requires PMA or that general controls would be inadequate to control the risks and special controls cannot be developed.

Obtaining FDA marketing authorization, de novo down-classification, or approval for medical devices is expensive and uncertain, and may take several years, and generally requires significant scientific and clinical data.

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 OMNI and TearCare products are regulated as Class II devices subject to 510(k) clearance.

Investigational Device Process

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval or to determine safety and effectiveness of a device for an investigational use must be conducted in accordance with the FDA's investigational device exemption, or 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 prior to commencing human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is

scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and effectiveness, even if the trial meets its intended success criteria.

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, or 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 the following:

- The FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- Patients do not enroll in clinical trials at the rate expected;
- Patients do not comply with trial protocols;
- Patient follow-up is not at the rate expected;
- Patients experience adverse events;
- Patients die during a clinical trial, even though their death may not be related to the products that are part of the trial;
- Device malfunctions occur with unexpected frequency or potential adverse consequences;
- Side effects or device malfunctions of similar products already in the market that change the FDA's view toward approval of new or similar PMAs or result in the imposition of new requirements or testing;

- Institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- Third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreement, investigational plan, good clinical practices, the IDE regulations, or other FDA or IRB requirements;
- Third-party investigators are disqualified by the FDA;
- We or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans, or otherwise fail to comply with the IDE regulations governing responsibilities, records, and reports of sponsors of clinical investigations;
- Third-party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or the company or investigators fail to disclose such interests;
- Regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- Changes in government regulations or administrative actions;
- The interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; or
- The FDA concludes that our trial design is unreliable or inadequate to demonstrate safety and effectiveness.

510(k) Clearance Process

Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent," as defined in the FDCA, 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 prior to 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. A device is considered to be substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics; or (ii) different technological characteristics, but the information provided in the 510(k) submission demonstrates that the device does not raise different questions of safety or effectiveness than the predicate device.

Before the FDA will accept a 510(k) premarket notification for substantive review, the FDA will first assess whether the submission satisfies a minimum threshold of acceptability. If the FDA determines that the 510(k) submission lacks necessary information for substantive review, the FDA will issue a "Refuse to Accept" letter which generally outlines the information the FDA believes is necessary to permit a substantive review and to reach a determination regarding substantial equivalence. An applicant must submit the requested information before the FDA will proceed with additional review of the submission. If a 510(k) submission is accepted for substantive review, the Medical Device User Fee Amendments sets a performance goal of 90 days for FDA review of a 510(k) submission, but the review time can be delayed if FDA raises questions or requests addition information during the review process. As a practical matter, clearance often takes longer, and clearance is never assured. Thus, as a practical matter, clearance often takes longer than 90 days. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is substantially equivalent to a predicate device, 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 requirements of the PMA approval process, 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 certain novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

Medical devices can only be marketed for the indications for use for which they are cleared or approved. 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* reclassification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), *de novo* request or a PMA in the first instance, but the FDA may review this determination to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained or a *de novo* request is granted. 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 recommended testing methods, where feasible.

Ongoing Regulation by the FDA

Even after the FDA permits a device to be marketed, 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, supplier/contractor selection, compliant handling, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- Labeling regulations, advertising and promotion requirements, restrictions on sale, distribution or sale of a device, each including the FDA prohibition against the promotion of products for any uses other than those authorized by the FDA, which are commonly known as "off-label" uses;
- The Medical Device Reporting, or MDR, 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;
- Medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- Recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;

- An order of repair, replacement, or refund;
- Device tracking requirements; and
- Post-market study and surveillance requirements.

After a device receives 510(k) clearance, any modification that could significantly affects its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) or possibly a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with our determination not to seek a new 510(k) clearance, the FDA may retroactively require us to seek 510(k) clearance or possibly a PMA. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or a PMA is obtained. Also, in these circumstances, we may be subject to significant regulatory fines and penalties.

Some changes to an approved PMA device, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new PMA application or PMA supplement, as appropriate, before the change can be implemented. Supplements to a PMA often require the submission of the same type of information required for an original PMA application, except that the supplement is generally limited to that information needed to support the proposed change from the device covered by the original PMA. The FDA uses the same procedures and actions in reviewing PMA supplements as it does in reviewing original PMA applications.

FDA regulations require us to register as a medical device manufacturer with the FDA. Additionally, some states also require medical device manufacturers and/or distributors doing business within the state to register with the state or apply for a state license, which could subject our facility to state inspection as well as FDA inspection on a routine basis for compliance with the QSR and any applicable state requirements. These regulations require that we manufacture our products and maintain related documentation in a prescribed manner with respect to manufacturing, testing and control activities.

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 shutdown of, or restrictions on, manufacturing operations and the recall or seizure of marketed products, which would have a material adverse effect on our business. The discovery of previously unknown problems with any of our 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 delays in processing, clearing, or approving submissions or applications for new products or modifications to existing products;
- Suspension or withdrawal of 510(k) clearances or PMA approvals that have already been granted;
- FDA refusal to issue certification to foreign governments needed to export our products for sale in other countries; or
- Criminal prosecution.

Our facilities, records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. Failure to comply with the applicable United States medical device regulatory requirements could result in, among other things, warning letters, untitled letters, fines, injunctions, consent decrees, civil penalties, unanticipated expenditures, repairs, replacements, refunds, recalls or seizures of products, operating restrictions, total or partial suspension of production, the FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries, the FDA's refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product clearances or approvals and criminal prosecution.

Regulation of Medical Devices in the European Union

The European Union, or EU, has adopted specific directives regulating the design, manufacture, clinical investigations, conformity assessment, labeling and adverse event reporting for medical devices. EU directives must be implemented into the national laws of the EU member states and national laws may vary from one member state to another.

Until May 25, 2021, medical devices were regulated by Council Directive 93/42/EEC, or the Medical Devices Directive, which have been repealed and replaced by Regulation (EU) No 2017/745, or the Medical Devices Regulation. Our current certificates have been granted under the Medical Devices Directive whose regime is described below. However, as of May 26, 2021, some of the Medical Devices Regulation requirements apply in place of the corresponding requirements of the Medical Devices Directive, with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements. Pursuing marketing of medical devices in the EU will notably require that our device be certified under the new regime set forth in the Medical Devices Regulation when our current certificates expire on May 26, 2024.

Medical Devices Directive

Under the Medical Devices Directive, all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in the Medical Devices Directive, including the requirement that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. A conformity assessment procedure generally requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality system (the notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485:2016 for Medical Devices Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU.

Notified body certificates of conformity are valid for a fixed duration (which shall not exceed five years). Throughout the term of the certificate, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant certificate(s).

Medical Devices Regulation

The regulatory landscape related to medical devices in the EU recently evolved. On April 5, 2017, the Medical Devices Regulation was adopted with the aim of ensuring better protection of public health and patient safety. The Medical Devices Regulation establishes a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation. Unlike the Medical Devices Directive, the Medical Devices Regulation is directly applicable in EU member states without the need for member states to implement into national law. This aims at increasing harmonization across the EU.

The Medical Devices Regulation became effective on May 26, 2021. The new regulation among other things:

- strengthens the rules on placing devices on the market (e.g. reclassification of certain devices and wider scope than the Medical Devices Directive) and reinforces surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- establishes explicit provisions on importers' and distributors' obligations and responsibilities;
- imposes an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;
- sets up a central database (Eudamed) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthens the rules for the assessment of certain high-risk devices, , such as implants, which may have to undergo a clinical evaluation consultation procedure by experts before they are placed on the market.

Devices lawfully placed on the market pursuant to the Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the Medical Devices Regulation, in particular the obligations described below.

The Medical Devices Regulation requires that before placing a device, other than a custom-made device, on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system (Eudamed), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address and contact details of the person or persons responsible for regulatory compliance. The new Regulation also requires that before placing a device, other than a custom-made device, on the market, manufacturers must assign a unique identifier to the device and provide it along with other core data to the unique device identifier, or UDI, database. These new requirements aim at ensuring better identification and traceability of the devices. Each device – and as applicable, each package – will have a UDI composed of two parts: a device identifier, or UDI-DI, specific to a device, and a production identifier, or UDI-PI, to identify the unit producing the device. Manufacturers are also notably responsible for entering the necessary data on Eudamed, which includes the UDI database, and for keeping it up to date. The obligations for registration in Eudamed will become applicable at a later date (as Eudamed is not yet fully functional). Until Eudamed is fully functional, the corresponding provisions of the Medical Devices Directive continue to apply for the purpose of meeting the obligations laid down in the provisions regarding exchange of information, including, and in particular, information regarding registration of devices and economic operators.

All manufacturers placing medical devices on the market in the EU must comply with the EU medical device vigilance system which has been reinforced by the Medical Devices Regulation. Under this system, serious incidents and Field Safety Corrective Actions , or FSCAs, must be reported to the relevant authorities of the EU member states. These reports will have to be submitted through Eudamed – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until Eudamed is fully functional, the corresponding provisions of the Medical Devices Directive continue to apply. A serious incident is defined as any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect, which, directly or indirectly, might have led or might lead to the death of a patient or user or of other persons or to a temporary or permanent serious deterioration of a patient's, user's or other person's state of health or a serious public health threat. Manufacturers are required to take FSCAs defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports.

The advertising and promotion of medical devices is subject to some general principles set forth in EU legislation. According to the Medical Devices Regulation, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular vis-à -vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland. Other countries, such as Switzerland, have entered into Mutual Recognition Agreements and allow the marketing of medical devices that meet EU requirements.

Brexit

Following a national referendum and enactment of legislation by the government of the United Kingdom, or the UK, the UK formally withdrew from the EU on January 31, 2020, commonly referred to as "Brexit", and, following the expiry of the Brexit transitional period on December 31, 2020, the UK now operates under a distinct regulatory regime and certain EU laws now only apply to the UK in respect of Northern Ireland (as laid out in the Protocol on Ireland and Northern Ireland). The Medicines and Healthcare products Regulatory Agency, or MHRA, is now the UK's standalone regulator. Although the UK and EU have now reached an agreement on its future trading relationship (implemented in the EU-UK Trade and Cooperation Agreement from January 1, 2021, or TCA), the agreement does not cover all regulatory areas regarding medical devices, which may be subject to future bilateral discussions going forward and could further change the relationship between the UK and the EU in this regard.

EU laws which were directly applicable before the end of the transitional period or have been. transposed into UK law through secondary legislation continue to be applicable as "retained EU law." However, new legislation such as Medical Devices Regulation (Regulation 2017/745) will not be applicable. The UK government has introduced a new Medicines and Medical Devices Act which seeks to address regulatory gaps through implementing regulations and delegated powers covering the fields of human medicines, clinical studies of human medicines, and medical devices.

Significantly, under the TCA there is no mutual recognition of regulatory regimes and certifications between the EU and the UK. CE marks issued by EU-based notified bodies will continue to be recognized by the UK until June 30, 2023, but from July 1, 2023, new devices placed on the Great Britain market will need to conform with the new UK Conformity Assessment, or UKCA, marking requirements. Since January 1, 2021, medical devices placed on the market in the UK must be registered with the MHRA, following a grace period ranging from four to 12 months. Manufacturers based outside the UK will also need to appoint a UK Responsible Person (which may be an individual or a corporate entity). Only a manufacturer established in the UK or a UK Responsible Person will be able to place a device on the market in Great Britain. Under the terms of the Protocol on Ireland and Northern Ireland, products placed on the market in Northern Ireland will continue to be subject to the European Union regulatory regime. A public consultation by the MHRA was opened until end of November 2021 on the post-Brexit regulatory framework for medical devices and diagnostics. The consultation proposes amendments to the UK Medical Devices Regulations 2002 (which are based on EU legislation, primarily the Medical Devices Directive), in particular to create a new access pathways to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform in vitro diagnostic regulation, and foster sustainability through the reuse and remanufacture of medical devices. The regime is expected to come into force in July 2023, coinciding with the end of the acceptance period for EU CE marks in Great Britain, subject to appropriate transitional arrangements. The consultation indicated that the MHRA will publish guidance in relation to the changes to the regulatory framework and may rely more heavily on guidance to add flexibility to the regime.

Healthcare Fraud and Abuse Laws

In the United States, we are subject to a number of federal and state healthcare regulatory laws that restrict business practices in the healthcare industry. These laws include, but are not limited to, federal and state anti- kickback, false claims, transparency and other healthcare fraud and abuse laws.

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, 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 healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including cash, improper discounts, and free or reduced price items and services. Among other things, the Anti-Kickback Statute has been interpreted to apply to arrangements between medical device manufacturers on the one hand and prescribers and purchasers on the other. 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. The government can exercise enforcement discretion in taking action against unprotected activities. Further, 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 to items or services reimbursed by any third-party payor, including commercial insurers and self-pay patients.

The federal false claims, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, 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, or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Moreover, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program.

The federal Health Insurance Portability and Accountability Act of 1996 created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S.

federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS 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 additional healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives.

Violations of fraud and abuse laws, including federal and state anti-kickback and false claims laws, may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Coverage and Reimbursement

In the United States, our currently cleared products are not separately reimbursed by any third-party payors, and if covered, are paid for as part of the procedure in which the product is used. 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 in which our products are used. Failure by physicians, hospitals, ambulatory surgery centers and other users of our products to obtain coverage and adequate 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, may adversely impact demand for our products.

Based on our experience to date, third-party payors generally reimburse for the procedures in which our products are used only if the patient meets the established medical necessity criteria for the procedure. Some payors are moving toward a managed care system and control their healthcare costs by establishing coverage policies that categorically restrict coverage of certain procedures, or by limiting authorization for procedures, including elective procedures using our devices. 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. 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 healthcare 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 our product unless reimbursement approval can be obtained and/or maintained from governmental and private third-party payors.

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.

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 healthcare and medical device industry to reduce the costs of products and services. Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, and exploration of more cost-effective methods of delivering healthcare. 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.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. In the EU, member states are facing increased pressure to limit public healthcare spending. There can be no assurance that procedures using our products will be covered for a specific indication, that our products will be considered cost- effective by third-party payors, that an adequate level of reimbursement will be available or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably. More and more, local, product specific reimbursement law is applied as an overlay to medical device regulation, which has provided an additional layer of clearance requirement.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare 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 healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare 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 healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act, or ACA, in the United States, for example, has changed healthcare 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 healthcare 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, executive and political challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. It is unclear how healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the law or our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030. Additionally, the American Taxpayer Relief Act of 2012, among other things, further 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 began in 2019 that are based on various performance measures and physicians' participation in alternative payment models, such as accountable care organizations.

We expect additional state, federal, and foreign healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal, state, and foreign governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

For instance, in December 2021, the EU Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. This regulation which entered into force in January 2022 intends to boost cooperation among EU member states in assessing health technologies, including some medical devices, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation foresees a three-year transitional period and will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary

cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health- related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, 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. In addition, certain state and non-U.S. laws, such as the CCPA, the CPRA and the GDPR, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

In Europe, the GDPR went into effect on May 25, 2018 and introduces strict requirements for processing the personal data of European Union data subjects. 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 preceding financial year of the noncompliant company, whichever is greater.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union.

Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom General Data Protection Regulation, or the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is also unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. The European Commission published a draft adequacy decision on February 19, 2021. If adopted, the decision will enable data transfers from EU member states to the United Kingdom for a four-year period, subject to subsequent extensions.

Human Capital

As of December 31, 2021, we had 212 full-time employees. Our highly qualified and experienced team includes scientists, physicians and professionals across sales, marketing, regulatory, finance and other important functions that are critical to our success. 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 we have good relations with our employees.

We believe that our continued success is reliant on the ability to attract, develop and retain top talent. To facilitate talent attraction and retention, we strive to foster an inclusive and safe workplace, with opportunities for our employees to grow and develop in their careers, supported by competitive compensation and benefits programs. In the attraction, development and retention of talent, we emphasize:

Compensation and Benefits. We strive to provide competitive compensation and benefits programs to attract and retain top talent and review these programs annually against the competitive landscape to ensure they continue to meet the

needs of our employees. In addition to salaries, these programs include a variety of short and long-term incentive plans such as annual bonuses, equity awards, an Employee Stock Purchase Plan, a 401(k) Plan, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, family care resources, flexible work schedules, and employee assistance programs. In addition to our broad-based equity award programs, we have used targeted equity-based grants with vesting conditions to facilitate the retention and engagement of our talent.

Talent Development. We believe employees are our greatest asset and we strive to provide development and promotional opportunities in order to help our employees reach their potential. We provide formal and informal training opportunities designed to enhance learning and development. Consistent with our performance review processes, we foster and encourage continuous manager and employee dialogue around performance and development.

Health, Safety and Wellness. We are committed to the health, safety and wellness of our employees. We provide our employees and their families with access to a variety of flexible and convenient health and wellness programs, including benefits that provide protection and security so they can have peace of mind concerning events that may require time away from work or that impact their financial well-being; that support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors. In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, as well as the communities in which we operate, and which comply with government regulations. This includes having the vast majority of our employees work from home, while implementing additional safety measures for essential employees who are continuing to perform on-site work, whether at Company facilities or at customer or other third-party locations.

Diversity, Equity, and Inclusion. One of our core values is diversity of thought, values, individual characteristics, beliefs and backgrounds. We are an equal opportunity employer and believe that diverse and differentiated views contribute to make us a better organization. It is our conscious effort to support the advancement of women and promote equal opportunity for all our employees within the workplace.

Additional Information

Sight Sciences, Inc. was incorporated as a Delaware corporation in 2010. We completed our initial public offering of our common stock in July 2021.

Our website is www.sightsciences.com. At our Investor Relations website, investors.sightsciences.com, we make available free of charge a variety of information for investors, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after we electronically file that material with or furnish it to the Securities and Exchange Commission, or the SEC, pursuant to Section 13(a) or 15(d) of the Exchange Act. The information found on our website is not part of this or any other report we file with, or furnish to, the SEC.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our condensed consolidated financial statements and the accompanying notes thereto included elsewhere in this Annual Report on Form 10-K, before investing in our common stock. Many of the risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. The risks and uncertainties described below are not the only ones we face. Additional risk and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. The realization of any of these risks and uncertainties could have a material adverse effect on our reputation, business, financial condition, results of operations, growth and future prospects, as well as our ability to accomplish our strategic objectives. In that event, the market price of our common stock could decline and you could lose part or all of your investment.

Risks Related to Our Business

We are an early-stage company with a history of significant losses, we expect to incur losses in the future and we may not be able to achieve or sustain profitability.

We have incurred annual net losses since our formation in 2010. For the years ended December 31, 2021 and 2020, we had net losses of $63.0 million and $34.7 million, respectively. As of December 31, 2021, we had an accumulated deficit of $153.0 million. To date, we have financed our operations primarily through equity and debt financings and from sales of our products, the OMNI® Surgical System, or OMNI, a device that enables canaloplasty followed by trabeculotomy for the reduction of intraocular pressure in adult patients with primary open-angle glaucoma, or POAG, and our TearCare® System, or TearCare, which is indicated for the application of localized heat therapy in adult patients with evaporative dry eye disease, or DED, due to meibomian gland dysfunction, or MGD, when used in conjunction with manual expression of the meibomian glands. The losses and accumulated deficit have primarily been due to the substantial investments we have made to develop our products, costs related to our sales and marketing efforts, general research and development expenses, including costs related to clinical trials and regulatory initiatives to obtain marketing clearance, and infrastructure improvements.

In addition, as a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. Accordingly, we expect to continue to incur losses for the foreseeable future and we cannot assure you that we will ever achieve profitability or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future would make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations. In addition, failure of our products to significantly penetrate our target markets would negatively affect our business, financial condition and results of operations.

Our revenue has been primarily generated from the sales of our products and is expected to continue to be so generated for the near future, and we are therefore highly dependent on the success of those products, and particularly on OMNI. We have limited commercial sales experience regarding our products, which makes it difficult to evaluate our current business, predict our future prospects and forecast our financial performance and growth.

We began selling VISCO360 and TRAB360, commercial predicate devices to OMNI, in 2015 and TearCare in 2019 and therefore do not have a long history operating as a commercial company. Currently, we are highly dependent on the success of OMNI and TearCare. To date, our revenue has primarily been derived, and we expect it to continue to be substantially derived in the near future, from sales of our Surgical Glaucoma and Dry Eye products. We are particularly dependent on the success of OMNI, which accounted for 95% of our total revenues for the year ended December 31, 2021. Because we devote substantially all of our resources to these products and rely on them as our sole source of revenue, any factors that negatively impact our products, and particularly OMNI, or result in a decrease in sales, could have a material adverse effect on our business, financial condition and results of operations.

Over the next several years, we expect to continue to devote a substantial amount of resources to expand our commercialization efforts, drive increased adoption of our products and continue to develop new and improved products. Our limited commercialization experience and limited number of products make it difficult to evaluate our current business and predict our future prospects. These factors also make it difficult for us to forecast our future financial performance and growth, and such forecasts are subject to a number of uncertainties, including our ability to successfully complete

preclinical studies and clinical trials or investigations and obtain FDA pre-market clearance or similar clearance, approval, or certification for our current products and for future planned products or changes to existing products.

Ophthalmologist and optometrist (together, eyecare professionals or ECPs) awareness of, and experience with, our products is currently limited. As a result, our products have limited product and brand recognition within the ophthalmic industry. The novelty of our products, together with our limited commercialization experience, makes it difficult to evaluate our current business and predict our future prospects. A number of factors, including some outside of our control, may contribute to fluctuations in our financial results, including:

- ECP and patient demand for our products;
- Our ability to obtain and maintain reimbursement coverage for procedures in which our products are used;
- Changes in reimbursement rates by government or commercial payors;
- The results of our clinical trials or investigations;
- Positive or negative media coverage, or public, patient and/or physician perception, of our products or competing products and treatments;
- Any safety or effectiveness concerns that arise regarding our products for either their currently authorized uses or the uses for which we are developing our products;
- The effectiveness of our marketing and sales efforts, including our ability to have a sufficient number of qualified sales representatives to sell our products;
- Unanticipated delays in product development or product launches;
- Our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of our products;
- Our ability to achieve and maintain compliance with all legal and regulatory requirements applicable to our products;
- Our ability to obtain, maintain, protect and enforce our intellectual property rights;
- Our third-party manufacturers' ability to supply our products in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements; and
- Introduction of new products or alternative treatments that compete with our products.

It is therefore difficult to predict our future financial performance and growth, and such forecasts are inherently limited and subject to a number of uncertainties. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

Our business is dependent upon the broad adoption of our products by ECPs and patients.

Our future growth and profitability largely depend on our ability to increase ECP and patient awareness of our products and on the willingness of ECPs and patients to adopt our products. ECPs may not adopt our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our products are clinically differentiated from, or otherwise preferable to, available alternatives. Even if we are able to raise awareness among ECPs, they may be slow to change their medical treatment practices and may be hesitant to select our products for a variety of reasons, including:

- Lack of experience with our products and concerns that we are relatively new to market;
- Perceived liability risk generally associated with the use of new products and treatment options;
- Lack, or perceived lack, of sufficient clinical evidence, including long-term data, supporting clinical benefits or the cost-effectiveness of our products over existing treatments;

- The failure of key ophthalmologist and optometrist leaders to provide recommendations regarding our products, or to assure physicians, patients and healthcare payors of the benefits of our products as an attractive alternative to other treatment options;
- Perceptions that our products are unproven;
- ECPs' long-standing relationships with companies, distributors and salespeople that sell competing products;
- Lack of availability of adequate third-party payor coverage or reimbursement, or changes in (or new) third-party payor coverage or reimbursement policies that are materially adverse to the Company's interest;
- Competitive response and negative selling efforts from providers of alternative treatments;
- Challenges of integrating TearCare into established ophthalmologic and optometric practices; and
- Perceptions regarding the time commitment and skill development that may be required to gain familiarity and proficiency with our products.

To effectively market and sell our products, we will need to continue to educate the medical community about the safety, efficacy, necessity and efficiency of our products and about the patient populations that would potentially benefit from the use of our products. We focus our sales, marketing and education efforts primarily on our target ECP providers, ambulatory surgery centers, hospital outpatient departments and potential patient populations. However, we cannot assure you that we will achieve broad education or market acceptance. For example, if first-line ECPs or primary care physicians that serve as the early point of contact for patients are not made aware of our OMNI products, they may not refer patients to ECPs who utilize our products, and those patients may be treated with alternative procedures or treatments. In addition, some physicians may choose to utilize our products on only a subset of their total patient population or may not adopt our products at all. If we are not able to effectively demonstrate that our products are beneficial for a broad range of patients, adoption of our products will be limited and may not occur as rapidly as we anticipate or at all, which would have a material adverse effect on our business, financial condition and results of operations. Further, if we are unable to obtain or maintain favorable third-party reimbursement coverage of procedures in which our OMNI product is used, if we are unable to obtain favorable reimbursement for procedures in which TearCare is used, or if competitive products obtain comparatively favorable third-party reimbursement coverage as compared to our products, adoption of our products by ECPs and patients will suffer. We cannot assure you that our products will achieve broad market acceptance among payors, physicians and patients. Any failure of our products to satisfy demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition and results of operations.

Adoption of OMNI and TearCare depends upon appropriate physician training, practice and patient selection.

The success of our products depends in part on the skill of the ECPs utilizing and administering products to treat patients and on their adherence to our stated patient selection criteria and the proper techniques that we provide in training sessions. We train ECPs on the correct use of OMNI. However, ECPs rely on their previous medical training and experience when performing ophthalmic surgical procedures and may deviate from the techniques we provide in training sessions. Furthermore, we cannot guarantee that all such ECPs who use OMNI will have the necessary skills or experience to safely and effectively perform these procedures. Similarly, though we train ECPs to ensure correct use of TearCare, including placement of TearCare SmartLids on patients’ eyelids and expression of the patients' meibomian glands, we cannot guarantee that all such ECPs will have the necessary skills or experience to safely and effectively use these devices.

We do not control which physicians utilize these medical devices in their treatments or how much training they receive, and physicians who have not completed our training sessions may nonetheless attempt to use OMNI as part of an ophthalmic surgical procedure or use TearCare to apply localized heat. In addition, a perception by physicians that OMNI or TearCare are difficult to use may negatively impact adoption by ECPs. If ECPs utilize these devices in a manner that is inconsistent with our labeled indications or with components that are not part of our products, such as viscoelastic fluid that is incompatible with OMNI, or without adhering to or completing our training sessions, the patient outcomes may be negative. This could negatively impact the perception of patient benefits and safety associated with OMNI and TearCare and limit adoption of our devices, which would have a material adverse effect on our business, financial condition and results of operations.

Development of TearCare for expanded indications depends upon positive clinical data, and the safety and efficacy of our products for the intended uses for which we intend to seek clearance, certification or approval are not yet supported by long-term clinical data, which could delay or prevent clearance by the FDA (or other foreign authorities or notified bodies) or limit sales if cleared, certified or approved and our products might therefore prove to be less safe or effective than initially thought.

We received clearance from the FDA for our TearCare product in December 2021 for the application of localized heat therapy in adult patients with evaporative dry eye disease (DED) due to meibomian gland dysfunction (MGD), when used in conjunction with manual expression of the meibomian glands, and we intend to continue to develop TearCare for expanded indications in the future.

We are conducting and intend to continue conducting additional clinical trials or investigations to develop our devices for expanded indications. Historical clinical results, including interim results, are not necessarily predictive of future clinical results, and we cannot assure you that the results reported in these studies will be consistent with, or better than, currently available clinical data. Moreover, the outcomes and updates resulting from these studies, including interim results, may be compared to the results of other products and treatments for POAG or MGD, and if the comparisons are not favorable, it may limit the ability to obtain clearance, certification or approval of the devices for the expanded indications for which we intend to seek clearance, certification or approval, as well as adoption of our products for their current authorized uses. In addition, our competitors and other third parties may also conduct clinical trials or investigations of our products without our participation. Unfavorable or inconsistent clinical data from existing or future clinical trials or investigations conducted by us, our competitors or other third parties, the interpretation of our clinical data or findings of new or more frequent adverse events, could subject us to mandatory or voluntary product recalls, suspension or withdrawal of FDA or other clearance, certification or approval, significant legal liability or harm to our business reputation and could have a material adverse effect on our business, financial condition and results of operations.

Our products will be adopted and compete, in part, based on long-term data regarding patient outcomes and the risk of our products relative to other treatment options. The long-term clinical outcomes of the use of OMNI for its cleared uses are not known and, due to the novelty of our products, there is no long-term data regarding patient outcomes beyond our clinical trials or investigations. The results of short-term clinical experience of our products do not necessarily predict long-term clinical outcomes. We believe that ECPs will compare the rates of long-term clinical outcomes for procedures using our products for their authorized uses against alternative procedures and treatment options. If the long-term data does not meet ECPs' expectations, or if the long-term data indicates that our products are not as safe or effective as other treatment options or as current short-term data would suggest, physicians may recommend alternative treatments for their patients and our products may not become widely adopted, which will negatively affect our business, financial condition and results of operations.

The safety and efficacy of some of our products is not yet supported by long-term clinical data, which could limit sales, and our products might therefore prove to be less safe or effective than initially thought.

The products that we market in the United States are regulated as medical devices by the FDA. OMNI and TearCare have received premarket clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA. 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 prior to May 28, 1976 (preamendments device), a device that was originally on the U.S. market pursuant to an approved PMA application and later down-classified, or a 510(k)-exempt device. This process is typically shorter and generally requires the submission of less supporting documentation than the FDA's PMA process and does not always require long-term clinical studies.

In the European Union, or EU, manufacturers of medical devices are required by the Medical Devices Regulation to collect post-marketing clinical data in relation to their CE marked medical devices. Post-market surveillance includes the conduct of post-market clinical follow-up studies permitting manufacturers to gather information concerning quality, safety or performance of medical devices after they have been placed on the market in the EU. All information collected as part of the post-market surveillance process must be reviewed, investigated and analyzed on a regular basis in order to determine whether trending conclusions can be made concerning the safety or performance of the medical device and decisions must be taken in relation to the continued marketing of medical devices currently on the market. We expect to incur ongoing costs to comply with these post-market clinical obligations in EU markets for so long as we continue to market and sell products in those markets, as well as in the European Economic Area, or EEA, markets (also including Norway, Liechtenstein, and Iceland).

We are conducting and intend to continue conducting additional clinical trials, including clinical trials to develop TearCare for expanded indications. In addition, our competitors and other third parties may also conduct clinical trials of our products without our participation. If future patient studies or clinical testing do not support our belief that our products are advantageous for their intended uses, market acceptance of our products could fail to increase or could decrease and our business could be harmed. Moreover, if future results and experience by us, our competitors or other third parties, indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory or voluntary product recalls, suspension or withdrawal of FDA or other governmental clearance or approval or certifications, significant legal liability or harm to our business reputation, which could have a material adverse effect on our business, financial condition and results of operations.

We believe that ECPs will compare the rates of long-term clinical outcomes for procedures using our products for their authorized uses against alternative procedures and treatment options. If we choose to, or are required to, conduct additional studies, equivocal or unfavorable results from such studies or experience could lead to a reduction in the rate of coverage and reimbursement by both public and private third-party payors for procedures that are performed with our products, slow market adoption of our products by ECPs, significantly reduce our ability to achieve expected revenues and prevent us from being profitable.

We have limited experience in training on, and marketing and selling, our products and we may provide inadequate training, fail to increase our sales and marketing capabilities or fail to develop broad brand awareness in a cost-effective manner.

We have limited experience marketing and selling our products. In the United States, we currently rely on our direct sales force and any failure to maintain and grow our sales force could harm our business. In Europe, we currently rely on a combination of direct sales personnel and independent distributors to sell our products, and we intend to grow our international sales through a combination of direct and distributor sales. If we are unable to identify and retain productive direct sales representatives and distributors in the international territories and jurisdictions that we have targeted for commercial expansion, we may not be able to achieve projected revenue goals and our business could suffer. Our sales representatives are trained and possess product specific sales expertise, which we believe is critical in driving the awareness and adoption of our products. The members of our U.S. sales force are at-will employees. The loss of these personnel to competitors, or otherwise, could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent expertise and qualifications, or if we are unable to successfully instill such expertise in replacement personnel, our business, financial condition and results of operations could be materially harmed.

In order to generate future growth, we plan to continue to significantly expand and leverage our commercial infrastructure to increase our customer base and increase adoption by existing customers to drive our growth. Identifying and recruiting qualified sales and marketing professionals and training them on our products, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It can take several months or more before a sales representative or distributor representative is fully trained and productive. Our direct sales force may subject us to higher fixed costs than those of companies with competing products or treatments that rely more heavily on independent third parties, placing us at a competitive disadvantage. Our business may be harmed if our efforts to expand and train our sales force and distribution chain do not generate a corresponding increase in product sales and revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Any failure to hire, develop and retain effective sales personnel, to identify and train distributors and independent sales representatives in targeted international territories, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could have a material adverse effect on our business, financial condition and results of operations.

Our ability to increase our customer base and achieve broader market acceptance of our products will depend, to a significant extent, on our ability to expand our sales and marketing and educational efforts. We plan to dedicate significant resources to our sales and marketing initiatives, and educational programs through leading medical publications and at large industry and scientific meetings, both directly and through key opinion leaders. Our business may be harmed if these efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of our products and reaching new ECPs and patients. Brand promotion activities may not impact ECP or patient awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the market

acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is an important factor for the broad adoption of our products.

Our products are designed to be used in a limited number of procedures, and there is a limited total addressable market for our products. The sizes of the potential and actual markets for our current products have not been established with precision and may be smaller than we estimate.

We currently market our OMNI device for use in the U.S. and select European geographies for canaloplasty followed by trabeculotomy to reduce intraocular pressure in adult patients with POAG. POAG is the most prevalent form of glaucoma and affects approximately 4.1 million people in the United States and over 60 million people worldwide. We currently market TearCare in the United States for the application of localized heat therapy in adult patients with evaporative DED due to MGD, when used in conjunction with manual expression of the meibomian glands. There are an estimated 739 million people globally and 38 million people in the U.S. who suffer from DED. DED is the most common reason for a patient visit to an eye doctor, yet of the estimated 38 million people with DED in the U.S., only approximately 17 million have been diagnosed with DED. Studies have shown that evaporative DED resulting from MGD is associated with approximately 86% of all DED cases.

The total addressable markets for our products are subject to change and may be limited by FDA restrictions or more narrowly defined indications, any of which could have a material adverse effect on our business, financial condition and results of operations.

Further, our estimates of the total addressable markets for our products are based on a number of internal and third-party estimates, including, without limitation, the number of patients with POAG and MGD, and the assumed prices at which we can sell our products in markets that have not yet been fully established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our current products may prove to be incorrect. If the actual number of patients who would benefit from our products or the price at which we can sell our products is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition and results of operations.

Our operations and financial results have been, and will continue to be, adversely impacted by the COVID-19 pandemic in the United States and the rest of the world.

In December 2019, a novel strain of coronavirus, SARS-CoV-2, was identified in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease, COVID-19, has spread worldwide. In response to the COVID-19 pandemic, numerous state and local jurisdictions have imposed, modified, removed and reimposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents. Such orders or restrictions have resulted in work stoppages, slowdowns and delays, travel restrictions and cancellation of events. Disruptions to our business from COVID-19 include the inability of our component suppliers and manufacturers to produce our products, components, or accessories on a timely basis, or at all; disruptions in our logistics and distribution providers to deliver our products to customers on a timely basis, or at all; potential disruption in our employee base as a result of COVID-19 regulations and requirements (including vaccination mandates); inventory shortages or obsolescence; diversion of or limitations on employee resources that would otherwise be focused on the operations of our business; delays in growing or reductions in our sales organization, including through delays in hiring, lay-offs, furloughs or other losses of sales representatives; limitations on the ability of our sales representatives and distributors to reach potential customers and reduced opportunities for market education; business adjustments or disruptions of certain third parties, including suppliers and customers; and additional government requirements or other incremental mitigation efforts that may further impact our or our suppliers' capacity to manufacture our products. For example, as a result of restrictions related to the COVID-19 pandemic we have seen customer delays or cancellations of elective procedures using our products from time to time, which has resulted at various periods in decreased revenues as against our forecast. Our sales representatives have been curtailed in their ability to conduct in-person meetings and demonstrations, and our market education and training efforts have been limited. We also have and may continue to experience delays in initiating or completing any clinical trials or investigations that we intend to conduct or are conducting, and we do not know whether our clinical trials or investigations will begin on time, need to be redesigned, enroll patients on time, or be completed on schedule, or at all.

We experienced a significant decrease in revenues for both of our products in the second quarter of 2020 as compared to the first quarter of 2020. As elective eyecare procedures in many facilities that utilize OMNI and TearCare were

temporarily suspended by governmental authorities, many patients avoided visiting ECPs, and, even in areas that allowed elective procedures, ECPs and healthcare facilities in general severely cut back on the scheduling and performance of such procedures. The decrease in demand due to COVID-19 most significantly impacted our revenues in the latter part of the first quarter and the first half of the second quarter of 2020. Beginning in June 2020, we began to see an increase in the number of procedures using our products. In the first quarter of 2021, our customers experienced a significant number of procedure cancellations which we believe was largely driven by patients postponing procedures until their COVID-19 vaccinations were completed as opposed to any restrictions imposed on elective procedures. Our normal business operations were again disrupted by the Delta variant in the third quarter of 2021 and the Omicron variant in the fourth quarter of 2021 and into early 2022.

Though demand for our products grew during the latter half of the second quarter as well as in the second half of 2021 and the first quarter of 2022, the procedure cancellations that we have observed at the end of the fourth quarter of 2021 and into the first quarter of 2022 illustrate the fact that the COVID-19 pandemic continues to impact our business. The extent to which the COVID-19 pandemic impacts our business in the future will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and spread of COVID-19, any new variants of the virus, the nature, extent and effectiveness of containment and treatment measures, the extent and duration of the effect on the economy and how quickly and to what extent normal economic and operating conditions can resume.

The COVID-19 pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of an infectious disease, including COVID-19, could materially affect our business. Such economic recession could have a material adverse effect on our long-term business as hospitals and surgical centers curtail and reduce capital and overall spending. Unfavorable economic conditions brought on or exacerbated by the pandemic have resulted in significant job losses and reductions in disposable income, which we believe has negatively impacted our revenues. If patients are unable to obtain or maintain health insurance policies or experience decreases in their income, this may significantly impact their ability to pay for the procedures utilizing our products, which could further negatively impact our business, financial condition and results of operations. We cannot predict the continued impacts of the COVID-19 pandemic and the degree to which our business, financial condition and results of operations may continue to be affected, particularly given the lengthy duration of the pandemic. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

We may not be able to incrementally secure or maintain adequate levels of third-party coverage and reimbursement for procedures in which OMNI is used, and third parties may rescind or modify their coverage or delay payments related to OMNI. We may not be able to incrementally secure any, or adequate levels of, third-party coverage and reimbursement for procedures in which TearCare is used, and even if third parties provide coverage they may rescind or modify their coverage or delay payments related to TearCare.

We derive revenue from sales of OMNI to physicians, ambulatory surgery centers and hospital outpatient departments, which typically bill all or a portion of the costs and fees associated with our products to various third-party payors, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations and other healthcare-related organizations, and then bill patients for any applicable deductibles or co-payments. As a result, access to adequate coverage and reimbursement for procedures in which OMNI is used by third-party payors is essential to its acceptance and adoption by patients and ECPs.

We also derive revenue from sales of TearCare to ECPs and eye care clinics, which also bill all or a portion of the costs and fees associated with treatments and products to patients or, on a limited basis, to third-party payors. We believe that access to adequate coverage and reimbursement for procedures in which TearCare is used by third-party payors is important to the broad acceptance and adoption of TearCare. Currently, however, no payors have formal policies establishing coverage for the procedures in which TearCare is used. We are pursuing a comprehensive long-term market development and patient access plan for TearCare and focusing our efforts on partnering with key strategic accounts to pursue prior authorization approvals and reimbursement claims for procedures in which TearCare is used, but there is no guarantee that we will be successful. If patients are not willing to pay for procedures in which TearCare is used, or if third-party payors continue to refuse to provide coverage and reimbursement or provide insufficient levels of coverage and reimbursement, it could have a negative impact on ECPs’ adoption of TearCare and sales of TearCare.

Coverage and reimbursement by governmental and third-party payors may depend upon a number of factors, including the determination that the product or service and its use or administration for a particular patient is:

- A covered benefit;
- Safe, effective reasonable and medically necessary;
- Appropriate for the specific patient;
- Supported by clinical data;
- Supported by guidelines established by the relevant professional societies;
- Cost-effective; and
- Neither experimental nor investigational.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, no uniform policy of coverage and reimbursement for procedures using our products exists among third-party payors. Therefore, coverage and reimbursement for procedures using our products can differ significantly from payor to payor. Obtaining and maintaining coverage and reimbursement can be a time-consuming process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to satisfy governmental and third-party payors that procedures using our products should be covered and reimbursed.

In the United States, the American Medical Association, or AMA, generally assigns specific billing codes for procedures under a coding system known as Current Procedure Terminology, or CPT, which surgeons use to bill third-party payors and receive reimbursement. Once a permanent (Category I) CPT code is established for a service, the Centers for Medicare & Medicaid Services, or CMS, establishes payment levels under Medicare, while other payors may establish rates and coverage rules independently. Canaloplasty followed by trabeculotomy procedures using OMNI are typically billed using the Category I CPT code 66174, which describes canaloplasty. Coding for ophthalmic surgical procedures is complex, and changes to the codes used to report services performed with our products may result in significant changes in reimbursement, which could negatively impact our revenue.

The AMA maintains a subset of temporary (Category III) CPT codes used for new and emerging technologies. For example, TearCare was assigned a Category III CPT code effective beginning January 1, 2020. Coverage for Category III CPT codes is often limited. Medicare does not generally establish national payment rates for Category III CPT codes on the Medicare Physician Fee Schedule, or MPFS. As a result, individual Medicare contractors and private payors may establish their own payment rates for services described by Category III CPT codes, as has been the case with TearCare, which payment rates are subject to change, may be variable across Medicare contractors, may be materially below the final reimbursement rates that we are currently targeting, or may determine not to reimburse services described by Category III CPT codes.

Payors also continually review new and existing technologies for possible coverage and can deny or reverse coverage for new or existing products and procedures. There can be no assurance that third-party payor policies provide coverage, or will continue to provide coverage, for procedures in which OMNI is used. If coverage policies change such that Medicare no longer covers procedures in which our products are used, there would be a material adverse effect on our business, financial condition and results of operations. For example, Medicare Administrative Contractors could issue local coverage determinations that could restrict the patients eligible for treatment with our products or that are otherwise unfavorable to our business. If we are not successful in reversing any proposed non-coverage policies, or if third-party payors that currently cover or reimburse procedures in which our products are used reverse or limit their coverage in the future, or if other third-party payors issue similar policies, this could have a material adverse effect on our business.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the United States and in international markets. Third-party coverage and reimbursement for procedures using our products or any of our products in development for which we may receive regulatory clearance, certification or approval may not be available or adequate in either the United States or international markets. Further, other devices or treatments that compete with our products may be more widely covered or subject to different co-pay policies and requirements, which could impact demand for our products. If hospital, surgical center, ECP

and/or patient demand for our products is adversely affected by third-party reimbursement policies and decisions, it could have a material adverse effect on our business, financial condition and results of operations.

The market for our products is highly competitive. Our competitors may have longer operating histories, more established products and greater resources than we do, and may be able to develop or market treatments that are safer, more effective or gain greater acceptance in the marketplace than our products.

The medical device industry is highly competitive, subject to rapid change and significantly affected by the introduction of new products and technologies and the other activities of industry participants. We compete, or plan to compete, with medical device and pharmaceutical companies that develop and commercialize products for eye conditions, including Glaukos, Ivantis, AbbVie/Allergan, Novartis, Alcon, Johnson & Johnson, and New World Medical. These companies, or other entrants into the market, may have or develop competing technologies, other products that are in or that enter clinical trials, new devices or additional indications for existing devices that could demonstrate better safety, effectiveness, clinical results, lower costs or greater ECP and market acceptance than our products.

We compete, or may compete in the future, against other companies which have longer, more established operating histories and significantly greater financial, technical, marketing, sales, distribution and other resources, which may prevent us from achieving significant market penetration or improved operating results. These companies may enjoy several competitive advantages, including:

- Established treatment patterns pursuant to which prescription medications, traditional glaucoma surgery or more conventional MIGS devices are generally first-line therapies for the treatment of POAG and eye drops or warm-compresses are first-line therapies for the treatment of MGD;
- Established relationships with ECPs who are familiar with their products and procedures for the treatment of POAG or MGD;
- Established relationships with key stakeholders, including hospital outpatient departments, ambulatory surgery centers, optometrists and ophthalmologists, general practitioners and administrators;
- Greater financial and human capital resources;
- Significantly greater name recognition;
- Additional lines of products, and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage; and
- Established sales, marketing and worldwide distribution networks.

One of the major hurdles to adoption of our products will be overcoming established treatment patterns, which will require educating ECPs and supportive clinical data. However, because of the size of the market opportunity for devices used in procedures to address POAG and MGD, we believe current and potential future competitors will dedicate significant resources to aggressively promote their products or develop new products or treatments, such as Glaukos' iStent infinite and iPRIME Viscodelivery System. Further, new treatment options may be developed that could compete more effectively with our products due to the prevalence of POAG and MGD, and the research and technological progress that exist within the market. Also, even if competitor products do not have indications for use or clinical data that are comparable to ours, ECPs can still choose these competitor products for a variety of reasons, including those set forth above. For instance, competitors may seek to bundle their products in a manner that is attractive to ECPs, which may result in decreased use or adoption of our products by ECPs, notwithstanding that our products may offer superior efficacy.

We rely on third parties to manufacture and supply OMNI and TearCare, and we may encounter delays or incur additional costs when we add new manufacturers and suppliers for our products.

Our business strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet customer demand, while adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs. We do not have any internal manufacturing capabilities or infrastructure. OMNI is currently being produced and assembled by Peter's Technology (Suzhou) CO LTD., or Peter's, a subsidiary of Peter's Co., Ltd., a Taiwan-based manufacturer, and we also maintain OMNI product inventory manufactured by Second Source Medical, LLC ("Second Source"), our previous OMNI manufacturer, which will be used to fulfill customer orders until such inventory has been depleted. We intend to fully transition OMNI production to Peter's and an

additional high-volume contract manufacturer with domestic U.S. production facilities in 2022. The Peter's Supply Agreement governs the assembly and supply of OMNI by Peter's, pursuant to which Peter's purchases components from our approved suppliers for assembly and we make purchases on a purchase order basis. We would likely encounter delays or incur additional costs in connection with the transition to a new contract manufacturer with domestic U.S. and Chinese production facilities for OMNI production. For the production of TearCare, we currently have supply arrangements with separate Chinese and U.S. medical device manufacturers for the production of TearCare's SmartLids, TearCare's SmartHubs, and TearCare's Clearance Assistant. These companies manufacture, assemble, inspect, test, package and ship OMNI and TearCare and related accessories.

While our existing manufacturers have generally met our demand requirements on a timely basis in the past, their ability and willingness to continue to do so going forward may be limited for several reasons, including if any of our manufacturers' facilities suffer damage or a force majeure event, our relative importance as a customer to each manufacturer or their inability to provide assembly services to manufacture our products, which may be affected by the COVID-19 pandemic. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these manufactured products if we cannot obtain an acceptable substitute.

The process of identifying alternative manufacturing facilities for any other reason could be time-consuming and expensive, may result in interruptions in our operations and product delivery, and could affect the performance specifications of our products. If we are required to change any of our contract manufacturers, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. We cannot assure you that we will be able to identify and engage alternative contract manufacturers on similar terms or without delay. Furthermore, our contract manufacturers could require us to move to a different production facility. The occurrence of any of these events could harm our ability to meet the demand for our products in a timely and cost-effective manner, which could have a material adverse effect on our business, financial condition and results of operations.

We are also subject to numerous other risks relating to our reliance on third parties, including:

- Inability to renew or extend contracts and arrangements with such third parties or renew any such contracts or arrangements on terms that are favorable to us;
- Interruption of supply resulting from modifications to, or discontinuation of, a third-party's operations;
- Delays in shipments resulting from uncorrected defects, reliability issues or a third-party's failure to manufacture and supply components, accessories, materials, and assembly that consistently meet our agreed specifications and quality requirements;
- Inability to obtain adequate supply or services in a timely manner or on commercially reasonable terms;
- Difficulty identifying and qualifying, and obtaining new regulatory approvals, for alternative suppliers for our products and product components in a timely manner;
- Inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements;
- Inability to comply with applicable provisions of the FDA's Quality System Regulation, or QSR, or other applicable laws or regulations enforced by the FDA, state and foreign regulatory authorities;
- Inability to ensure the quality of products and components manufactured by third parties;
- Failure to timely increase production capacity or volumes to meet demand;
- Production delays related to the evaluation and testing of products and components from alternative third parties and corresponding regulatory qualifications;
- An outbreak of disease or similar public health threat, such as the COVID-19 pandemic, particularly as it may impact our supply chain;
- Long lead time for the production of certain components of our products;
- Price fluctuations due to a lack of long-term supply arrangements with certain of our suppliers;

- Risk of delays or interruption stemming from trade wars; and
- General delays in delivery by our suppliers.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. As demand for our products increases, we will have to invest additional resources to manage the manufacturing process. If we fail to secure increased production capacity efficiently, we may not be able to fill customer orders on a timely basis, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. In addition, although some future products may share product features, components, sub-assemblies and materials with our existing products, the manufacture of these products may require modification of the current production processes or unique production processes, the identification of new suppliers for specific components, sub-assemblies and materials or the development of new manufacturing technologies. It may not be possible for our current third-party manufacturers to produce these products at a cost or in quantities sufficient to make these products commercially viable or to maintain current operating margins, all of which could have a material adverse effect on our business, financial condition and results of operations.

We depend on a limited number of single source suppliers.

We rely on a limited number of third-party manufacturers, many of which are single source suppliers, for a portion of the components, accessories, materials and assembly that we utilize in our products. These items are critical and, for certain items, there are relatively few or no readily available alternative sources of supply. These single source suppliers may be unwilling or unable to supply these items reliably and at the levels we anticipate or that are required by the market. Additionally, although we require our suppliers and providers to supply us with components and services that meet our specifications and other applicable legal and regulatory requirements in our agreements and contracts, and appropriate inspections, testing or other acceptance activities are performed to ensure the components meet our requirements, there is a risk that these third parties will not always act consistent with our best interests, and may not always supply components or provide services that meet our requirements or in a timely manner.

While our suppliers have generally met our demand requirements on a timely basis in the past, we cannot guarantee that suppliers will in the future be able to meet our demand, either because of acts of nature, global pandemics, such as the COVID-19 pandemic, the nature of our agreements with those suppliers or our relative importance to them as a customer, and our suppliers may decide in the future to discontinue or reduce the level of business they conduct with us. We may also fail to obtain additional suppliers for any of the components used in our products. If we are unable to meet our demand requirements on a timely basis, we may not have a sufficient number of our products available for delivery to support ECPs that utilize our products as part of their treatment. For instance, if our supply of OMNI products from Peter's were to be interrupted or suspended for any significant period, we may be unable to meet customer demand for our products until such time that another supplier (or suppliers) can ramp production to meet this shortfall, or Peter's can resume its product supply in accordance with our purchasing requirements. Any shortfall in the supply of products may result in lower adoption and usage rates of our products and have a material adverse effect on our business, financial condition and results of operations.

The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business.

We rely on suppliers, vendors, outsourcing partners, consultants, alliance partners and other third parties to help research, develop, manufacture, commercialize and distribute our products and manage certain parts of our business. Using these third parties poses a number of risks, such as: (i) they may not perform to our standards or legal requirements; (ii) they may not produce reliable results; (iii) they may not perform in a timely manner; (iv) they may not maintain confidentiality of our proprietary information; (v) disputes may arise with respect to ownership of rights to technology developed with our partners; and (vi) disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration. Moreover, some third parties are located in markets subject to political and social risk, corruption risk, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory, and other obligations may materially adversely affect our business.

The failure of OMNI or TearCare to meet patient expectations or the occurrence of adverse events from use of OMNI or TearCare could limit their adoption and impair our financial performance.

Our future success depends in part upon patients having an experience with our products that meets their expectations in order to increase ECPs' demand for our products as a result of positive feedback, social media and word-of-mouth. Patients may be dissatisfied if their expectations of the procedures performed by ECPs using our products, among other things, are not met. Despite what we believe to be the strong safety profile of our products for their intended uses, patients may experience adverse events following canaloplasty or trabeculotomy with OMNI, including, but not limited to, hyphema, mild anterior chamber inflammation and spikes in intraocular pressure. Similarly, patients may experience adverse events following application of localized heat with TearCare, including discomfort, pain or erythema of the eyelids.

If experiences with OMNI or TearCare do not meet the expectations of patients, or if patients experience adverse events, it could discourage the patient and treating physician from referring our products to others. Dissatisfied patients may express negative opinions through social media or other public forums. Any failure to meet patient expectations and any resulting negative publicity could harm our reputation and future sales and therefore adversely affect our business, financial condition and results of operations.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but keep limited components, sub-assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our third-party suppliers, we forecast anticipated materials requirements and demand for our products in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our limited historical commercial experience, rapid growth, failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance and adoption of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs, which would negatively impact our gross margins and impair the strength of our brand. Conversely, if we underestimate customer demand for our products or our own requirements for components, sub-assemblies and materials, our third-party suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements, which could result in inadequate inventory levels or interruptions, delays or cancellations of deliveries to our customers, any of which would damage our reputation, customer relationships and business. In addition, several components, sub-assemblies and materials incorporated into our products require lengthy order lead times, and additional supplies or materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, and our third-party suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our business, financial condition and results of operations.

Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business.

Our quarterly and annual results of operations, including our revenue, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance or of the results for the year in which such quarter or period occurs. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuations in quarterly and annual results may decrease the value of our common stock or result in volatility of our common stock. Because our quarterly results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- The level of demand for our products which may vary significantly;
- Results of clinical trials or investigations involving the use of our products;
- Regulatory decisions or announcements, including product recalls;
- Data and results relating to our products that are presented in journal publications;

- Expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- Sales and marketing efforts and expenses;
- Pricing pressures;
- The rate at which we grow our sales force and the speed at which newly hired salespeople become effective;
- Changes in the productivity of our sales force;
- Our ability to expand the geographic reach of our sales force;
- The degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners;
- Changes in coverage and reimbursement policies with respect to the procedures in which our products and our competitors' products are used, and potential future products that compete with our products;
- Positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry;
- The timing of customer orders or medical procedures using our products and the number of available selling days in any quarterly period, which can be impacted by holidays, the mix of products sold and the geographic mix of where products are sold;
- The timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our products, which may change from time to time;
- The costs of enforcing and defending our intellectual property rights, whether through litigation or otherwise;
- The cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers; and
- Future accounting pronouncements or changes in our accounting policies.

Our long-term growth depends on our ability to enhance our products, expand our indications and develop and commercialize additional products in a timely manner. If we fail to identify, acquire and develop other products, we may be unable to grow our business.

The markets for our products are highly competitive, dynamic, and marked by rapid and substantial technological development and product innovation. New entrants or existing competitors could attempt to develop products that compete directly with ours. Demand for our products and future related products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our products could become obsolete and our revenue would decline as our customers purchase our competitors' products. Developing and improving products is expensive and time-consuming and could divert management's attention away from our existing products. The success of any new product offering or product enhancements to our solutions will depend on several factors, including our ability to:

- Maintaining strong relationships with ECPs;
- Assemble sufficient resources to acquire or discover additional products;
- Properly identify and anticipate physician and patient needs;
- Develop and introduce new products and product enhancements in a timely manner;
- Avoid infringing upon, misappropriating or otherwise violating the intellectual property rights of third parties;
- Demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials or investigations;

- Obtain the necessary regulatory clearances, certifications or approvals for expanded indications, new products or product modifications;
- Comply with the requirements of FDA and similar foreign regulatory authorities regarding the marketing of new devices or modified products;
- Produce new products in commercial quantities at an acceptable cost;
- Provide adequate training to potential users of our products;
- Receive adequate coding, coverage and reimbursement for procedures performed with our products; and
- Develop an effective and dedicated sales and marketing team.

If we are unable to develop or improve products, applications or features due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors devote a considerably greater amount of funds to their research and development programs than we do, and those that do not may be acquired by larger companies that could allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

In addition, we may choose to focus our efforts and resources on potential products or indications that ultimately prove to be unsuccessful, or to license or purchase marketed products that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other potential products or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such potential products through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights, which could adversely impact our business, financial condition and results of operations.

Changes in public health insurance coverage and government reimbursement rates for our products could affect the adoption of our products and our future revenue.

The federal government is considering ways to change, and has changed, the manner in which healthcare services are paid for in the U.S. Individual states may also enact legislation that impacts Medicaid payments to hospitals, surgical centers and physicians. In addition, CMS establishes Medicare payment levels for hospitals, surgical centers and physicians on an annual basis, which can increase or decrease payment to such entities, including for procedures involving our products. Internationally, medical reimbursement systems vary significantly from country to country, with some countries limiting medical centers' spending through fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third-party reimbursement. Even if we succeed in bringing our products to market in additional foreign countries, uncertainties regarding future healthcare policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at acceptable prices.

Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and results of operations. Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell our products at prices necessary to support our current business strategies.

In an effort to reduce costs, many clinics and hospitals in the United States, including some of our customers, are members of Group Purchasing Organizations, or GPOs, and Integrated Delivery Networks, or IDNs. GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our revenue and margins.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative products due to the price or quality offered by other companies, which could result in a decline in our sales volumes and revenue.

Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third-party payors. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for pricing concessions in the future. Additionally, GPOs, IDNs and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices of our products. Such downward pressure on the prices of our products may affect our results of operations and our ability to support our current business strategies.

We may not be able to achieve or maintain satisfactory pricing and margins for our products.

Medical device companies have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. Any decline in the amount that payors reimburse our customers for procedures that use OMNI or in the amount that customers are willing to pay or that payors reimburse for procedures that use TearCare in the future, could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products or add more components to our products, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We are, and will continue to be, subject to significant pricing pressure, which could negatively affect our business, financial condition and results of operations.

We may be unable to manage the anticipated growth of our business.

In order to grow, we need to expand our commercial team, and general and administrative infrastructure. In addition to the need to scale our organization, future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. Rapid expansion in personnel could mean that less experienced people market and sell our products, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. For example, we currently rely on a combination of direct sales personnel and independent distributors to sell our products in Europe, and we intend to grow our international sales through a combination of direct and distributor sales. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

As demand for our current products or any of our future products increases, we will need to continue to expand customer service, billing and systems processes and enhance our internal quality assurance program. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing data or inability to meet increased demand.

Performance issues, service interruptions or price increases by our shipping carriers and distributors could negatively affect our business, financial condition and results of operations and harm our reputation and the relationship between us and the ECPs we work with.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to

replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our solutions and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis. These factors could negatively affect our business, financial condition and results of operations and harm our reputation and the relationship between us and the ECPs we work with.

Our products may become obsolete in the future.

The medical device industry is characterized by rapid and significant change. There can be no assurance that other companies will not succeed in developing or marketing devices or products that are more effective than our products or that would render our products obsolete or noncompetitive. Additionally, new surgical procedures, medications and other therapies could be developed that replace or reduce the importance of our products. Accordingly, our success will depend in part on our ability to respond quickly to medical and other changes through the development and introduction of new products. Product development involves a high degree of risk, and there can be no assurance that our new product development efforts will result in any commercially successful products.

We bear the risk of potential warranty claims on our products.

We provide limited warranties regarding our products, including warranties pertaining to freedom from defects and conformance to specifications. We are generally obligated under our sales contracts to repair, replace or credit or refund the purchase price of defective products. As a result, we bear the risk of potential warranty claims on our products. In the event that we attempt to recover some or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery under any warranty or indemnity provided to us by such suppliers or vendors and any recovery from such vendor or supplier may not be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us.

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

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

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products.

Disputes between us and any collaborators we may have in the future may result in litigation or arbitration which would increase our expenses and divert the attention of our management. These arrangements may consume management time and resources to establish and maintain. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. Any

termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our products, could delay the development and commercialization of our products and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations. If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license and/or seek damages arising out of the alleged breach, which could adversely affect our competitive business position and harm our business prospects.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Although we carry product liability insurance, we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not be available on acceptable terms, if at all. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. Defending a suit, regardless of its merit or eventual outcome, could be costly, could divert management's attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals.

Operating as a public company has also made it more difficult and more expensive for us to obtain and maintain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition and results of operations.

We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees will negatively affect our business, financial condition and results of operations.

Our success depends largely on the continued services of key members of our executive management team and others in key management positions. For example, the services of Paul Badawi, our Chief Executive Officer and David Badawi, our Chief Technology Officer, are essential to driving adoption of our products, executing on our corporate strategy and ensuring the continued operations and integrity of financial reporting within our company. In addition, the services of our sales professionals are critical to driving the growth in sales of our products. Any of our employees may terminate their employment with us at any time. We currently maintain a key person life insurance policy on Mr. Badawi. If we lose one or more key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy, which in turn would negatively affect our business.

In addition, our research and development programs, clinical and quality operations and sales efforts depend on our ability to attract and retain highly skilled engineers and sales professionals, as well as experienced regulatory, quality and clinical professionals. We may not be able to attract or retain qualified professionals in the future due to the competition for qualified personnel. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we do. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages.

In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because of unfavorable

fluctuations or declines in our stock price or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the market price of our common stock approaches or falls below the exercise price of their vested and unvested option shares. Substantial declines in the market price of our common stock will also reduce the effectiveness of any restricted stock unit or other equity incentive awards in attracting and retaining employees, especially within the current highly competitive labor market. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, it will negatively affect our business, financial condition and results of operations.

The use, misuse or off-label use of our products may result in injuries that lead to product liability suits, which could be expensive, divert management's attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.

Our products are cleared or authorized by the FDA and certified in the EU to be marketed for certain specific intended uses. If physicians elect to use our products in manners outside of the intended uses that have been cleared, authorized, or certified, then such off-label use of our products may result in outcomes and adverse events that are sight threatening, necessitate medical or surgical intervention to preclude permanent impairment of vision, or result in a permanent impairment of vision, potentially leading to product liability claims. However, we cannot prevent a physician from using our products for off-label applications or using components or products that are not our products when performing procedures with our products. There may be increased risk of injury to patients if physicians attempt to use our devices off-label. In addition, we cannot guarantee that physicians are trained by us or their peers prior to utilizing our products. Complications resulting from the use of our products off-label or use by physicians who have not been trained appropriately, or at all, may not effectively treat the applicable conditions and may expose us to product liability claims or litigation by our customers or their patients and may harm our reputation.

In addition, if our products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation initiated by hospitals, surgical centers, ECPs or patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management's attention from our core business, attract negative publicity, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, we may not have sufficient insurance coverage for future product liability claims. We are not able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation, significantly increase our expenses, and reduce product sales. Product liability claims could cause us to incur significant legal fees and deductibles and claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results.

We may need additional funding to finance our planned operations, and may not be able to raise capital on acceptable terms, if at all, which could force us to delay, reduce or eliminate our product development programs and commercialization efforts.

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. Since our inception, our operations have been financed primarily by net proceeds from the sale of our convertible preferred stock in private placements, indebtedness and, to a lesser extent, product revenue from sales of our products. As of December 31, 2021, we had $260.7 million in cash and cash equivalents, and an accumulated deficit of $153.0 million. Based on our current planned operations, we expect that our cash and cash equivalents and additional borrowings available under our credit facility will enable us to fund our operations for at least the next twelve months. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

We expect to continue to invest in clinical trials or investigations that are designed to provide clinical evidence of the safety and efficacy of our products, the growth of our sales and marketing organization, and research and development of product improvements and future products. Moreover, we expect to incur additional expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance, investor relations and other expenses. Because of these and other factors, we expect to continue to incur net losses and negative cash flows from operations for the foreseeable future. Our future funding requirements will depend on many factors, including:

- The degree and rate of market acceptance of our products and procedures;
- Whether we acquire third-party companies, products or technologies;
- The impact on our business from the ongoing COVID-19 pandemic, or any other pandemic, epidemic, or outbreak of an infectious disease;
- Repayment of debt;
- The scope and timing of investment in our sales force and expansion of our commercial organization;
- The scope, rate of progress and cost of our current or future clinical trials or investigations and registries;
- The cost of our research and development activities;
- The cost and timing of additional regulatory clearances, certifications or approvals;
- The costs associated with any product recall that may occur;
- The costs of attaining, defending, protecting and enforcing our intellectual property rights;
- The terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- The emergence of competing technologies or other adverse market developments;
- Our ability, and our competitors' ability, to obtain and maintain favorable reimbursement for our products; and
- The rate at which we expand internationally.

We may seek to raise additional capital through equity offerings or debt financings and such additional financing may not be available to us on acceptable terms, or at all. In addition, any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. For example, if we raise funds by issuing equity or equity-linked securities, the issuance of such securities could result in dilution to our stockholders. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline, and the price per share at which we sell additional shares of our common stock, or securities convertible into or exercisable or exchangeable for shares of our common stock, in future transactions may be higher or lower than the price per share paid by investors in the IPO.

In addition, the terms of debt securities issued or borrowings could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to pay dividends, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, such as relinquishment or licensing of certain technologies or products that we otherwise would seek to develop or commercialize ourselves, or reserve for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us.

If we are unable to obtain adequate financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials or investigations necessary to market our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition and results of operations.

We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future.

In November 2020, we entered into credit and security agreements with MidCap Financial Services, which provide for a term loan facility and revolving line of credit, or the 2020 MidCap Credit Facility. The 2020 MidCap Credit Facility consists of a term loan of up to $35.0 million, or the 2020 Term Loan, which has a stated floating interest rate equal to

reserve-adjusted LIBOR plus 7.00%, and a revolving line of credit of $5 million, or the 2020 Revolver, with a stated floating interest rate equal to reserve-adjusted LIBOR plus 4.50%, a 0.5% unused line fee and a 0.5% collateral management fee. We further amended the 2020 MidCap Facility in October 2021 and November 2021 for purposes of relaxing certain financial reporting obligations and other operating covenants. As of December 31, 2021 we had an aggregate of approximately $35.0 million in principal borrowings outstanding under the 2020 MidCap Credit Facility, excluding debt discounts. We must make interest payments under the 2020 MidCap Credit Facility, which has diverted and will continue to divert resources from other activities. We incurred an aggregate interest expense of $4.4 million and $2.4 million in the years ended December 31, 2021 and 2020, respectively.

Our obligations under the 2020 MidCap Credit Facility are collateralized by a security interest in substantially all of our assets, and we are subject to customary financial and operating covenants limiting our ability to, among other things, relocate or dispose of assets, undergo a change in control, merge or consolidate, enter into certain transactions with affiliates, make acquisitions, incur debt, pay dividends, grant liens, store certain amounts of inventory or equipment with third parties and make investments, in each case subject to certain exceptions. We are also subject to minimum trailing revenue targets that are evaluated on a monthly basis. The covenants related to the 2020 MidCap Credit Facility, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies.

While we have not previously breached and are not currently in breach of these or any other covenants contained in the 2020 MidCap Credit Facility, there can be no guarantee that we will not breach these covenants in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the 2020 MidCap Credit Facility. If not waived, future defaults could cause all of the outstanding indebtedness under the 2020 MidCap Credit Facility to become immediately due and payable and terminate commitments to extend further credit and foreclose on the collateral granted to it to collateralize such indebtedness. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

In order to service this indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This may place us at a competitive disadvantage compared to our competitors that have less indebtedness or greater financial resources to service their debt.

Uncertainty relating to the LIBOR calculation process and potential phasing out of LIBOR may adversely affect the market value of our current or future debt obligations.

The London Inter-bank Offered Rate, or LIBOR, and certain other interest "benchmarks" may be subject to regulatory guidance and/or reform that could cause interest rates under our current or future debt agreements to perform differently than in the past or cause other unanticipated consequences. The United Kingdom's Financial Conduct Authority, which regulates LIBOR, has announced that it intends to stop encouraging or requiring banks to submit LIBOR rates after 2021, and it is unclear if LIBOR will cease to exist or if new methods of calculating LIBOR will evolve. If a published LIBOR rate is unavailable after 2021, the interest rates on instruments which are indexed to LIBOR will be determined using alternative methods, which may result in interest obligations which are more than or do not otherwise correlate over time with the payments that would have been made on such debt if LIBOR was available in its current form. Any new proposals or consequences could have a material adverse effect on our financing costs, including our interest rates on borrowings under our 2020 Term Loan and 2020 Revolver, and as a result, our financial condition, operating results and cash flows.

We may acquire other companies or technologies, which could fail to result in a commercial product or net sales, divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our business and adversely affect our results of operations.

Although we currently have no agreements or commitments to complete any such transactions and are not involved in negotiations to do so, we may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. However, we cannot assure you that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product or technology in a cost-effective and non-disruptive manner. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

To date, the growth of our operations has been largely organic, and we have limited experience in acquiring other businesses or technologies. Furthermore, the anticipated benefit of any strategic alliance, joint venture or acquisition may not materialize, or such strategic alliance, joint venture or acquisition may be prohibited. In November 2020, we amended and restated our credit facilities and entered into the 2020 Term Loan and 2020 Revolver and then further amended the 2020 Term Loan and 2020 Revolver in October 2021 and November 2021. The 2020 Term Loan and the 2020 Revolver restrict our ability to pursue certain mergers, acquisitions, amalgamations or consolidations that we may believe to be in our best interest.

We may not be able to successfully integrate any acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our business, financial condition and results of operations may be negatively affected. Additional risks we may face in connection with acquisitions include:

- Diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- Coordination of research and development and sales and marketing functions;
- Integration of product and service offerings;
- Retention of key employees from the acquired company;
- Changes in relationships with strategic partners as a result of product acquisitions or strategic positioning resulting from the acquisition;
- Cultural challenges associated with integrating employees from the acquired company into our organization;
- Integration of the acquired company’s accounting, management information, human resources and other administrative systems;
- The need to implement or improve controls, procedures, and policies at a business that prior to the acquisition may have lacked sufficiently effective controls, procedures and policies;
- Financial reporting, revenue recognition or other financial or control deficiencies of the acquired company that we don’t adequately address and that cause our reported results to be incorrect;
- Liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, misappropriation or other violation, violations of laws, commercial disputes, tax liabilities and other known and unknown liabilities;
- Unanticipated write-offs or charges; and
- Litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties.

Our failure to address these risks or other problems encountered in connection with acquisitions and investments could cause us to fail to realize the anticipated benefits of these acquisitions or investments, cause us to incur unanticipated liabilities, and harm our business generally.

Taxing authorities may successfully assert that we should have collected or in the future should collect sales and use, gross receipts, value added or similar taxes and may successfully impose additional obligations on us.

One or more jurisdictions may seek to impose additional tax collection obligations on us, including for past sales. A successful assertion by a state, country, or other jurisdiction that we should have been or should be collecting additional sales, use, or other taxes on our services could, among other things, result in substantial tax liabilities for past sales, create significant administrative burdens for us, discourage users from purchasing our products, or otherwise harm our business, results of operations and financial condition.

Our ability to utilize our net operating loss carryforwards, disallowed interest expense carryforwards and research and development carryforwards may be limited.

As of December 31, 2021, we had U.S. federal and state net operating loss carryforwards, or NOLs, of $28.7 million and $6.5 million, respectively, and U.S. federal and state research and development credit carryforwards of $1.2 million and $0.9 million, respectively. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change by value in its equity ownership over a rolling three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards could be subject to limitation under Sections 382 and 383 of the Code if we have undergone, or undergo in the future, any ownership changes for purposes of these provisions. If our NOLs and research and development credit carryforwards are subject to these limitations, we may not be able to utilize a material portion of the NOLs and research and development credit carryforwards, even if we attain profitability. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes.

In addition, the tax benefit of NOLs, temporary differences and credit carryforwards are required to be recorded as an asset to the extent that we assess that realization is more likely than not. We believe that recognition of the deferred tax asset arising from these future tax benefits is not likely to be realized and, accordingly, have provided a valuation allowance of $38.8 million and $24.5 million for the years ended December 31, 2021 and 2020, respectively.

The impact of the Tax Cuts and Jobs Act and the CARES Act on our financial results is not entirely clear and could differ materially from the financial statements provided herein.

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act, or the TCJA, that significantly reformed the Code. The TCJA, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense; limitation (as modified by the CARES Act as discussed below) of the deduction for NOLs and elimination of NOL carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); and modifying or repealing many business deductions and credits.

On March 27, 2020, President Trump signed the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), aimed at helping American workers and businesses impacted by the COVID-19 pandemic. The CARES Act, among other things, temporarily removes the current-law taxable income limitation established under the Tax Cuts and Jobs Act of 2017, and permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019 and 2020 to be carried back to each of the five preceding taxable years. The NOL provisions of the CARES Act are not expected to result in a cash benefit to the Company nor did they impact our NOL balance upon enactment.

The financial statements contained herein reflect the effects of the TCJA and the CARES Act based on current guidance. However, there remain uncertainties and ambiguities in the application of certain provisions of the TCJA and the CARES Act, and, as a result, we made certain judgments and assumptions in the interpretation thereof. The U.S. Treasury Department and the Internal Revenue Service may issue further guidance on how the provisions of the TCJA and the CARES Act will be applied or otherwise administered that differs from our current interpretation. In addition, the TCJA and the CARES Act could be subject to potential amendments and technical corrections, any of which could materially lessen or increase certain adverse impacts of the legislation on us.

The planned international expansion of our business will expose us to market, legal, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

We intend to increase our international presence, including securing additional regulatory approvals in targeted countries outside the United States. This strategy may include establishing and maintaining physician outreach and education capabilities outside of the United States and expanding our relationships with international payors. Doing business internationally involves a number of risks, including:

- Difficulties in staffing and managing our international operations;
- Multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- Reduced or varied protection for intellectual property rights in some countries;
- Obtaining regulatory clearance, certification or approval where required for our products in various countries;
- Requirements to maintain data and the processing of that data on servers located within such countries;
- Complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- Limits on our ability to penetrate international markets if we are required to manufacture our products locally;
- Financial risks, such as longer payment cycles, difficulty collecting accounts receivable, foreign tax laws and complexities of foreign value-added tax systems, the effect of local and regional financial pressures on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- Restrictions on the site-of-service for use of our products and the economics related thereto for physicians, providers and payors;
- Changes in foreign currency exchange rates and costs associated with hedging against such changes;
- Natural disasters, political and economic instability, including wars, such as the current military conflict between Russia and Ukraine, terrorism, political unrest, outbreak of disease, boycotts, curtailment of trade and other market restrictions; and
- Regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the United States Foreign Corrupt Practices Act of 1977, or FCPA, U.K. Bribery Act of 2010 and comparable laws and regulations in other countries.

Any of these factors could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our business, financial condition and results of operations.

We could be adversely affected by violations of the FCPA and similar worldwide anti-bribery laws and any investigation, and the outcome of any investigation, by government agencies of possible violations by us of the FCPA could have a material adverse effect on our business.

The FCPA and similar worldwide anti-bribery and anti-corruption laws prohibit companies and their intermediaries from corruptly providing any payments or other benefits to government officials for the purpose of obtaining or retaining business. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the FCPA, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control, or OFAC. In addition, the U.K. Bribery Act of 2010, or the Bribery Act, prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that fails to prevent bribery by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented adequate procedures to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or

with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions.

We have commenced commercial sales of OMNI in certain European countries through a combination of direct sales personnel and independent distributors, and we are also in the process of conducting an EU-based clinical investigation. Further, a portion of our business with respect to our manufacturing is conducted outside of the United States. We expect our international activities to increase in the future. Though we maintain policies, internal controls and other measures reasonably designed to promote compliance with applicable anticorruption and anti-bribery laws and regulations, and certain safeguards designed to ensure compliance with U.S. trade control laws, our employees or agents may nevertheless engage in improper conduct for which we might be held responsible. Any violations of these anti-corruption or trade controls laws, or even allegations of such violations, can lead to an investigation and/or enforcement action, which could disrupt our operations, involve significant management distraction, and lead to significant costs and expenses, including legal fees. If we, or our employees or agents acting on our behalf, are found to have engaged in practices that violate these laws and regulations, we could be subject to criminal and civil enforcement action, suffer severe fines and penalties, profit disgorgement, injunctions on future conduct, securities litigation, bans on transacting government business, delisting from securities exchanges and other consequences that may have a material adverse effect on our business, financial condition and results of operations. In addition, our reputation, our net sales or our stock price could be adversely affected if we become the subject of any negative publicity related to actual or potential violations of anti-corruption, anti-bribery or trade control laws and regulations.

Changes in government trade policies, including the imposition of tariffs and export restrictions, could have a negative impact on our manufacturing process, which may materially and adversely affect our sales and results of operations.

Certain public officials, including members of the current U.S. Congress, have made public statements indicating the possibility of significant changes in U.S. trade policy and have taken certain actions that may impact U.S. trade policy, including imposing new or increased tariffs on certain goods imported into the United States during the Trump administration. For example, the United States and China have imposed a number of tariffs and other restrictions on items imported or exported between the United States and China, and have proposed to impose a number of additional tariffs. We cannot predict what actions may ultimately be taken with respect to tariffs or trade relations between the United States and China or other countries, what products may be subject to such actions, or what actions may be taken by the other countries in retaliation.

Since certain of our critical product and product component manufacturers are located outside the United States, such changes, if adopted, could have a negative impact on our business and make our products more expensive and less competitive in domestic markets. Furthermore, changes in U.S. trade policy could trigger retaliatory actions by affected countries, which could impose restrictions on our ability to do business in or with affected countries or prohibit, reduce or discourage purchases of our products by foreign customers. Changes in, and responses to, U.S. trade policy could reduce the competitiveness of our products and cause our sales to decline, which could materially and adversely impact our business, financial condition and results of operations.

The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

Following a national referendum and enactment of legislation by the government of the United Kingdom, or UK, the UK formally withdrew from the EU. The EU-UK Trade and Cooperation Agreement, or TCA, came into effect on January 1, 2021. The TCA does not specifically refer to medical devices. However, as a result of Brexit, the EU Medical Devices Regulation will not be implemented in the UK, and previous legislation that mirrored the EU Medical Devices Regulation in UK law has been revoked. The regulatory regime for medical devices in Great Britain (England, Scotland and Wales) will continue to be based on the requirements derived from current EU legislation, and the UK may choose to retain regulatory flexibility or align with the (EU) Medical Devices Regulation going forward. CE marks will continue to be recognized in the UK, and certificates issued by EU-recognized notified bodies will be valid in the UK, until June 30, 2023. For medical devices placed on the market in Great Britain after this period, a UK Conformity Assessed, or UKCA, marking will be mandatory. In contrast, UKCA marking and certificates issued by UK notified bodies will not be recognized on the EU market. The TCA does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardization related activities, exchanges of officials, and coordinated product recalls (or other similar actions). These developments, or the perception that any related developments could occur, have had and may continue to have an adverse effect on global economic conditions and financial markets, and may significantly reduce global market liquidity, restrict the ability of key market

participants to operate in certain financial markets or restrict our access to capital. Any of these factors could have an adverse effect on our business, financial condition and results of operations and reduce the price of our common stock.

The withdrawal has also given rise to calls for the governments of other EU member states to consider withdrawal. These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our common stock. Any of these factors could have a material adverse effect on our business, financial condition and results of operations.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or our customer's patients, or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we may become exposed to, or collect and store, sensitive data, including procedure-based information and legally-protected health information, credit card, and other financial information, insurance information, and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. We are taking measures to implement policies and procedures designed to ensure compliance with applicable data security and privacy-related laws and regulations and protect sensitive information from unauthorized access or disclosure. However, our information technology, or IT, and infrastructure, and that of our third-party billing and collections provider and other technology partners and providers, may be vulnerable to cyber-attacks by hackers or viruses or breaches due to employee error, malfeasance or other disruptions. We rely extensively on IT systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided and/or used by third parties or their vendors, to assist in conducting our business. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media or storage devices. For example, companies have experienced an increase in phishing and social engineering attacks from third parties in connection with the COVID-19 pandemic. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. We are investing in protections and monitoring practices of our data and IT to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems, and such breakdowns or breaches could adversely affect our business, financial condition and reputation. We also intend to mitigate the risks related to these risks by purchasing cybersecurity insurance. However, such insurance, if purchased, will not necessarily cover all costs and impacts related to these risks.

Risks Related to Our Intellectual Property

Our success will depend on our, and any of our future licensors', ability to obtain, maintain and protect our intellectual property rights.

Our commercial success will depend in part on our, and any of our future licensors', success in obtaining and maintaining issued patents, trademarks and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we, or any of our future licensors, do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We rely on a combination of contractual provisions, confidentiality procedures and patent, copyright, trademark, trade secret and other intellectual property laws to protect the proprietary aspects of our products, brands, technologies and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual

property and proprietary information. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining and maintaining other intellectual property rights. We may not be able to obtain or maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage.

In addition, despite our efforts to enter into confidentiality agreements with our employees, consultants, suppliers, clients and other vendors who have access to information that we regard as proprietary, our trade secrets, data, know-how and other proprietary information and technology could be subject to unauthorized access, use, misappropriation, or disclosure to unauthorized parties, and could otherwise become known or be independently discovered by third parties. Our intellectual property, including trademarks, could be challenged, invalidated, infringed, misappropriated, violated and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our products, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands and causing us to suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion.

Failure to obtain and maintain intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our patents, trademarks, data, technology and other intellectual property and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated.

Our business relies, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including making any payments required in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent is expensive, time consuming and complex, and we may not be able to prepare, file, prosecute, maintain, enforce or license all necessary or desirable patent applications and patents at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted, maintained, and/or enforced in a manner consistent with the best interests of our business. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. Additionally, if there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent positions of medical device companies may involve complex legal and factual questions and have been the subject of much litigation in recent years, and therefore, the scope, validity and enforceability of any patent claims that we have or may obtain cannot be predicted with certainty. We cannot offer any assurances about which of our patent applications will issue, the breadth of any resulting patent or whether any of the issued patents will be found to be infringed, invalid or unenforceable or will be threatened or challenged by third parties. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We cannot offer any assurances that the breadth of our granted patents will be sufficient to stop a competitor from developing and commercializing a product in a non-infringing manner that would be competitive with one or more of our products, or otherwise provide us with any competitive advantage. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for our commercial success.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years. Further, if we encounter delays in any future regulatory approvals, the period of time during which we could market a product under patent protection could be reduced, and, given the amount of time required for the development, testing and regulatory review of planned or future products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Patents, if issued, may be challenged, deemed unenforceable, invalidated, narrowed or circumvented. Proceedings challenging our patents or patent applications could result in either loss of the patent, or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Any successful challenge to our patents and patent applications could deprive us of exclusive rights necessary for our commercial success. In addition, defending such challenges in such proceedings may be costly. Thus, any patents that we may own may not provide the anticipated level of, or any, protection against competitors. Furthermore, an adverse decision may result in a third party receiving a patent right sought by us, which in turn could affect our ability to commercialize our products. Competitors could purchase our products and attempt to replicate or reverse engineer some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate or otherwise violate our intellectual property rights, design around our patents, or develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. Further, the laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated, found unenforceable or interpreted narrowly, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

Some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- Any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products;
- Any of our pending patent applications will issue as patents;
- We will be able to successfully commercialize our products on a substantial scale, if approved, before our relevant patents we may have expire;
- We were the first to make the inventions covered by each of our patents and pending patent applications;
- We were the first to file patent applications for these inventions;
- Others will not develop similar or alternative technologies that do not infringe our patents;
- Any of our challenged patents will be found to ultimately be valid and enforceable;
- Any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- We will develop additional proprietary technologies or products that are separately patentable; or
- Our commercial activities or products will not infringe upon the patents of others.

Even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. Issued patents may be challenged, narrowed, invalidated or circumvented. Decisions by courts and governmental patent agencies may introduce uncertainty in the enforceability or scope of patents owned by or that are in the future licensed to us. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable or not infringed; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the patent owner or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license to itself. We cannot be sure that if we acquired intellectual property in the future it will be free from government rights or regulations pursuant to the Bayh-Dole Act. If, in the future, we own, co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

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 U.S. Patent and Trademark Office, or 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, financial condition and results of operations.

We may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our current and/or future products.

A third party may hold intellectual property rights, including patent rights that are important or necessary to the development and commercialization of our current and/or future products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our current and/or future products, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights, we may not be able to develop, manufacture or market a product or future product, which could have a material adverse effect on our business, financial condition and results of operations.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products, and could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents or our future patents.

Our ability to obtain patents and the breadth of any patents obtained is uncertain in part because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and other countries. Furthermore, changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we own or that we might obtain or license in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. Changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them, or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in other countries, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

We may become a party to intellectual property litigation or administrative proceedings that could be costly, time-consuming, unsuccessful, and could interfere with our ability to sell and market our products.

Our commercial success depends, in part, upon our ability and the ability of future collaborators, if any, to develop, manufacture, market and sell our products and use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights and intellectual property of third parties. The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business. It is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets or infringing third parties' trademarks. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference proceedings, post grant review and *inter partes* review before the USPTO or equivalent foreign regulatory authority. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. Because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued

patents, which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on the commercial success of our current and any future products. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. We will have similar burdens to overcome in foreign courts in order to successfully challenge a third-party claim of patent infringement.

If we are found to infringe, misappropriate or otherwise violate a third party's valid and enforceable intellectual property rights, we could be required to obtain a license from such third party to continue developing, manufacturing and marketing our products and technology. 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 and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and 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 or other intellectual property right. A finding of infringement could prevent us from manufacturing and commercializing our products or force us to cease some or all 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, financial condition, results of operations and prospects.

Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and 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 will 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. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us may increase. 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, misappropriate or otherwise 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. In addition, vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secret.

We cannot be certain that we were the first to file any patent application related to our products, in part because patent applications are confidential for a period of time after filing. Competitors may also contest our patents, if issued, by demonstrating that the claimed invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents, patent applications or other intellectual property, as a result of the work they performed on our behalf. Although we generally require all of our employees and consultants and any other partners or collaborators who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

Any lawsuits relating to intellectual property rights could subject us to significant liability for damages and invalidate our intellectual property or proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- Stop making, selling or using products or technologies that allegedly infringe, misappropriate or otherwise violate the asserted intellectual property;
- Lose the opportunity to license our intellectual property to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- Incur significant legal expenses;
- Pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, misappropriating or otherwise violating;
- Pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing, misappropriating or otherwise violating;
- Redesign those products or technologies that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and
- Attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties.

Any litigation or claim against us, even those without merit and even those where we prevail, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products.

If third parties assert infringement, misappropriation or other claims against our customers, these claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

Similarly, interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine priority with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or force us to take a license under the patent rights of the prevailing party, if available. Furthermore, our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. We may also become involved in other proceedings, such as reexamination, *inter partes* review, derivation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Our defense of any litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a significant adverse impact on our business, financial condition and results of operations.

Additionally, competitors or other third parties may currently, or in the future, infringe, misappropriate or otherwise violate our issued patents or other intellectual property, and we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. In certain circumstances it may not be practicable or cost-effective for us to enforce our intellectual property rights fully, particularly in certain developing countries or where the initiation of a claim might harm our business relationships. We may also be hindered or prevented from enforcing our rights with respect to a government entity or instrumentality because of the doctrine of sovereign immunity. Our ability to enforce our patent or other intellectual property rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service.

If we initiate legal proceedings against a third party to enforce a patent covering one of our products, the defendant could counterclaim that the patent covering our product is invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Any claims we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In a patent or other intellectual property infringement proceeding, a court may decide that a patent or other intellectual property of ours is invalid or unenforceable, in whole or in part, construe the patent's claims or other intellectual property narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents or other intellectual property do not cover the technology in question. Furthermore, even if our patents or other intellectual property 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. An adverse result in any litigation or administrative proceeding could put one or more of our patents or other intellectual property at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition and results of operations. Moreover, even if we are successful in any litigation, we may incur significant expense in connection with such proceedings, and the amount of any monetary damages may be inadequate to compensate us for damage as a result of the infringement and the proceedings.

Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose some, and perhaps all, of the patent protection on our products.

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 during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Any of the foregoing may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation.

On September 16, 2021, we filed suit in the U.S. District Court for the District of Delaware (C.A. No. 1:21-cv-01317) alleging that Ivantis, Inc. directly or indirectly infringes U.S. Patent Nos. 8,287,482, 9,370,443, 9,486,361, and 10,314,742 previously issued to us by making, using, selling, and offering for sale the Hydrus® Microstent. We are presently unable to predict the outcome of this lawsuit or to reasonably estimate the potential financial impact of the lawsuit, which exposes us to the intellectual property litigation risk factors described above.

If we are unable to protect the confidentiality of our other proprietary information, our business and competitive position may be harmed.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how, and/or other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be

difficult to protect and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Although we generally require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event the unwanted use is outside the scope of the provisions of the contracts or in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property or other proprietary information protection is inadequate or incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors may independently develop knowledge, methods and know-how equivalent to our trade secrets. Our competitors could also purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations.

Costly and time consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. Further, it is possible that others will independently develop the same or similar technology or products or otherwise obtain access to our unpatented technology, and in such cases we could not assert any trade secret rights against such parties. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology or products similar to ours or competing technologies or products, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these security measures and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. Also, if the steps taken to maintain our trade secrets we may have are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently develop our trade secrets and proprietary information.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

A company may attempt to commercialize competing products utilizing our proprietary technology, design, trademarks or tradenames in foreign countries where we do not have any patents or patent applications, trademarks, and/or other forms of intellectual property and where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting and defending patents or trademarks on our current and future products in all countries throughout the world would be prohibitively expensive. The requirements for patentability and trademark protection may differ in certain countries, particularly developing countries. The laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from utilizing our inventions and trademarks in all countries outside the United States. Competitors may use our technologies or trademarks in jurisdictions where we have not obtained patent or trademark protection to develop or market their own products and further, may export otherwise infringing products to territories where we have patent and trademark protection, but enforcement on infringing activities is inadequate. These products or trademarks may compete with our products or trademarks, and our patents, trademarks or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product or technology. For example, certain jurisdictions do not allow for patent protection with respect to method of treatment.

While we seek to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our products in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trademarks and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent and trademarks rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and trademarks in those jurisdictions, as well as elsewhere at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities and our competitive position may be impaired. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

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.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical 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 or competitors or other third parties. In addition, we may be subject to claims that we are infringing, misappropriating or otherwise violating other intellectual property rights, such as trademarks or copyrights. To the extent that our employees, consultants or contractors use intellectual property or proprietary information owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our current or future patents, patent applications, or other intellectual property, including as an inventor or co-inventor. We may be subject to ownership or inventorship disputes in the future arising, for example, from conflicting obligations of consultants, contractors or others who are involved in developing our products. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property, and other owners may be able to license their rights to other third parties, including our competitors. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other 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, a court could prohibit us from using technologies or features 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 or features that are important or essential to our products could have a material adverse effect on our business, financial condition and results of operations, 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 have an adverse effect on our business, financial condition and results of operations.

If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected.

We use our trademarks, service marks, tradenames and brand names to distinguish our products from the products of our competitors, and have registered or applied to register these trademarks. Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on other marks. We cannot assure you that our trademark applications will be approved for registration. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many

foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel trademark registrations. Opposition or cancellation proceedings may be filed against our trademark filings in these agencies, and such filings may not survive such proceedings. Our competitors may also infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks, which may have a material adverse effect on our business. While we may be able to continue the use of our trademarks in the event registration is not available, particularly in the United States, where trademark rights are acquired based on use and not registration, third parties may be able to enjoin the continued use of our trademarks if such parties are able to successfully claim infringement in court. 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 towards advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected.

We have become aware of a third party's use of and pending U.S. application for the TEARCLEAR trademark in connection with ophthalmic pharmaceuticals, which we believe may be an infringement of our TEARCARE trademark. We are currently considering assessing appropriate actions to take in this matter, which may include filing a complaint for trademark infringement in federal court.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- We, or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- We, or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- It is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- Issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop additional proprietary technologies that are patentable;
- The patents of others may harm our business; and
- We may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

Our products, business practices, and operations are subject to extensive government regulation and oversight in the United States and elsewhere.

Our products are regulated as medical devices by the FDA and foreign regulatory authorities. We and our products are subject to extensive regulation in the United States and elsewhere, including by state agencies, the FDA and the FDA's foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical

devices: design, development, manufacturing and release; laboratory, preclinical and clinical testing; labeling, packaging, content and language of instructions for use and storage; product safety and efficacy; establishment registration and device listing; marketing, sales and distribution; pre-market clearance, approval, and certification; service operations; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market studies; and product import and export.

The law and regulations to which we are subject are complex, burdensome to understand and apply and have tended to become more stringent over time. Legal and regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA and foreign regulatory authorities enforce these regulatory requirements through, among other means, periodic (unannounced) inspections and periodic reviews of public marketing and promotion materials. We do not know whether we will be found compliant in connection with any future FDA or foreign inspections or reviews. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; untitled letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances, approvals, or certifications; withdrawals or suspensions of current approvals or certifications, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

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

In the U.S., 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 FDCA or approval of a pre-market approval application, or 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 prior to 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, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. 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 U.S., we have obtained clearance from the FDA of OMNI and TearCare through the 510(k) clearance process. Any further modification to these products or their intended uses may require us to submit a new 510(k) premarket notification and obtain clearance, or submit a PMA and obtain FDA approval prior to 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 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 that our products are safe or effective for their intended uses;
- The disagreement of the FDA with the design or conduct of our clinical trials or the interpretation of data from preclinical studies or clinical trials;
- Serious and unexpected adverse device effects experienced by participants in our clinical trials;
- The data from our preclinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- 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 to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

Subject to the transitional provisions and in order to sell our products in EU member states, our products must comply with the general safety and performance requirements of the Medical Devices Regulation, which repeals and replaces the Medical Devices Directive. Compliance with these requirements is a prerequisite to be able to affix the European Conformity (CE) mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the Medical Devices Regulation including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. To demonstrate compliance with the general safety and performance requirements, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. A conformity assessment procedures generally requires the intervention of a notified body. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU.

We must inform the notified body that carried out the conformity assessment of the medical devices that we market or sell in the EU and the EEA of any planned substantial changes to our quality system or substantial changes to our medical devices that could affect compliance with the general safety and performance requirements laid down in Annex I to the Medical Devices Regulation or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the Medical Devices Regulation. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the general safety and performance requirements and quality system requirements laid down in the Annexes to the Medical Devices Regulation.

We are currently working with our notified body, BSI (which has been designated to certify products and services in accordance with the Medical Devices Regulation), to progress on compliance with the Medical Devices Regulation and have reached a first milestone in February 2022 by successfully passing our Medical Devices Regulation audit. However, as a result of the transition towards the new regime, notified body review times have lengthened, and obtaining re-certification of our products, seeking product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business in the EU. – *See – Risk Factor "Our ability to continue sales of our products in the European Union may be materially impaired if we do not take necessary steps to comply with the certification requirements of the new EU Medical Devices Regulation."*

The aforementioned EU rules are generally applicable in the EEA. Non-compliance with the above requirements would also prevent us from selling our products in these three countries.

We may incur significant liability if it is determined that we are promoting off-label uses of our products in violation of federal and state regulations in the United States or elsewhere.

The FDA and other regulatory authorities strictly regulate the promotional claims that may be made about medical devices. In particular, the FDA requires that medical devices be labeled, advertised and promoted only in accordance with their approved or cleared indications for use (or, in the case of products which are exempt from premarket review, in accordance with the regulations pertaining to such premarket clearance-exempt product classification). Similar limitations are imposed through certain national and international requirements outside of the U.S.

The FDA and foreign regulatory authorities do not generally regulate the behavior of physicians in their choice of treatments. While physicians may choose to use medical devices for uses that are not described in the product's labeling and for uses that differ from those authorized by the FDA or certified in foreign jurisdictions, our promotional materials, promotional activities and training methods must comply with applicable FDA regulations and other applicable federal, state and foreign laws and regulations, including the prohibition on the promotion of off-label uses of our products.

If the FDA or equivalent foreign authorities determine that our labeling, promotional materials or other communications (including communications by our employees or other agents) constitute promotion of an off-label use, they could request or require that we modify our promotional materials or subject us to regulatory or enforcement actions, including the issuance of a warning letter or untitled letter, suspension or withdrawal of a product from the market, or requiring a recall or institution of fines, which could result in the disgorgement of money, operating restrictions, injunctions, civil fines and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties, such as laws prohibiting false or fraudulent claims for payment of government funds, such as the U.S. federal False Claims Act. In that event, our reputation could be damaged and adoption of our products could be impaired.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow medical device companies to engage in truthful, non-misleading and non-promotional scientific exchange concerning their products. If the FDA or other regulatory or enforcement authorities determine that our communications regarding our marketed products are not in compliance with the relevant regulatory requirements and that we have improperly promoted off-label uses, we may be subject to significant liability, including civil, criminal and administrative penalties.

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 from the FDA for OMNI and TearCare in the U.S. and certifications for OMNI in the EU, 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, we must maintain an active registration of our facilities and listing of our products in order to legally market them in the United States. If the FDA were to disagree with our product listing or otherwise take issue with our registration and listing compliance, it could result in delisting of our products or other enforcement action resulting in potential inability to market our products. For example, in October 2020, the FDA communicated to us that the previous version of our TearCare

System may not have been eligible for an exemption from 510(k) clearance. In response to that communication, among other things, we submitted a 510(k) premarket notification seeking clearance for TearCare in November 2020. The FDA requested several safety tests and modifications to this submission which we believe would have required additional time to complete beyond the designated review process. We voluntarily withdrew this submission in May 2021 to allow us to comply with the FDA's requests in a comprehensive manner. We completed the additional testing and modifications requested by the FDA and received 510(k) clearance of TearCare for an expanded indication for use in December 2021. In February 2022, we received further communications from the FDA regarding the appropriateness of the marketing and distribution of our legacy TearCare Systems as a 510(k)-exempt device without premarket notification to and authorization from the FDA. We are conducting a voluntary recall of our legacy TearCare System because the FDA has informed us that the legacy system's advanced technology makes it ineligible for an exemption from 510(k) clearance. Further, this voluntary recall does not involve the new version of the TearCare System, which has received premarket clearance from the FDA and will remain on the market.

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. Even after we have obtained the proper regulatory clearance to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, 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, warning letters or adverse publicity;
- 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 clearance, certification or approval of new products, new intended uses, or modifications to existing products;
- Withdrawals or suspensions of 510(k) clearances or certifications, or requirements for new 510(k) clearances or certifications, resulting in prohibitions on sales of our products pending such further clearance or certification;
- 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 and foreign regulatory authorities may change its clearance or certification policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay clearance, approval, or certification of our future products under development or impact our ability to modify our currently cleared or certified 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, approvals, or certifications, increase the costs of compliance or restrict our ability to maintain our clearances and certifications of our current products.

Our products must be manufactured in accordance with federal, state and foreign regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's QSR and subject to transitional provisions, the European Union Medical Devices Regulation, both of which are complex regulatory schemes that cover 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 maintain, and 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, various laws and regulations of

foreign countries governing manufacturing and a requirement for adherence to industry standards of the International Standards Organization, or ISO, in connection with our medical device operations outside of the United States. Failure to comply with applicable FDA or foreign requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of clearances, approvals, or certifications; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's foreign regulatory authorities' or notified bodies' refusal to grant pending or future clearances, approvals, or certifications for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us, our suppliers, or our employees.

We have received ISO 13485:2016 certification for our quality management system. ISO certification generally includes recertification audits every third year, scheduled annual surveillance audits and periodic unannounced audits.

We can provide no assurance that we will be found to remain in compliance with the QSR or ISO standards upon a regulator's review. If the FDA, other regulator, or notified body, inspect or audit any of our manufacturers' facilities and discovers compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Any of the actions noted above could significantly and negatively affect supply of our products. Taking corrective action may be expensive, time-consuming and a distraction for management. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs.

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 (or similar foreign authorities), and if we fail to do so, we would be subject to sanctions that could negatively affect our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA (and other foreign regulatory authorities) 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 based on the date we become aware of the adverse event as well as on 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 or its foreign counterparts could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of device clearance, approval or certification, seizure of our products or delay in clearance, approval, or certification of future products, which could have a negative impact on us.

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.

If we initiate a correction or removal for our products to reduce a risk to health posed by them or to remedy a violation of law that may present a risk to health, we would be required to submit a report to the FDA and may be required to submit similar notifications to other regulatory authorities. This report could lead to increased scrutiny by the FDA, other foreign regulatory agencies and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports, to the extent made publicly available in accordance with FDA regulations, could be used by competitors against us or otherwise publicized and cause physicians to delay or cancel product orders, which will harm our reputation.

If we assess a potential quality issue or complaint as not requiring either a field action or regulatory notification, regulators may review documentation of that decision during a subsequent audit. If regulators disagree with our decision, or take issue with either our investigation process or the resulting documentation, regulatory agencies may impose sanctions and we may be subject to regulatory enforcement actions, including warning letters, all of which will negatively affect our business, financial condition and results of operations.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA or FDA's foreign counterparts may require, or we may decide, that we will need to obtain new clearances, certifications or approvals for the device before we may market or distribute the corrected device. Seeking such clearances, certifications 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 or foreign regulatory authorities. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA or foreign regulatory authorities. If the FDA or foreign regulatory authorities disagrees with our determinations, it could require us to report those actions as recalls, and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and will negatively affect our reputation, business, financial condition and results of operations.

If we do not obtain and maintain applicable regulatory registrations, clearances, certifications or approvals for our products, we will be unable to market and sell our products outside of the U.S.

We intend to expand our sales operations outside of the U.S. Sales of our products outside of the U.S. are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the U.S. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we obtain the clearance or approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations, clearances, certifications or approvals, can be expensive and time-consuming, and we may not receive regulatory clearances, certifications or approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations, clearances, certifications or approvals, if required by other countries, may be longer than that required for FDA clearance or approval, and requirements for such registrations, clearances, certifications or approvals may significantly differ from FDA requirements. If we modify our products, we may need to apply for regulatory clearances or approvals before we are permitted to sell the modified product.

In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Regulatory clearance or approval by the FDA does not ensure registration, clearance, certification or approval by regulatory authorities or notified bodies in other countries, and registration, clearance, certification or approval by one or more foreign regulatory authorities or notified bodies does not ensure registration, clearance, certification or approval by regulatory authorities or notified bodies in other foreign countries or by the FDA. However, a failure or delay in obtaining registration or regulatory clearance, certification or approval in one country may have a negative effect on the regulatory process in others.

The clinical trial or investigation process is lengthy and expensive with uncertain outcomes. Results of earlier studies may not be predictive of future clinical trial or investigation results, or the safety or efficacy profile for such products for such uses. Further, we may incur significant fines, penalties and other liabilities if it is determined that we are failing or have failed to comply with applicable regulatory requirements for the conduct of our clinical trials.

Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. The results of preclinical studies and clinical trials and investigations of our products conducted to date and ongoing or future studies, trials and investigations of our current, planned or future products may not be predictive of the results of later clinical trials or investigations, and interim results of a clinical trial or investigation do not necessarily predict final results. Our interpretation of data and results from our clinical trials or investigations does not ensure that we

will achieve similar results in future clinical trials or investigations. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials or investigations have nonetheless failed to produce strong results in later clinical trials or investigations. Products in later stages of clinical trials or investigations may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials or investigations. We incur substantial expense for, and devote significant time to, clinical trials or investigations but cannot be certain that such trials will yield positive results relating to our products. Failure can occur at any stage of clinical testing. Our clinical trials or investigations may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

The initiation and completion of any of our clinical trials may be prevented, delayed, or halted for numerous reasons. We may experience delays in our ongoing clinical trials for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical trials, including related to the following:

- We may be required to submit an Investigational Device Exemption, or IDE, application to the FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials;
- Regulators and other comparable foreign regulatory authorities may disagree as to the design or conduct of our clinical trials or investigations;
- Regulators and/or institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial or investigation, or to conduct or continue a clinical trial or investigation at a prospective or specific trial site;
- We may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- Clinical trials or investigations may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or investigations or abandon product development programs;
- The number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials or investigations may be insufficient or slower than we anticipate, and the number of clinical trials or investigations being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials or investigations at a higher rate than we anticipate;
- Our third-party contractors, including those manufacturing products or conducting clinical trials or investigations on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- We might have to suspend or terminate clinical trials or investigations for various reasons, including difficulties in patient enrollment or a finding that the subjects are being exposed to unacceptable health risks;
- We may have to amend clinical trial or investigation protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB or other reviewing bodies and/or regulatory authorities for re-examination;
- Regulators, IRBs or other reviewing bodies, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- The cost of clinical trials or investigations may be greater than we anticipate;
- Clinical sites may not adhere to our clinical protocol or may drop out of a clinical trial or investigation;
- We may be unable to recruit a sufficient number of clinical trial or investigation sites;
- Regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement

for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials or investigations may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;

- Approval policies or regulations of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- Our current or future products may have undesirable side effects or other unexpected characteristics.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in our planned and ongoing clinical trials or investigations. If COVID-19 continues to spread, we may experience disruptions that could have a material adverse impact on our clinical trial plans and timelines, including:

- Delays in receiving authorizations from local regulatory authorities to initiate planned clinical trials or investigations;
- Delays or difficulties in enrolling patients in our clinical trials or investigations;
- Delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- Delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials or investigations, including interruptions in global shipping that may affect the transport of clinical trial or investigation materials;
- Changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials or investigations are conducted, which may result in unexpected costs, or to discontinue the clinical trials or investigations altogether;
- Diversion of healthcare resources away from the conduct of clinical trials or investigations, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials or investigations;
- Interruption of key clinical trial or investigation activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- Risk that participants enrolled in our clinical trials or investigations will contract COVID-19 while the clinical trial or investigation is ongoing, which could impact the results of the clinical trial or investigation, including by increasing the number of observed adverse events;
- Delays in necessary interactions with local regulators, ethics committees and other third parties and contractors due to limitations in employee resources or forced furlough of government employees;
- Limitations in employee resources that would otherwise be focused on the conduct of our clinical trials or investigations, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- Refusal of the FDA or foreign regulatory authorities to accept data from clinical trials or investigations in affected geographies.

Any of these factors may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials or investigations may also ultimately lead to the denial of regulatory approval of our product candidates, which may also significantly harm our business, financial condition and prospects.

Patient enrollment in clinical trials or investigations 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 or investigation, patient compliance, competing clinical trials or investigations 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. For example, patients may be discouraged from enrolling in our clinical trials or investigations if the trial protocol requires them to

undergo extensive post-treatment procedures, monitoring or follow-up to assess the safety and efficacy of a product, or they may be persuaded to participate in contemporaneous clinical trials or investigations of a competitor's product. In addition, patients participating in our clinical trials or investigations may drop out before completion of the trial or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial or investigation may delay commencement or completion of the clinical trial or investigation, cause an increase in the costs of the clinical trial or investigation and delays, or result in the failure of the clinical trial.

Clinical trials and investigations must be conducted in accordance with the regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs or other regulatory bodies at the medical institutions where the clinical trials or investigations are conducted. In addition, clinical trials and investigations must be conducted with supplies of our devices produced under QSR requirements and other regulations. Further, clinical trials of medical devices for investigational uses must be conducted in accordance with the FDA's IDE regulations, which govern investigational device labeling, prohibit promotion of the device for investigational uses, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators.

For certain devices which present 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 prior to commencing clinical trials. The FDA's IDE regulations, among other things, 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. Further, clinical trials of investigational devices which are non-significant risk devices must still comply with applicable regulatory requirements, including abbreviated IDE requirements, such as ensuring that investigators obtain informed consent, and labeling and record-keeping requirements. 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, or IRB, for each clinical site. We have in the past, and may in the future, conduct clinical trials and investigations that do not comply with all applicable regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines. For example, we did not seek an IDE from the FDA for the conduct of the GEMINI trial, but instead submitted a justification to the IRB that OMNI was a non-significant risk device. The non-significant risk justification and informed consent documents for the GEMINI trial both initially described the trial as a post-market trial. Subsequently, we amended the study protocol and obtained informed consent for a revised description of the trial. Even if we conclude that the conduct of any of our clinical trials or investigations comply with the applicable requirements, regulations or guidelines, there can be no guarantee that the FDA or other applicable regulatory authorities will agree with such conclusion. The FDA may conclude that our ongoing or planned clinical studies require the submission and approval of an IDE, which would require us to devote additional resources to ensuring compliance with IDE requirements in the conduct of our clinical programs.

If the FDA determines that we have failed to comply with applicable regulatory requirements for the conduct of our clinical trials and investigations, the FDA may refuse to accept any data generated from such clinical trials and investigations in any future premarket applications, and may take a variety of other compliance or enforcement actions, which may result in, among other things, warning letters, untitled letters, fines, injunctions, consent decrees, civil penalties, unanticipated expenditures, repairs, replacements, refunds, recalls or seizures of products, operating restrictions, total or partial suspension of production, the FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries, the FDA's refusal to grant future premarket clearances or approvals, suspensions of current product clearances or approvals and criminal prosecution.

Furthermore, we may rely on CROs, and clinical trial or investigation sites to ensure the proper and timely conduct of our clinical trials or investigations and we may have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials or investigations in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials and investigations, fail to conduct the study to GCP 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. In addition, clinical trials and investigations that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Even if our future products are cleared or approved in the U.S., commercialization of our products in foreign countries would require clearance, certification or approval by regulatory authorities or notified bodies in those countries. Clearance, certification or approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical trials or investigations. Any of these occurrences could have an adverse effect on our business, financial condition and results of operations.

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

The ability of the FDA, foreign regulatory authorities and notified bodies to review and approve or certify new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's, foreign regulatory authorities', and notified bodies' ability to perform routine functions. Average review times at the FDA, foreign regulatory authorities and notified bodies 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, other agencies, and notified bodies may also slow the time necessary for new devices to be reviewed and/or approved, cleared, certified by necessary government agencies or notified bodies, 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 inspections of foreign manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020 the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Other regulatory authorities have adopted 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 business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

In the EU, notified bodies must be officially designated to certify products and services in accordance with the Medical Devices Regulation. Several notified bodies, including our notified body (BSI), have been designated under the MDR. However, the COVID-19 pandemic has significantly slowed down their designation process and the current designated notified bodies are facing a large amount of requests with the new regulation as a consequence of which review times may have lengthened. This situation may impact the ability of our notified body to timely review and process our regulatory submissions.

We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws that could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. We may also be subject to privacy and security regulation related to patient, customer, employee and other third-party information by both the federal government and the states and foreign jurisdictions in which

we conduct our business. The healthcare 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, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. The U.S. government has interpreted this law broadly and has historically applied the law to the marketing and sales activities of manufacturers. Moreover, 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. Violations of the federal False Claims Act may result in significant civil monetary penalties, plus up to three times the remuneration involved. Violations of the Anti-Kickback Statute can result in criminal penalties, including significant criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;

- The federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. These laws can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill third-party payors. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose significant civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- The federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. 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 to have committed a violation;

- The federal Physician Payments Sunshine Act which requires certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, or CHIP, to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, which is defined broadly to include other healthcare providers, and teaching hospitals, and to report annually ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in significant civil monetary penalties (and additional penalties for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH Act, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security

standards can result in significant civil monetary penalties, and, in certain circumstances, criminal penalties with fines and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state;

- The FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- Federal and state laws and regulations regarding billing and claims payment applicable to our products and regulatory agencies enforcing those laws and regulations; and
- Analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the EU General Data Protection Regulation, or GDPR, governing the privacy and security of personal (including health) information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing and other promotional and research activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, ambulatory surgery centers, physicians or other potential purchasers of our products. We have entered into consulting agreements with physicians, including some who have ownership interests in us, which could be viewed as influencing the purchase of or use of our products in procedures they perform. Compensation under some of these arrangements includes the provision of stock or stock options. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

Any action brought against us for violations of these laws or regulations, even if successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private qui tam actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act including mandatory treble damages and significant per-claim penalties.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business, financial condition and results of operations. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to.

Our activities, including those relating to providing billing, coding, coverage and reimbursement information about procedures using our products to our customers and the sale and marketing of our products, may be subject to scrutiny under these laws. The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to significant penalties, including significant criminal, civil, and administrative penalties, damages, fines, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputation harm and disgorgement and we could be required

to curtail, restructure or cease our operations. Any of the foregoing consequences will negatively affect our business, financial condition and results of operations.

We are subject to governmental regulations and other legal obligations, particularly related to privacy, data protection and information security, and we are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In the conduct of our business, we may at times process personal information, including health-related personal information. The U.S. federal government and various states have adopted or proposed laws, regulations, guidelines and rules for the collection, distribution, use and storage of personal information of individuals. We may also be subject to U.S. federal rules, regulations and guidance concerning data security for medical devices, including guidance from the FDA. According to the Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. State privacy and security laws vary from state to state and, in some cases, can impose more restrictive requirements than U.S. federal law.

In addition, certain state and non-U.S. laws, such as the European Union General Data Protection Regulation (2016/679), or GDPR, govern the privacy and security of personal (including health) data in certain circumstances, some of which are more stringent than U.S. federal law and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The GDPR is directly applicable in each member state and is extended to the EEA. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Where state laws are more protective, we must comply with the stricter provisions. In addition to fines and penalties that may be imposed for failure to comply with state law, some states also provide for private rights of action to individuals for misuse of personal information. For example, California enacted the California Consumer Privacy Act, or 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 data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA significantly amends the CCPA and will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging.

In Europe, the GDPR went into effect on May 25, 2018 and imposes strict requirements for processing the personal data of data subjects within the 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 preceding financial year of the noncompliant company, whichever is greater.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain; in July 2020, the Court of Justice of the EU, or the CJEU, limited how organizations could lawfully transfer personal data from the EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses, or SCCs. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses

arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the UK; the UK's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom General Data Protection Regulation, or the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is also unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews or extends that decision.

Any actual or perceived failure by us or the third parties with whom we work to comply with privacy or security laws, policies, legal obligations or industry standards, or any security incident that results in the unauthorized release or transfer of personally identifiable information, may result in governmental enforcement actions and investigations including by European Data Protection Authorities and U.S. federal and state regulatory authorities, fines and penalties, litigation and/or adverse publicity, including by consumer advocacy groups, and could cause our customers, their patients and other healthcare professionals to lose trust in us, which could harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

We cannot assure you that any third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information. Increasing use of social media could also give rise to liability, breaches of data security or reputational damage.

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, CROs, 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.

Our employees, consultants, and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants, distributors and other commercial partners and business associates may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate federal and/or state laws and regulations, such as laws or regulations requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the U.S. and internationally or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the

healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, 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 programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees, consultants 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 these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could adversely affect our business, financial condition and results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and reputational harm, and divert the attention of management in defending ourselves against any of these claims or investigations.

Compliance with environmental laws and regulations could be expensive, and the failure to comply with these laws and regulations could subject us to significant liability.

Our research and development operations involve the use of hazardous substances, such as isopropyl alcohol and various adhesives. We are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, handling, generation, manufacture, treatment, discharge and disposal of, hazardous substances. Our products may also contain hazardous substances, and they are subject to laws and regulations relating to labelling requirements and to their sale, collection, recycling, treatment, storage and disposal. Compliance with these laws and regulations may be expensive and noncompliance could result in substantial fines and penalties. Environmental laws and regulations also impose liability for the remediation of releases of hazardous substances into the environment and for personal injuries resulting from exposure to hazardous substances, and they can give rise to substantial remediation costs and to third-party claims, including for property damage and personal injury. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence, and they tend to become more stringent over time, imposing greater compliance costs and increased risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations, or releases of or exposure to hazardous substances, will not occur in the future or have not occurred in the past, including as a result of human error, accidents, equipment failure or other causes. The costs of complying with environmental laws and regulations, and liabilities that may be imposed for violating them, or for remediation obligations or responding to third-party claims, could negatively affect our business, financial condition and results of operations.

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

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce healthcare 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 healthcare reform initiative implemented in the future could impact our revenue from the sale of our products. The Affordable Care Act, or ACA, made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the ACA:

- Imposed a new federal excise tax on the sale of certain medical devices, which was suspended, effective January 1, 2016, and permanently repealed in December 2019;
- Established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- Implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- Expanded the eligibility criteria for Medicaid programs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. By way of example, the Tax Cuts and Jobs Act of 2017, or TCJA, was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. It is unclear how healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the law and our business. Any expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payors for procedures using OMNI, and/or reduced medical procedure volumes, any of which may have a material adverse effect on our business, financial condition or results of operations.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. 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. 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, or MACRA, enacted on April 16, 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. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our products or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the U.S. may negatively affect our business, financial condition and results of operations. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- Our ability to set a price that we believe is fair for our products;
- Our ability to generate revenue and achieve or maintain profitability; and
- The availability of capital.

Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our products, which in turn could impact our ability to successfully commercialize these devices and could have a material adverse effect on our business, financial condition and results of operations.

Our ability to continue sales of our products in the European Union may be materially impaired if we do not take necessary steps to comply with the certification requirements of the new EU Medical Devices Regulation.

The EU landscape concerning medical devices recently evolved. On May 25, 2017, the Medical Devices Regulation entered into force, which repeals and replaces the Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i.e., without the need for adoption of EU member state laws implementing them) in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. Devices lawfully placed on the market pursuant to the Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid. Our current certificates which were granted under the Medical Devices Directive are valid until May 26, 2024. However, to date, we must comply with a number of new or reinforced requirements set forth in the Medical Devices Regulation with regard to registration of economic operators and of devices, post-market surveillance, market surveillance and vigilance requirements.

We are currently working with our notified body, BSI, to progress on compliance with the Medical Devices Regulation and have reached a first milestone in February 2022 by successfully passing our Medical Devices Regulation audit.

Non-compliance with the Medical Devices Regulation may affect our business or the way we intend to conduct our business in the EU. In addition, as a result of the transition towards the new regime, notified body review times have lengthened, and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

Risks Related to Our Common Stock

The price of our common stock may fluctuate substantially or may decline regardless of our operating performance and you could lose all or part of your investment

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

- Changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' estimates;
- Quarterly variations in our or our competitors' results of operations;
- Periodic fluctuations in our revenue, which could be due in part to the way in which we recognize revenue;
- The financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- Future sales of our common stock or other securities, by us or our stockholders, as well as the anticipation of lock-up releases or lock-up waivers;
- The trading volume of our common stock;
- General market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;
- Changes in reimbursement by current or potential payors;
- Changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- Actual or anticipated changes in regulatory oversight of our products;
- The results of our clinical trials;
- The loss of key personnel, including changes in our board of directors and management;
- Product recalls or other problems associated with our products;
- Legislation or regulation of our market;
- Lawsuits threatened or filed against us, including litigation by current or former employees alleging wrongful termination, sexual harassment, whistleblower or other claims;
- The announcement of new products or product enhancements by us or our competitors;
- Announced or completed acquisitions of businesses or technologies by us or our competitors;
- Announcements related to patents issued to us or our competitors and related litigation; and
- Developments in our industry.

In addition, the trading prices for common stock of other medical device companies have been highly volatile as a result of the COVID-19 pandemic. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance.

In addition, in the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and harm our business, results of operations, financial condition and reputation. These factors may materially and adversely affect the market price of our common stock.

Securities analysts may not publish favorable research or reports about our business, may publish no information at all, or may publish favorable research or reports about our competitors, which could cause our stock price or trading volume to decline.

Our stock price and trading volume may be heavily influenced by the way analysts and investors interpret our financial information and other disclosures, as well as their interpretations of our competitors' financial, regulatory, reimbursement and other disclosures. If securities or industry analysts do not publish research or reports about our business, delay publishing reports about our business, publish negative reports about our business, or publish favorable reports about our competitors' businesses, regardless of accuracy, our common stock price and trading volume could decline.

As the trading market for our common stock matures, the trading market will be influenced to some extent by the research and reports that industry or financial analysts publish about us and our competitors and our respective businesses. We do not control these analysts. As a newly public company, we may be slow to attract research coverage and the analysts who publish information about our common stock will have had relatively little experience with us or our industry, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. If any of the analysts who cover us provide inaccurate or unfavorable research or issue an adverse opinion regarding our stock price or prospects, our stock price could decline. Further, if analysts provide favorable reports or forecasts regarding our competitors, this information, regardless of its accuracy, may cast doubt on the strength and durability of our business performance and prospects. We may also fail to meet the expectations of these analysts, leading to a reduction in the market price of our common stock. For instance, if we are unable to meet analyst expectations regarding OMNI procedure growth in the standalone market, our stock price could suffer. If one or more of these analysts cease coverage of us or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline.

Even if our common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over-reliance by analysts or investors on any particular metric to forecast our future results may lead to forecasts that differ significantly from our own.

We are an emerging growth company and a smaller reporting company and we cannot be certain if the reduced disclosure requirements applicable to us will make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and we take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not emerging growth companies. In particular, while we are an emerging growth company, we are not required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act; we are exempt from any rules that could be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor’s report on financial statements; we are subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and we are not required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

In addition, while we are an emerging growth company we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of this extended transition period and, as a result, our operating results and financial statements may not be comparable to the operating results and financial statements of companies who have adopted the new or revised accounting standards.

We will remain an emerging growth company until the earlier of (1) December 31, 2026, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, or (4) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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 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 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.

Investors may find our common stock less attractive to the extent we rely on the exemptions and relief granted by the JOBS Act. We have elected to take advantage of these exemptions and relief. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or become more volatile.

Sales of substantial amounts of our common stock in the public markets, or the perception that sales might occur, could cause the trading price of our common stock to decline.

Sales of a substantial number of shares of our common stock into the public market, particularly sales by our executive officers, directors and principal stockholders, or the perception that these sales might occur in large quantities, could cause the trading price of our common stock to decline. None of our securityholders are subject to any contractual lock-up or other contractual restriction on the transfer or sale of their shares.

Moreover, assuming the availability of certain public information about us, (i) non-affiliates who have beneficially owned our common stock for at least six months may rely on Rule 144 promulgated under the Securities Act of 1933, as amended ("Rule 144"), to sell their shares of common stock, and (ii) our executive officers, directors and other affiliates who have beneficially owned our common stock for at least six months will be entitled to sell their shares of our common stock subject to volume and other limitations under Rule 144 and various vesting agreements.

In addition, we filed a registration statement to register all shares subject to equity awards under our equity compensation plans. As of December 31, 2021, we had stock options outstanding that, if fully exercised, would result in the issuance of 4,996,945 shares of common stock, as well as 53,250 shares of common stock subject to RSU awards. Accordingly, these shares will be able to be freely sold in the public market upon issuance, subject to applicable vesting requirements and compliance by affiliates with Rule 144.

Moreover, certain holders of our common stock have rights, subject to some 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. Any registration statement we file to register additional shares, whether as a result of registration rights or otherwise, could cause the trading price of our common stock to decline or be volatile.

Our directors, executive officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of December 31, 2021, our executive officers, directors and principal stockholders each holding more than 5% of our common stock will collectively control approximately 63.0% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and most 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 of control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

We incur significant additional costs as a result of being a public company, and our management is required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, we incur costs associated with corporate governance requirements, including rules and regulations of the SEC, under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the Exchange Act, as well as the rules of Nasdaq. These rules and regulations are expected to significantly increase our accounting, legal and financial compliance costs and make some activities more time-consuming. We expect

such expenses to further increase after we are no longer an emerging growth company. We also expect these rules and regulations to make it more expensive for us to maintain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers. Furthermore, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs. Accordingly, increases in costs incurred as a result of becoming a publicly traded company may adversely affect our business, financial condition and results of operations.

We may also be subject to more stringent state law requirements. For example, on September 30, 2018, California signed into law Senate Bill 826, which generally requires public companies with principal executive offices in California to have a minimum number of females on their board of directors, and on September 30, 2020, California signed into law Assembly Bill 979, which generally requires public companies with principal executive offices in California to have a minimum number of members of an "underrepresented community" on their boards of directors. To be a member of an "underrepresented community, an individual must self-identify as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, or Alaska Native, or as gay, lesbian, bisexual, or transgender. Pursuant to the terms of Senate Bill 826, by December 31, 2019, each public company with principal executive offices in California was required to have at least one female on its board of directors. By December 31, 2021, each public company was required to have at least two females on its board of directors if the company has at least five directors, and at least three females on its board of directors if the company has at least six directors. Pursuant to the terms of Assembly Bill 979, by December 31, 2021, each public company with principal executive offices in California was required to have at least one director from an underrepresented community on its board of directors. By December 31, 2022, each public company is required to have at least two directors from underrepresented communities if the company has at least five directors, and at least three directors from underrepresented communities if the company has at least nine directors These new laws do not provide a transition period for newly listed companies. We are currently compliant with the gender requirements of Senate Bill 826 but we are not in compliance with the diversity requirements of Assembly Bill 979. These new laws provide the California Secretary of State with the power to levy a $100,000 fine for the first violation and a $300,000 fine for each subsequent violation. We are seeking to further diversify our board of directors, with the intent of coming into compliance with Assembly Bill 979. However, there are no assurances that we can come into compliance with this law or remain in compliance with these or other diversity laws that come into effect. If we are unable to recruit, attract and/or retain qualified members of the board and meet the requirements of the California laws it may expose us to penalties and/or reputational harm.

If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our company.

As a public company, we are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. Although we will be required to disclose changes made in our internal controls and procedures on a quarterly basis, we are not required to make our first annual assessment of our internal control over financial reporting pursuant to Section 404 until the year following our first annual report required to be filed with the SEC. As an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event material weaknesses have been identified in our internal control over financial reporting.

To comply with the requirements of being a public company, we need to undertake actions, such as implementing new internal controls and procedures and hiring additional accounting or internal audit staff. Testing and maintaining internal control can divert our management's attention from other matters that are important to the operation of our business. In addition, when evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404. If we identify any material weaknesses in our internal controls over financial reporting or we are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting once we are no longer an emerging growth company, investors may lose

confidence in the accuracy and completeness of our financial reports. As a result, the market price of our common stock could be materially adversely affected.

Material weaknesses in our internal control over financial reporting may cause us to fail to timely and accurately report our financial results or result in a material misstatement of our financial statements.

In connection with the preparation of our financial statements in connection with our IPO, we identified a material weakness in our internal controls due to a lack of sufficient full-time accounting personnel with requisite experience and deep technical accounting knowledge to (i) identify and resolve complex accounting issues under generally accepted accounting principles in the United States, or GAAP, and (ii) enable appropriate segregation of duties and reviews over the financial reviews over the financial close and reporting process.

We are evaluating and implementing additional internal controls and procedures to remediate this material weakness, however, we cannot assure you that these or other measures will fully remediate the material weakness in a timely manner or prevent future material weaknesses from occurring. As part of our remediation plan to address the material weakness identified above, we have hired additional accounting employees with specific technical accounting and financial reporting experience necessary for a public company. We will continue to assess the adequacy of our accounting personnel and resources, and will add additional personnel, as well as adjust our resources, as necessary, commensurate with any increase in the size and complexity of our business.

If we identify future material weaknesses in our internal controls over financial reporting or fail to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. If additional material weaknesses exist or are discovered in the future, and we are unable to remediate any such material weaknesses, our reputation, financial condition, and operating results could suffer.

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

Upon the closing of the initial public offering of our common stock, we became subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions include those establishing:

- A classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- No cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- The exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;
- The ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- The ability of our board of directors to alter our bylaws without obtaining stockholder approval;
- The required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our restated certificate of incorporation regarding the election and removal of directors;
- A prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- The requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- Advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our restated certificate of incorporation designates specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, the rules and regulations thereunder 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 restated certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our restated certificate of incorporation described above.

We believe these provisions benefit us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes and in the application of the Securities Act by federal judges, as applicable, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The provision may also have the effect of resulting in increased costs to a stockholder seeking to bring a claim against our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in our restated certificate of incorporation to

be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters are located in Menlo Park, California, where we lease approximately 10,823 square feet of office, research and development, engineering and laboratory space pursuant to a lease that commenced effective August 1, 2021, and expires on August 31, 2024. We also lease approximately 2,040 square feet of office space, which is primarily used by our commercial leadership team, in Southlake, Texas, pursuant to a lease that commenced on April 30, 2019 and expires on May 15, 2024. We believe that our existing facilities are adequate to meet our business requirements for the near-term, and that additional space will be available on commercially reasonable terms, if required.

Item 3. Legal Proceedings.

On September 16, 2021, the Company filed suit in the U.S. District Court for the District of Delaware (C.A. No. 1:21-cv-01317) alleging that Ivantis, Inc. directly or indirectly infringes U.S. Patent Nos. 8,287,482, 9,370,443, 9,486,361, and 10,314,742 by making, using, selling, and offering for sale the Hydrus® Microstent. The Company's Complaint seeks money damages and injunctive relief. Ivantis, Inc. answered the Complaint on January 2022, however no trial date has yet been set. The Company is presently unable to predict the outcome of this lawsuit or to reasonably estimate the potential financial impact of the lawsuit on the Company, if any.

We may, 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 effectiveness 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 business, financial condition and results of operations. Additionally, any such claims, whether or not successful, could damage our reputation and business.

Item 4. Mine Safety Disclosures.

None.

PART II

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

Market for Common Stock

Our common stock has been listed on the Nasdaq Global Market under the symbol "SGHT" since July 15, 2021. Prior to this date, there was no public market for our common stock.

Holders of Record

As of March 18, 2022, there were approximately 22 holders of record of our common stock. The actual number of stockholders is greater than this number of holders of record and includes stockholders who are beneficial owners but whose shares are held in the street name by brokers and other nominees.

Initial Public Offering

On July 14, 2021, our registration statement on Form S-1 (File No. 333-257320) relating to our initial public offering ("IPO") of common stock became effective. The IPO closed on July 15, 2021, at which time we issued 11,500,000 shares of our common stock at a price of $24.00 per share.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus dated July 14, 2021 and filed with the SEC on July 15, 2021 pursuant to Rule 424(b) under the Securities Act.

Dividend policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, to fund the operation, development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects, and other factors our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Item 6. Selected Financial Data.

Not applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with the information presented in our financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements based upon current plans, expectation, and beliefs that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by these forward-looking statements. Please also see the section of this Annual Report on Form 10-K titled "Forward-Looking Statements." A discussion of the year ended December 31, 2020 compared to the year ended December 31, 2019 has been reported previously in our final prospectus dated July 14, 2021 (File No. 333-257320) filed with the SEC on July 15, 2021 pursuant to Rule 424(b)(4) of the Securities Act (the "Prospectus"), under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Overview

Sight Sciences' mission is to transform ophthalmology and optometry through the development and commercialization of proprietary devices that target the underlying causes of the world's most prevalent eye diseases. We are passionate about improving patients' lives. Our objective is to develop and market products for use in new treatment paradigms and to create an interventional mindset in eyecare whereby our products may be used in procedures which supplant conventional outdated approaches. Our business philosophy is grounded in the following principles:

- comprehensively understand disease physiology,
- develop products that are intended to restore natural physiological functionality to diseased eyes;
- develop and market products that achieve superior effectiveness versus current treatment paradigms while minimizing complications or side effects,
- provide intuitive, patient friendly solutions to ophthalmologists and optometrists; and
- deliver compelling economic value to all stakeholders, including patients, providers and third-party payors such as Medicare and commercial insurers

Our initial product development has focused on the treatment of two of the world's most prevalent and underserved eye diseases, glaucoma and dry eye disease. We have commercialized products in each of our two reportable segments. Our Surgical Glaucoma segment consists of sales of the OMNI Surgical System, or OMNI, and also included sales of VISCO360 and TRAB360, OMNI's predicate devices, until they were discontinued in the first quarter of 2019. Our Dry Eye segment includes sales of the TearCare System, or TearCare, and related components and accessories. For the year ended December 31, 2021, 95% and 5% of our revenues were derived from our Surgical Glaucoma and Dry Eye segments, respectively. Both systems are primarily sold through a highly-involved direct sales model that offers intensive education, training and customer service. We believe this philosophy and model not only enables us to differentiate our products and our overall company from competitors, but also to expand our addressable market by educating ECPs, patients and other stakeholders on our products and evolving treatment paradigms. Outside of the U.S., we have historically sold OMNI primarily through a network of distributors, although we began employing a small direct sales force outside of the United States in April 2021.

We commercially launched OMNI and TearCare in February 2018 and April 2019, respectively. In May 2020, we introduced our next generation OMNI Surgical System that incorporated extensive feedback from our physician users and that we believe improved upon the first-generation device. We sell OMNI to facilities where ophthalmic surgeons perform outpatient procedures, mainly ASCs and HOPDs, which are typically reimbursed by Medicare or private payors for procedures using our products. We sell TearCare to optometrist and ophthalmologist practices. Currently, there is no meaningful reimbursement coverage by Medicare or private payors for MGD procedures, including TearCare, and patients typically pay out-of-pocket for TearCare. We are continuing our controlled commercial launch and are focused upon our comprehensive, clinical data-driven long-term market development plan that aims to improve awareness and patient access to TearCare. As of December 31, 2021, we employed over 100 people to execute our commercial strategy in direct sales, marketing, training and professional services. The overall success of our approach to eyecare to date is evidenced by the over 85,000 estimated uses of OMNI and its direct predicates in over 1,200 hospitals and ASCs in the U.S. and Europe, and over 15,000 estimated uses of TearCare in over 550 eyecare facilities in the U.S. through December 31, 2021.

We currently operate no manufacturing facilities and instead contract with third parties for our production requirements. We believe our suppliers will be able to meet our current and anticipated manufacturing needs across all our products. We plan to continue to utilize third party contract manufacturers for our products and any related components.

Our gross margin in our Surgical Glaucoma segment for the years ended December 31, 2021 and 2020 was 86.1% and 72.8%, respectively. Beginning with the production of finished goods inventory in Q1 2021, we shifted our primary production of OMNI from a U.S.-based third-party contract manufacturer, to a lower cost, higher volume contract manufacturer in Asia. We are in the process of supplementing this OMNI production capacity with a U.S.-based contract manufacturer. These cost optimization initiatives contributed to the increase in gross margins in our Surgical Glaucoma segment in 2021 as compared to the same period in 2020. The TearCare System includes the SmartHub component, which is typically only sold in initial purchase orders, and single-use SmartLids which are sold as part of initial purchase orders and through repeat orders as the ECP performs procedures over time. In an effort to build a meaningful TearCare installed base and encourage product trial and adoption by ECPs, our pricing strategy for SmartHubs has not focused on gross profit maximization. As the installed base of TearCare customers grows, we believe SmartLids, which currently generate higher gross margins than SmartHubs, will increase as a proportion of total Dry Eye segment revenues and gross profit. Given the earlier stage of TearCare's commercial development and our pricing strategy with respect to SmartHubs, we expect our Dry Eye segment's gross margins to be lower than our Surgical Glaucoma segment's gross margins for the near and medium-term. Our gross margin for our Dry Eye segment for the years ended December 31, 2021 and 2020 was 13.1% and (30.5%), respectively.

We believe in the importance of continued strategic investment in initiatives that: further demonstrate our products' clinical effectiveness and safety to potential customers, patients, payors and regulators; enhance our commercial capabilities, including resources dedicated to sales, marketing and education; ensure the broadest possible patient access to the treatment alternatives that our products are cleared to offer; enhance and improve upon our existing product technologies; and allow us to innovate new products, devices or drugs, in glaucoma and DED or in new eye disease areas. As a result, we intend to continue to invest in clinical studies, sales and marketing, education initiatives, market access, and product development. Because of these and other factors, we expect to continue to incur net losses for at least the next several fiscal years. Moreover, we expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and those of the Nasdaq Stock Market, additional insurance expenses, investor relations activities and other administrative and professional services. As a result of these and other factors, we may require and seek additional debt and equity financing to fund our operations and planned growth.

To date, our primary sources of capital has been private placements of redeemable convertible preferred stock, debt financing agreements, the sale of common stock in our IPO, and revenue from the sale of our products. In July 2021, we completed our IPO, including the underwriters full exercise of their option to purchase additional shares, selling 11,500,000 shares of our common stock at $24.00 per share. Upon completion of our IPO, we received net proceeds of $252.2 million, after deducting underwriting discounts and commissions and offering costs. As of December 31, 2021, we had an outstanding term loan balance of $35.0 million (excluding debt discount and amortized debt issuance costs). As of December 31, 2021, we had cash and cash equivalents of $260.7 million and an accumulated deficit of $153.0 million.

During the year ended December 31, 2021, we generated revenue of $49.0 million, with a gross margin of 82.4%. Our net loss for the year ended December 31, 2021 was $63.0 million. For the year ended December 31, 2020, we generated revenue of $27.6 million, with a gross margin of 66.7%. Our net loss for the year ended December 31, 2020 was $34.7 million. For all periods presented, substantially all of our revenue was generated from customers in the U.S.

Impact of COVID-19

The global COVID-19 pandemic impacted and is expected to continue to impact demand for our products, which are used in procedures and therapies that are considered elective. Although some of these governmental restrictions have since been lifted or scaled back, recent and future surges of COVID-19 may result in restrictions being re-implemented in response to efforts to reduce the spread of COVID-19. As elective eyecare procedures in many facilities that utilize our products were temporarily suspended by governmental authorities, many patients avoided visiting ECPs, and, even in areas that allowed elective procedures, ECPs and healthcare facilities in general substantially reduced or in some cases halted, the scheduling and performance of such procedures. The decrease in demand for our products due to COVID-19 most significantly impacted our revenues in the latter part of the first quarter and the first half of the second quarter of 2020. Beginning in June 2020, we began to see an increase in the number of procedures using our products. In the first quarter of

2021, our customers experienced a significant number of procedure cancellations which we believe were largely driven by patients postponing in-office treatments until their COVID-19 vaccinations were completed (as opposed to any restrictions imposed on elective procedures), thus adversely impacting our revenues. As vaccine availability and the vaccinated population increases across the U.S., the recovery of our end markets resumed in the second quarter of 2021. Our normal business operations were again disrupted by resurgence of the Delta variant in the third quarter of 2021 and emergence of the Omicron variant in the fourth quarter of 2021 and into early 2022.

We are continuing to closely monitor the global COVID-19 pandemic. In order to operate in a safe manner, we are following the health and safety guidelines of the U.S. Centers for Disease Control and Prevention, Occupational Safety and Health Administration, and local and state public health departments where we operate. The majority of our employees at our headquarters have been asked to work from home, with only limited access given to employees to work in the office when necessary. For roles that require employees to be on-site, such as our R&D and manufacturing technical staff, we are providing protective equipment, practicing social distancing, and enforcing mask wearing and we have increased sanitization standards. In addition, we have created a business continuity plan and incident management team to respond quickly and effectively to COVID-19 related issues in order to offer customers uninterrupted products, services and support while safeguarding the best interests of employees, suppliers and stakeholders. The ultimate impact of the global COVID-19 pandemic on our operations is unknown and will depend on future developments which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the COVID-19 pandemic, the status of health and safety actions taken to contain its spread and any additional preventative and protective actions that governments, or we, may direct, any resurgence of COVID-19 that may occur and how quickly and to what extent economic and operating conditions normalize within the markets in which we operate. The global COVID-19 pandemic could disrupt the operations of our third-party manufacturers and other suppliers. Although we have not experienced material disruptions in our supply chain to date, we cannot predict how long the pandemic and measures intended to contain the spread of COVID-19 will continue and what effect COVID-19 and the associated containment measures will have on our suppliers and vendors, in particular for any of our suppliers and vendors that may not qualify as essential businesses and suffer more significant disruptions to their business operations. We are working closely with our manufacturing partners and suppliers to help ensure we are able to source key components and maintain appropriate inventory levels to meet customer demand.

Factors Affecting our Business and Results of Operations

We believe there are several important factors that have impacted and that will continue to impact our business and results of operations. These factors include, but are limited to:

Product Development

We believe our product development approach is a key differentiator of our team and our company. We are focused on continuous innovation and design and utilize input from our network of expert employees (including several ophthalmologists on staff), advisors and customers to rapidly iterate our pre-and post-commercial product designs with the aim of better satisfying the needs of our customers and their patients, and increasing adoption and utilization of our solutions. Once our products are launched, our customer feedback loop helps us further develop our products. This is particularly evident in the evolution of our OMNI Surgical System, which originated from the combined functionality of two internally developed, commercial predicate devices, each of which had their own multiple commercial iterations. We further refined ergonomics and functionality in our next generation OMNI Surgical System, which we launched in May 2020. Our future growth is dependent on our ability to continue innovating and applying our expertise of disease physiology to improve existing products and develop new products.

Market Education and Training on the Benefit of our Products vis-à-vis Existing Treatment Alternatives

One of the key drivers of our success is educating ophthalmologists, optometrists, patients, and third-party payors about the clinical and safety benefits of our products and of the benefits of more proactive, interventional approach to treating glaucoma and DED. We believe the required market education and development is best accomplished through a differentiated, highly involved commercial approach. As such, we devote significant resources to onboarding our sales professionals and to continuously augmenting their knowledge and capabilities. Our sales professionals provide ECPs with the necessary education, training and support to adopt and continue to use our products. We believe that increasing acceptance and usage of our products will require continued investment in our sales force and education efforts to ensure ECPs, patients and third-party payors learn more about our products and appreciate our benefits to their target patient populations.

Maximizing Product Usage by Customers

Demand for our products will be highly dependent on our ability to develop their potential addressable markets and maximize the breadth of patients our products can serve. OMNI is indicated for canaloplasty followed by trabeculotomy to reduce IOP in adult patients with POAG in the U.S. and with OAG, in the EU. We believe that OMNI is the only device that is authorized by the FDA as an *ab interno* procedure to: reduce IOP in adult patients with POAG across the spectrum of disease severity; be used in Mild-to-Moderate Combination Cataract or Standalone procedures; access 360 degrees of the diseased conventional outflow pathway through a single clear corneal incision; and facilitate two consecutive procedures, canaloplasty and trabeculotomy, to comprehensively treat all three primary points of resistance in the conventional outflow pathway in a single operating room visit. Our ability to establish OMNI as the standard of care for all POAG patients by continuing to grow its adoption and utilization in Combination Cataract procedures and by pioneering the development of the market for interventional standalone procedures will have a substantial impact on our future growth.

TearCare is a unique open-eye heating and expression device designed to melt and remove meibomian gland obstructions. We believe TearCare has a compelling physiological profile to address obstruction from meibomian gland disease, or MGD, which is the primary cause of evaporative DED, a disease characterized by low quality tears that evaporate prematurely. The current DED treatment market primarily consists of an abundance of OTC and prescription eyedrops that seek to lubricate the ocular surface, alleviate inflammation and/or increase tear production. However, OTC and prescription eyedrops are incapable of clearing obstructions in the meibomian glands and do not address MGD's eyelid-borne physiology and poor tear quality. MGD is associated with 86% of DED cases and is a leading root cause of evaporative DED, which is characterized by low quality tears that evaporate prematurely. Clinical studies have demonstrated that treating MGD by liquefying and removing clogged meibum is the most effective method to eliminate obstructions and restore the lipid layer of tear film, thereby preventing premature evaporation of tears. TearCare was designed to be administered during the course of a routine office visit to an ECP, which makes it convenient for patients, and allows providers to maintain procedural throughput in their practices. Our ability to improve patient access and market education on TearCare and the benefits of proactive MGD treatment will be key drivers of TearCare's future growth.

Operational excellence and cost efficiency

We aim to achieve operating and financial milestones with optimal capital efficiency, and focus on our market value relative to invested capital as a key measurement of our performance. To date, we have raised $402.4 million in net proceeds from equity and debt financings, including $252.2 million from our IPO. With a portion of these net proceeds (our December 31, 2021 cash and equivalents was $260.7 million), we believe we have developed and commercially launched two clinically differentiated products, funded multiple completed and ongoing clinical trials, and built our management team and company infrastructure to support the continued growth of our business. We believe that this level of operational and commercial progress relative to our total capital investment to date compares favorably to medical technology peers. We seek to design products that can achieve attractive long-term gross margins. For example, we generated significantly higher gross margins in our Surgical Glaucoma segment in 2021 than prior years, which was a key financial objective we targeted for the year.

Components of our Results of Operations

Revenue

We currently derive the majority of our U.S. revenue from the sale of OMNI to ASCs and HOPDs and TearCare to ophthalmology and optometry practices. During the years ended December 31, 2021 and 2020, the revenues from our Surgical Glaucoma segment, including OMNI and its predicate devices, accounted for over 90% of our total revenues. Substantially all of our revenues for 2021 and 2020 were generated from sales within the U.S. Our OMNI customers place orders based on their expected procedure volume and reorder as needed, typically on a biweekly, monthly or bimonthly basis. Our TearCare customers typically purchase a TearCare System which consists of one or more SmartHubs, multiple single-use SmartLids and other accessories. After utilizing their initial inventory, customers will reorder SmartLids as needed. No single customer accounted for 10% or more of our revenue for the years ended December 31, 2021 and 2020.

The growth in our revenue is driven by the demand for elective surgery and treatment utilizing our products. Such demand is often lower during summer months because of ECP vacations and in winter months in certain parts of the world because of fewer business or surgery days due to holidays and adverse weather conditions.

Cost of Goods Sold and Gross Margin

Our products are produced by third-party manufacturers. Our cost of goods sold consists primarily of amounts paid for our products to third-party manufacturers, and our manufacturing overhead costs, which consist primarily of personnel expenses, including salaries, benefits and stock-based compensation, and reserves for excess, obsolete and non-sellable inventory. Cost of goods sold also includes depreciation expenses for production equipment which we provide to our third-party manufacturers and certain direct costs, such as shipping and handling costs.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, including differences in segment gross margins, changes in average selling prices, product sales mix, production and ordering volumes, manufacturing costs, product yields, and headcount. In the near term, we expect our gross margins to increase as we transition production of OMNI to lower-cost manufacturers and as we expect Surgical Glaucoma revenues will grow as a percentage of our overall revenue mix. In general, we expect our gross margins to increase over the long-term to the extent our production and ordering volumes increase and to the extent we spread the fixed portion of our overhead costs over a larger number of units produced. We intend to use our design, engineering and manufacturing know-how and capabilities to further advance and improve the efficiency of our suppliers' manufacturing processes, which we believe will reduce costs and increase our gross margins. Our gross margins could fluctuate from quarter to quarter as we transition to new suppliers, introduce new products and adopt new manufacturing processes and technologies.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of engineering, product development, clinical studies to develop and support our products, including clinical trial design, clinical trial site initiation and study costs, internal and external costs associated with our regulatory compliance and quality assurance functions, medical affairs, cost of products used for clinical trials and other costs associated with products and technologies – either new or enhancements of existing platforms – that are in development. These expenses also include personnel expenses, including salaries, benefits and stock-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses, depreciation expenses for equipment and an allocation of IT and facility overhead expenses. Our R&D expenses as a percentage of revenue may vary over time depending on the level and timing of new product development efforts, as well as clinical development, clinical trial and other related activities. We expect our R&D expenses to increase for the next several years as we continue to invest in our active clinical trial program, develop new products and improve our existing products.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist primarily of personnel expenses, including salaries, benefits and stock-based compensation related to selling, marketing and corporate functions, allocation of IT and facility overhead expenses, bad debt expense, finance, legal and human resource costs. Other SG&A expenses include training, travel expenses, promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, professional services fees (including external legal, audit, consulting and tax fees), insurance costs, and general corporate expenses. We expect SG&A expenses to continue to increase in absolute dollars as we expand our infrastructure to both drive and support the anticipated growth in revenue and due to additional legal, accounting, insurance and other expenses associated with being a public company.

Interest Expense

Interest expense consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and issuance costs associated with our outstanding loan.

Interest Income

Interest income consists of interest earned on our balances of cash and cash equivalents.

Other Income (Expense), Net

Other income (expense), net primarily consists of gains and losses resulting from the remeasurement of the fair value of our redeemable convertible preferred stock warrant liability during each reporting period. The redeemable convertible preferred stock warrants were exercised during 2021 and the final fair value of the warrant liability was reclassified to stockholders' equity. We will no longer record any related periodic fair value adjustments.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

	Year Ended December 31,		Change	
	2021	2020	$	%
	(unaudited)			
Revenue				
Surgical Glaucoma	$ 46,496	$ 26,000	$ 20,496	78.8%
Percentage of total revenue	*95.0%*	*94.1%*		
Dry Eye	2,460	1,640	820	50.0
Percentage of total revenue	*5.0%*	*5.9%*		
Total	48,956	27,640	21,316	77.1
Cost of goods sold				
Surgical Glaucoma	6,473	7,069	(596)	(8.4)
Dry Eye	2,137	2,140	(3)	(0.1)
Total	8,610	9,209	(599)	(6.5)
Gross profit				
Surgical Glaucoma	40,023	18,931	21,092	111.4
Dry Eye	323	(500)	823	(164.6)
Total	40,346	18,431	21,915	118.9
Gross margin				
Surgical Glaucoma	*86.1%*	*72.8%*		
Dry Eye	*13.1%*	*-30.5%*		
Total	*82.4%*	*66.7%*		
Operating expenses				
Research and development	15,634	8,874	6,760	76.2
Selling, general and administrative	76,190	41,745	34,445	82.5
Total operating expenses	91,824	50,619	41,205	81.4
Loss from operations	(51,478)	(32,188)	(19,290)	59.9
Interest income	—	30	(30)	(100.0)
Interest expense	(4,366)	(2,403)	(1,963)	81.7
Other expense, net	(6,928)	(71)	(6,857)	9,657.7
Loss before income tax	(62,772)	(34,632)	(28,140)	81.3
Provision (benefit) for income tax	$ 188	$ 61	127	208.2
Net loss and comprehensive loss	(62,960)	(34,693)	$ (28,267)	81.5%

Revenue. Revenue in the year ended December 31, 2021 was $49.0 million, an increase of $21.3 million, or 77.1%, from our revenue in 2020. Surgical Glaucoma and Dry Eye sales contributed $46.5 million and $2.5 million, respectively. The overall increase in revenue was primarily attributable to an increase in the number of OMNI units sold as a result of growth in the number of facilities ordering OMNI and an increase in unit utilization per ordering facility, which resulted in a $20.5 million increase in Surgical Glaucoma revenues.

Cost of Goods Sold and Gross Profit. The $0.6 million decrease in cost of goods sold from 2020 to 2021 was attributable to a $1.0 million decrease in the reserve for obsolete inventory from a 2020 write-down of legacy OMNI inventory, as well as manufacturing efficiencies. As we transitioned primary OMNI manufacturing to Asia in early 2021, we were able to lower our production cost per unit. This lower production cost per unit also assisted in allowing the Company to lower cost of goods sold while driving sales growth.

Our total gross profit increased $21.9 million from $18.4 million in the year ended December 31, 2020 to $40.3 million in the year ended December 31, 2021. Our total gross margin increased from 66.7% to 82.4% between 2020 and 2021 primarily due to higher sales volume as well as lower production cost associated with shifting production to lower cost contract manufacturers. Gross margin in our Surgical Glaucoma segment increased from 72.8% in 2020 to 86.1% in 2021, and in our Dry Eye segment gross margin increased from (30.5)% in 2020 to 13.1% in 2021. Our Dry Eye segment had a lower gross margin than our Surgical Glaucoma segment because TearCare is earlier in its commercial cycle than

OMNI and SmartHub equipment is priced to encourage new user adoption rather than to maximize gross profit for its one-time, upfront purchase by ECPs.

Research and Development Expenses. The $6.8 million increase in research and development expenses from 2020 to 2021 was primarily attributable to costs related to the development of our next generation OMNI Surgical System, an increase of $1.3 million in contract manufacturing for Dry Eye product development, $0.6 million in clinical studies, $0.5 million in patent related legal expenses, and an increase of $2.0 million in personnel expenses primarily as a result of increased headcount. We expect our research and development expenses to increase as we initiate and execute additional clinical trials over the coming years, develop new products and improve our existing products.

Selling, General, and Administrative Expenses. The $34.4 million increase in SG&A expenses from 2020 to 2021 was primarily due to our continued commercial investment and scaling of operations and corporate headcount to support our growth, which resulted in an increase of $20.0 million in personnel expenses, including higher stock-based compensation ($4.6 million increase from 2020 to 2021) and commissions during the current year. In addition, legal, accounting, and consulting costs increased $5.2 million from 2020 to 2021 due, in part, to incurred fees associated with the IPO in July 2021.

Interest Expense. The $2.0 million increase in interest expense from 2020 to 2021 was attributable to the executed debt financing in November 2020.

Other Expense, Net. The $6.9 million increase in other expense from 2020 to 2021 was primarily due to fair value adjustments on the preferred stock warrants during the current year.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Years Ended December 31,	
	2021	2020
Net cash used in operating activities	$ (52,540)	$ (32,174)
Net cash used in investing activities	$ (813)	$ (953)
Net cash provided by financing activities	$ 252,529	$ 73,401
Net increase in cash	$ 199,176	$ 40,274

Net Cash Used in Operating Activities.

Net cash used in operating activities for the year ended December 31, 2021 was $52.5 million, consisting primarily of a net loss of $63.0 million. The primary add-backs to net cashed used in operating activities was the $6.9 million change in fair value of redeemable convertible warrants, issued in November 2020 as part of the debt refinancing, and $5.1 million in stock-based compensation expense. The increased stock-based compensation expense coincided with the Company increasing stock awards in advance of and associated with the public offering in July 2021. The $7.6 million increase in our operating assets consisted of a $3.7 million increase in accounts receivable, a $1.3 million increase in our inventory, and a $3.0 million increase in our prepaid expenses, each to support the continued growth of our operations. In addition, the Company's operating liabilities increased by $3.4 million. This was primarily driven by a $1.2 million increase in accounts payable due to increase inventory purchasing activity and a $1.9 million increase in accrued compensation, from an increased employee headcount.

Net cash used in operating activities for the year ended December 31, 2020 was $32.2 million, consisting primarily of a net loss of $34.7 million, which included a $2.2 million benefit from the proceeds from our Paycheck Protection Program, or PPP, loan under the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, and an increase in net operating assets of $0.7 million, partially offset by non-cash charges of $4.0 million. The $0.7 million increase in our operating assets was primarily due to a $1.5 million increase in accounts receivable, a $1.7 million increase in our inventory, and a $0.7 million increase in our prepaid expenses, each to support the continued growth of our operations, partially offset by a $1.9 million increase in accrued compensation and $2.0 million in accrued and other liabilities. The non-cash charges primarily consisted of a $1.4 million provision for excess and obsolete inventories, primarily related to the write-down of legacy first generation OMNI inventory due to the launch of our next generation of OMNI Surgical System in 2020, $0.5 million related to stock- based compensation, $0.6 million of right of use asset amortization related to

office lease, $0.6 million of accretion of debt discount and amortization of debt issuance costs and $0.6 million in depreciation and amortization.

Net Cash Used in Investing Activities.

Net cash used in investing activities in the years ended December 31, 2021 and 2020 was $0.8 and $1.0 million, consisting of purchases of property and equipment.

Net Cash Provided by (Used in) Financing Activities.

Net cash provided by financing activities in the year ended December 31, 2021 of $252.5 million primarily relates to proceeds from the issuance of common stock, net of related offering costs, of $252.2 million.

Net cash provided by financing activities in the year ended December 31, 2020 of $73.4 million primarily relates to proceeds from issuance of debt of $20.3 million and proceeds of $53.4 million from the issuance of our Series E redeemable convertible preferred stock and Series F redeemable convertible preferred stock, partially offset by the related offering costs of $0.3 million.

Liquidity and Capital Resources

Sources of Liquidity

To date, our primary sources of capital have been private placements of redeemable convertible preferred stock, debt financing agreements, the sale of common stock in our IPO, and revenue from the sale of our products. Since our inception, we have raised an aggregate of approximately $402.4 million in net proceeds from sales of our redeemable convertible preferred stock and common stock and borrowed $32.9 million of net proceeds under our term loans.

As of December 31, 2021, we had cash and cash equivalents of $260.7 million, an accumulated deficit of $153.0 million and $35.0 million outstanding under our term loan agreement (before debt discount). Based on our current planned operations, we expect our cash and cash equivalents and additional borrowings available under the 2020 Term Loan and the 2020 Revolver will enable us to fund our operations for at least the next twelve months.

MidCap Loan Agreements

In January 2019, we entered into loan and security agreements, or the 2019 MidCap Credit Facility, with MidCap Financial Services, or the Lender, which provided for a term loan facility, or the 2019 Term Loan, and a revolving line of credit, or the 2019 Revolver. In November 2020, we entered into an amended and restated loan and security agreement, or the 2020 MidCap Credit Facility, with the Lender, which replaced the 2019 MidCap Credit Facility, and provided for a term loan facility, or the 2020 Term Loan, and a revolving line of credit, or the 2020 Revolver. Together with the 2019 Term Loan and 2019 Revolver, the 2020 Term Loan and 2020 Revolver are referred to as the MidCap Loan Agreements. The 2020 MidCap Credit Facility includes a maximum of $40.0 million credit facility consisting of a senior secured term loan of up to $35.0 million and a $5.0 million revolver.

Our obligations under the 2020 MidCap Credit Facility are guaranteed by us and our future subsidiaries, subject to exceptions for certain foreign subsidiaries. Our obligations under the agreements are secured by substantially all of our assets, including our material intellectual property. Additionally, we are subject to customary affirmative and negative covenants, including covenants that limit or restrict the ability of us to, among other things, incur indebtedness, grant liens, merge or consolidate, make investments, dispose of assets, make acquisitions, pay dividends or make distributions, repurchase stock and enter into certain transactions with affiliates, in each case subject to certain exceptions. The 2020 MidCap Credit Facility agreements also have financial covenants that relate to minimum trailing revenue targets, which began in November 2020, and are tested on a monthly basis. As of December 31, 2021, the Company was in compliance with all financial and non-financial covenants.

The MidCap Loan Agreements each contain events of default that include, among others, non-payment of principal, interest or fees, breach of covenants, inaccuracy of representations and warranties, cross-defaults and bankruptcy and insolvency events.

2020 Term Loan

The 2020 Term Loan agreement amended the maturity date to November 1, 2025 and adjusted the stated floating interest rate to reserve-adjusted LIBOR, *plus* 7.00%. Outstanding principal amounts of Tranche One Loans and Tranche Two Loans borrowed under the 2019 Term Loan were designated as Tranche One Loans and Tranche Two Loans under the 2020 Term Loan. The Tranche Three Loan commitment amount was increased to $21.0 million and the full amount was drawn in November 2020. Principal payments under the 2020 Term Loan are scheduled to begin in December 2022. However, if certain conditions are met, the initiation of principal payments can be delayed to either December 2023 or December 2024. In addition, the final payment fee was amended to 6.0%. We are subject to certain financial and non-financial covenants.

We incurred $0.7 million of issuance costs in conjunction with the 2020 Term Loan which were netted against the borrowed funds in the balance sheet and are being accreted using the effective interest method as interest expense over the contractual period of five years.

In conjunction with the funding of the 2020 Term Loan, we issued a 10-year warrant to the Lender to purchase 300,000 shares of our Series F redeemable convertible preferred stock at an exercise price of $21.8779 per share, or the 2020 MidCap Warrant, with the estimated fair value of $1.8 million. The 2020 MidCap Warrants were recorded at the fair value as a debt discount and as a warrant liability. The debt discount is being accreted using the effective interest method as interest expense over the contractual period of four years for the 2020 Term Loan.

2020 Revolver

The maturity date of the 2020 Revolver was amended to November 1, 2025 and the stated floating interest rate was adjusted to reserve-adjusted LIBOR plus 4.50%. As of December 31, 2021, $5.0 million was available to be drawn under the 2020 Revolver which remains undrawn upon. Other key terms of the 2020 Revolver remained substantially unchanged compared to those of 2019 Revolver.

2019 Term Loan

In November 2020, the 2019 Term Loan was amended and restated pursuant to the 2020 Term Loan. The 2019 Term Loan had a four-year term and a stated floating interest rate which equated to reserve- adjusted LIBOR, *plus* 6.75%. Under certain circumstances, the floating interest rate could have been based on the prime rate instead of LIBOR. The 2019 Term Loan was split into three tranches as follows: (i) the Tranche One Loans provided for $12.0 million in term loans, (ii) the Tranche Two Loans provided for up to $2.0 million in term loans, and (iii) the Tranche Three Loans provided for up to $6.0 million in term loans. We borrowed $14.0 million under the Tranche One Loans and Tranche Two Loans. Although the conditions necessary to draw the Tranche Three Loans had been met as of December 31, 2019, we did not draw the Tranche Three Term Loans.

We incurred $1.5 million of issuance costs in conjunction with the 2019 Term Loan which were netted against the borrowed funds in the balance sheet and were being accreted using the effective interest method as interest expense over the contractual period of four years.

In conjunction with the funding of Tranche One Loans and Tranche Two Loans under the 2019 Term Loan, we issued a 10-year warrant to the Lender to purchase 29,514 shares of our Series C redeemable convertible preferred stock, or the 2019 MidCap Warrants, at an exercise price of $9.4868 per share. The estimated fair value of the 2019 MidCap Warrants was $0.2 million. The 2019 MidCap Warrants were recorded at the fair value as a debt discount and as a warrant liability.

The 2019 Term Loan granted us the right to voluntarily prepay the borrowings in full, with a prepayment premium beginning at 3.0% in the first year from tranche funding and declining to 2.0% in the second year from tranche funding, to 1.0% in the third year from tranche funding thereafter. In addition, a final payment fee of 5% of the original Tranche One Loans and Tranche Two Loans amounts borrowed was payable at the end of the term or when the borrowings are repaid in full. The borrowings were collateralized by a security interest in substantially all of our assets.

2019 Revolver

In November 2020, the 2019 Revolver was amended and restated pursuant to the 2020 Revolver. The 2019 Revolver had a four-year term and had a stated floating interest rate which equated to reserve- adjusted LIBOR, *plus* 4.25%. Under certain circumstances, the floating interest rate could have been based on the prime rate instead of LIBOR. An unused line fee of 0.5% was payad aable monthly based on the average unused balance and a collateral management fee of 0.5% was payable monthly based on the outstanding balance of the 2019 Revolver. We could have requested to increase the 2019 Revolver commitment amount to $10.0 million under the terms of the agreement.

Paycheck Protection Program Loan

In May 2020, we received a loan of $2.2 million pursuant to the Paycheck Protection Program, or PPP, under the CARES Act. The Small Business Administration required that PPP loans only be used for eligible payroll costs, business mortgage interest payments, rent or utilities. Per SBA guidelines, we would be eligible to apply for loan forgiveness if we used the loan proceeds for acceptable expenses during the 8-week period after disbursement. The PPP loan was forgiven in June 2021. The Company has elected to recognize this government grant income as a reduction of the related expenses.

In connection with the PPP loan, we executed a promissory note in favor of Bank of America. Because the SBA confirmed full and complete forgiveness of the unpaid balance of the PPP loan and reimbursed Bank of America for the total outstanding balance, principal and interest, our obligations under the PPP loan are deemed fully satisfied and paid in full.

Lease Agreements

Our corporate headquarters are located in Menlo Park, California, where we lease approximately 10,823 square feet of office, research and development, engineering and laboratory space which was originally pursuant to a sublease agreement which was effective as of September 17, 2019 and expired on July 31, 2021. Effective August 1, 2021, we remain in the same space under a new lease agreement with the direct landlord to that space which will extend through August 31, 2024. We also lease approximately 2,040 square feet of office space, which is primarily used by our commercial leadership team, in Southlake, Texas, pursuant to a lease that commenced on April 30, 2019 and expires on May 15, 2024.

Critical Accounting Policies and Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. 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 to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Revenue Recognition

Revenue recognized during the years ended December 31, 2021 and 2020 relates entirely to the sale of our products within the Surgical Glaucoma and Dry Eye segments. These sales are primarily to hospitals, medical centers, and ECPs throughout the United States through sales representatives and distributors.

Our revenue arrangements consist of a single performance obligation. We recognize revenue at the point in time when control of the promised goods transfers to our customers. Revenue is measured at the amount of consideration expected to be received in exchange for the transfer of goods. The amount of revenue that is recognized is based on the transaction price, which represented the invoiced amounts and includes estimates of variable consideration, such as discounted, where applicable. We do not offer right of return, except in the case where item is defective as manufactured, and the company does not typically provide customers with a right to a refund. The amount of variable consideration included in the transaction price may be constrained and is included only to the extent that it is probable that a significant reversal in the

amount of the cumulative revenue recognized under the contract will not occur in a future period. Payment terms, typically 30 days, are offered to our customers and do not include a significant financing component. We extend credit to our customers based upon their financial condition and credit history and generally require no collateral. We do not have any contract balances related to product sales.

Shipping and handling costs incurred for the delivery of goods to customers are included in cost of goods sold. In cases where we bill shipping and handling cost to customers, we classify those amounts in net revenue. As a practical expedient, we recognize the incremental costs of obtaining contracts, such as sales commissions, as an expense when incurred since the amortization period of the asset we otherwise would have recognized is one year or less. Sales commissions are recorded within selling, general, and administrative expenses in the statements of operations

Inventory

Inventory represents finished goods purchased from a third-party manufacturer and is valued at the lower of cost or net realizable value. Cost is determined using actual costs on a first-in, first-out basis for all inventory. Net realizable value is determined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. We regularly review inventory quantities in consideration of actual loss experiences, projected future demand, and remaining shelf life to record a provision for excess and obsolete inventory when appropriate. The shelf life of our Surgical Glaucoma inventory averages approximately 24 months while the shelf life of our Dry Eye inventory varies depending on the component of TearCare, as SmartHubs have no expiration date while SmartLids have a shelf life of 24 months. Our policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected lower of cost or net realizable value, and inventory in excess of expected requirements. The estimate of excess quantities is judgmental and primarily dependent on our estimates of future demand for the particular product.

Stock-Based Compensation and Fair Value of Common Stock

We maintain an equity incentive plan that permits the grant of share-based awards, such as stock options and restricted stock units (RSUs), to employees and directors. We recognize equity-based compensation expense for awards of equity instruments based on the grant date fair value of those awards. We estimate the fair value of our stock option awards made to employees and directors based on the estimated fair values as of the grant date using the Black-Scholes option-pricing model, net of estimated forfeitures.

The fair value of restricted stock unit ("RSU") awards is determined based on the number of units granted and the closing price of the Company's common stock as of the grant date. The model requires us to make a number of assumptions, including expected volatility, expected term, risk-free interest rate, and expected dividend yield. We expense the fair value of our equity-based compensation awards on a straight-line basis over the requisite service period, which is the period in which the related services are received.

Redeemable Convertible Preferred Stock Warrants

Our redeemable convertible preferred stock warrants were classified as liabilities as the underlying redeemable convertible preferred stock was considered contingently redeemable and we were obligated to transfer assets to the holders upon occurrence of a deemed liquidation event. The warrants were recorded at fair value upon issuance and subject to remeasurement to fair value at each balance sheet date, with changes in fair value recognized as other expense in the statements of operations. The warrant liability was recorded as other noncurrent liabilities in the balance sheets. We continued to adjust the warrant liability for changes in fair value until the conversion of redeemable convertible preferred stock into common stock. At the time of conversion, the liability associated with the redeemable convertible preferred stock warrants was converted into warrants to purchase common stock and reclassified to additional paid-in capital. As a result, the redeemable convertible preferred stock warrant liability was settled and is no longer subject to remeasurement.

Recent accounting pronouncements

See Note 2 to our consolidated financial statements appearing under Part II, Item 8 for more information about recent accounting pronouncements, the timing of their adoption, and our assessment.

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

Not applicable to a smaller reporting company.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Sight Sciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Sight Sciences, Inc. and subsidiary (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ DELOITTE & TOUCHE LLP

San Jose, California
March 24, 2022

We have served as the Company’s auditor since 2019.

SIGHT SCIENCES, INC.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 260,687	$ 61,511
Accounts receivable, net	8,709	5,363
Inventory, net	3,475	2,598
Prepaid expenses and other current assets	4,164	1,161
Total current assets	277,035	70,633
Property and equipment, net	1,454	1,269
Operating lease right-of-use assets	1,495	518
Other noncurrent assets	202	386
Total assets	$ 280,186	$ 72,806
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,351	$ 2,158
Accrued compensation	5,987	4,070
Accrued and other current liabilities	4,166	3,086
Total current liabilities	13,504	9,314
Long-term debt	32,656	31,955
Other noncurrent liabilities	1,919	3,055
Total liabilities	48,079	44,324
Commitments and contingencies (Note 6)		
Redeemable convertible preferred stock:		
Redeemable convertible preferred stock, $0.001 par value; 14,241,390 shares authorized as of December 31, 2020, 12,767,202 shares issued and outstanding as of December 31, 2020; aggregate liquidation preference of $118.6 million as of December 31, 2020	—	117,331
Stockholders' equity (deficit):		
Preferred stock par value of $0.001 per share; 10,000,000 authorized; no shares issued and outstanding as of December 31, 2021 and 2020, respectively	—	—
Common stock par value of $0.001 per share; 200,000,000 and 21,831,000 shares authorized as of December 31, 2021 and 2020, respectively; 47,504,704 and 9,509,182 shares issued and outstanding as of December 31, 2021 and 2020, respectively	48	9
Additional paid-in-capital	385,060	1,183
Accumulated deficit	(153,001)	(90,041)
Total stockholders' equity (deficit)	232,107	(88,849)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 280,186	$ 72,806

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

SIGHT SCIENCES, INC.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Years Ended December 31,	
	2021	**2020**
Revenue	$ 48,956	$ 27,640
Cost of goods sold	8,610	9,209
Gross profit	40,346	18,431
Operating expenses:		
Research and development	15,634	8,874
Selling, general and administrative	76,190	41,745
Total operating expenses	91,824	50,619
Loss from operations	(51,478)	(32,188)
Interest income	—	30
Interest expense	(4,366)	(2,403)
Other expense, net	(6,928)	(71)
Loss before income taxes	(62,772)	(34,632)
Provision for income taxes	188	61
Net loss and comprehensive loss	$ (62,960)	$ (34,693)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.36)	$ (3.71)
Weighted-average shares outstanding, basic and diluted	26,734,097	9,356,218

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

SIGHT SCIENCES, INC.
Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2019	9,804,640	$ 64,256	9,319,466	$ 9	$ 656	$ (55,348)	$ (54,683)
Issuance of Series E redeemable convertible preferred stock, net of issuance costs of $106	1,899,847	30,044	—	—	—	—	—
Issuance of Series F redeemable convertible preferred stock, net of issuance costs of $219	1,062,715	23,031	—	—	—	—	—
Exercise of common stock warrants	—	—	129,310	—	6	—	6
Exercise of stock options	—	—	60,406	—	24	—	24
Stock-based compensation expense	—	—	—	—	497	—	497
Net loss and comprehensive loss	—	—	—	—	—	(34,693)	(34,693)
Balance at December 31, 2020	12,767,202	117,331	9,509,182	9	1,183	(90,041)	(88,849)
Conversion of redeemable convertible preferred stock to common stock upon initial public offering	(12,767,202)	(117,331)	25,534,404	26	117,305	—	117,331
Issuance of common stock in connection with initial public offering, net of underwriting discounts and commissions and other offering costs of $23.8 million	—	—	11,500,000	12	252,162	—	252,174
Conversion of redeemable convertible preferred stock warrants to common stock warrants upon initial public offering	—	—	—	—	8,973	—	8,973
Exercise of common stock warrants	—	—	483,554	1	(1)	—	—
Exercise of stock options	—	—	477,564	—	355	—	355
Stock-based compensation expense	—	—	—	—	5,083	—	5,083
Net loss and comprehensive loss	—	—	—	—	—	(62,960)	(62,960)
Balance at December 31, 2021	—	—	47,504,704	48	385,060	(153,001)	232,107

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

SIGHT SCIENCES, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (62,960)	$ (34,693)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	632	554
Accretion of debt discount and amortization of debt issuance costs	701	574
Stock-based compensation expense	5,083	497
Provision for doubtful accounts receivable	348	209
Provision for excess and obsolete inventories	436	1,362
Noncash operating lease cost	569	563
Change in fair value of redeemable convertible preferred stock warrant	6,861	64
Loss on disposal of property and equipment	115	158
Proceeds from Paycheck Protection Program loan	—	(2,246)
Changes in operating assets and liabilities:		
Accounts receivable	(3,694)	(1,477)
Inventory	(1,313)	(1,716)
Prepaid expenses and other current assets	(3,003)	(735)
Other noncurrent assets	185	(237)
Accounts payable	1,168	448
Accrued compensation	1,918	1,900
Accrued and other current liabilities	342	1,987
Other noncurrent liabilities	72	614
Net cash used in operating activities	(52,540)	(32,174)
Cash flows from investing activities:		
Purchases of property and equipment	(813)	(953)
Net cash used in investing activities	(813)	(953)
Cash flows from financing activities:		
Proceeds from issuance of common stock upon initial public offering, net of underwriting discounts and commissions	256,680	—
Payment of other offering costs related to the initial public offering	(4,506)	(42)
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	53,075
Proceeds from the issuance of debt	—	20,480
Debt issuance costs	—	(142)
Proceeds from exercise of common stock warrants	—	6
Proceeds from exercise of common stock options	355	24
Net cash provided by financing activities	252,529	73,401
Net change in cash and cash equivalents	199,176	40,274
Cash and cash equivalents at beginning of period	61,511	21,237
Cash and cash equivalents at end of period	$ 260,687	$ 61,511
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 3,105	$ 1,286
Supplemental disclosure of non-cash investing and financing information		
Acquisition of property and equipment included in accounts payable and accrued liabilities	$ 162	$ 41
Unpaid initial public offering costs in accounts payable and accrued liabilities	$ —	$ 325
Common Stock issued on conversion of convertible preferred stock	$ 117,331	$ —
Common stock warrants issued on conversion of preferred stock warrants and the reclassification of the warrant liability	$ 8,973	$ —

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

Note 1. The Company and Nature of Business

Description of Business

Sight Sciences, Inc. (the "Company") was incorporated in the State of Delaware in 2010. The Company is located and headquartered in Menlo Park, California and has principal commercial offices in Southlake, Texas. The Company is an ophthalmic medical device company focused on the development and commercialization of surgical and nonsurgical technologies for the treatment of prevalent eye diseases. The Company's Surgical Glaucoma segment's product portfolio features the OMNI® Surgical System, a device that facilitates the performance of both canaloplasty and trabeculotomy with a single device and single corneal incision to reduce intraocular pressure in adult patients with primary open-angle glaucoma. The Company's Dry Eye segment's product portfolio consists of the TearCare® System ("TearCare") for ophthalmologists and optometrists. TearCare is a wearable eyelid technology that delivers highly targeted and adjustable heat to the meibomian glands of the eyelids in adult patients with evaporative dry eye disease due to meibomian gland disfunction.

Initial Public Offering

In July 2021, the Company completed an initial public offering ("IPO") of its common stock in which the Company issued and sold 10,000,000 shares of its common stock, and sold an additional 1,500,000 shares of common stock upon the full exercise of the underwriters' option to purchase additional shares of the Company's common stock. These sales occurred at the initial public offering price of $24.00 per share. The Company received net proceeds of approximately $252.2 million from the IPO, after deducting underwriting discounts and commissions of $19.3 million and offering costs of $4.5 million, of which $0.4 million were incurred as of December 31, 2020.

Immediately prior to the closing of the IPO, all then-outstanding shares of redeemable convertible preferred stock were converted into 25,534,404 shares of common stock. Further, all outstanding redeemable convertible preferred stock warrants were converted into warrants to purchase 659,028 shares of common stock, which resulted in the reclassification of the convertible preferred stock warrant liability to additional paid-in capital.

In connection with the Company's IPO, the Company's certificate of incorporation was amended and restated to provide for 200,000,000 authorized shares of common stock with a par value of $0.001 per share and 10,000,000 authorized shares of preferred stock with a par value of $0.001 per share.

Stock Split

In July 2021, the Company effected a 2-for-1 stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's redeemable convertible preferred stock. Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the redeemable convertible preferred stock conversion ratios.

Significant Risks and Uncertainties

Since inception, the Company has incurred losses and negative cash flows from operations. As of December 31, 2021, the Company had an accumulated deficit of $153.0 million and recorded a net loss of $63.0 million for the year then ended and expects to incur future additional losses. If the Company's revenue levels from its products are not sufficient or if the Company is unable to secure additional funding when desired, the Company may need to delay the development of its products and scale back its business and operations.

The Company believes that its existing sources of liquidity will satisfy its working capital and capital requirements for at least 12 months from the issuance of its financial statements. Failure to generate sufficient revenues, achieve planned gross margins, or control operating costs will require the Company to raise additional capital through equity or debt financing. Such additional financing may not be available on acceptable terms, or at all, and could require the Company to modify, delay, or abandon some of its planned future expansion or expenditures or reduce some of its ongoing operating

costs, which could harm its business, operating results, financial condition, and ability to achieve its intended business objectives.

The ongoing COVID-19 pandemic has impacted, and is expected to continue to impact, demand for the Company's products, which are used in procedures and therapies that are considered elective. COVID-19 may also, directly or indirectly, have an unfavorable impact on other areas of the Company's business including, but not limited to, supply chain, sales, third party manufacturing, research and development costs and clinical studies. The full effect of the COVID-19 pandemic on the Company's financial condition and results of operations remain highly uncertain and cannot be predicted with confidence, and will depend on certain developments, including the duration and severity of the COVID-19 pandemic and its potential variants. The impact on the Company's customers and suppliers and the range of governmental and community reactions to the pandemic are uncertain. The Company may continue to experience reduced customer demand or constrained supply that could materially adversely impact business, financial condition, results of operations, liquidity and cash flows in future periods.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (US GAAP). The Company’s consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Sight Sciences UK, Ltd. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent liabilities at the date of the financial statements, and the reported amounts of revenues and expense during the reporting period. The most significant estimates related to inventory excess and obsolescence, the selection of useful lives of property and equipment, determination of the fair value of stock option grants, the fair value of the redeemable convertible preferred stock warrants, and provisions for income taxes and contingencies. Management evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors, including the current economic environment, and makes adjustments when facts and circumstances dictate. These estimates are based on information available as of the date of the financial statements. Actual results could differ from these estimates and such differences could be material to the Company’s financial position and results of operations.

Fair Value of Financial Instruments

The Company’s financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, redeemable convertible preferred stock, short-term and long-term debt and redeemable convertible preferred stock warrant liability. The Company states accounts receivable, accounts payable, and accrued and other current liabilities at their carrying value, which approximates fair value due to the short time to the expected receipt or payment. The carrying amount of the Company’s short-term debt approximates its fair value as the effective interest rate approximates market rates currently available to the Company. The redeemable convertible preferred stock warrant liability associated with the Company’s redeemable convertible preferred stock was carried at fair value based on unobservable market inputs. The carrying value of the warrants continued to be adjusted until the completion of the IPO, which occurred in July 2021. At that time, the preferred stock warrant liability was adjusted to fair value and reclassified to additional paid-in capital.

Concentration of Credit Risk

Financial instruments that subject the Company to concentration of credit risk consist of cash and cash equivalents and accounts receivable. The Company’s cash and cash equivalents are deposited with a high-quality financial institution. Deposits at this institution may, at times, exceed federally insured limits. Management believes that this financial institution is financially sound and, accordingly, that minimal credit risk exists. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company relies on third-party contract manufacturers for the manufacture of all of our commercial products currently available for sale. Disruption in production would have a negative impact on the Company's financial position, results of operations and cash flows.

For the years ended December 31, 2021 and 2020, there were no customers that represented 10% or more of the Company's revenue.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting and other fees and costs relating to the Company's IPO, were deferred until completion of the IPO. As of December 31, 2020, deferred offering costs of $0.4 million were capitalized and are included in "Other noncurrent assets". In July 2021, upon closing of the IPO, total deferred costs of $4.5 million were offset against the Company's IPO proceeds in additional paid in capital.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash and cash equivalents. Cash and cash equivalents are recorded at cost, which approximate fair value. As of December 31, 2021 and 2020, cash consists primarily of checking and savings deposits. The Company's cash balances exceed those that are federally insured. To date, the Company has not recognized any losses caused by uninsured balances.

Accounts Receivable and Provision for Doubtful Accounts

Accounts receivable are stated at invoiced amounts, net of estimated provisions for doubtful accounts. The majority of customers are not extended credit and, therefore, time to maturity for receivables is short. The Company makes estimates of the collectability of customer accounts and provisions based primarily on analysis of historical trends and experience and changes in customers' financial condition. The Company uses its judgment, based on the best available facts and circumstances, and records a provision against amounts due to reduce the receivable to the amount that is expected to be collected. These specific provisions are reevaluated and adjusted as additional information is received that impacts the amount reserved. To date, the Company has not experienced material credit-related losses. The provision for doubtful accounts was $0.6 million and $0.3 million as of December 31, 2021 and 2020, respectively.

Inventory

Inventory represents finished goods purchased from a third-party manufacturer and is valued at the lower of cost or net realizable value. Cost is determined using actual costs on a first-in, first-out basis for all inventory. Net realizable value is determined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The Company regularly reviews inventory quantities in consideration of actual loss experiences, projected future demand, and remaining shelf life to record a provision for excess and obsolete inventory when appropriate. The Company's policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected lower of cost or net realizable value, and inventory in excess of expected requirements. The estimate of excess quantities is judgmental and primarily dependent on the Company's estimates of future demand for the particular product.

Property and Equipment, net

Property and equipment are recorded at cost, less accumulated depreciation. Repairs and maintenance costs are expensed as incurred. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, typically two to five years. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations in the period realized.

Construction-in-process assets consist primarily of tools and equipment that have not yet been placed in service. These assets are stated at cost and are not depreciated. Once the assets are placed into service, assets are reclassified to the appropriate asset class based on their nature and depreciated in accordance with the useful lives above.

Impairment of Long-Lived Assets

The Company assesses long-lived assets, including property and equipment, whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. If indicators of impairment exist, an impairment loss may be recognized when estimated undiscounted future cash flows expected to result from the use of the assets and their eventual disposition are less than their carrying amount. Impairment, if any, is measured as the amount by which the carrying amount of the long-lived assets exceeds their fair value. Fair value is determined through various valuation techniques, including discounted cash flow models, quoted market values, and third-party independent appraisals, as considered necessary. The Company did not record any impairment of long-lived assets for the years ended December 31, 2021 and 2020.

Leases

Contractual arrangements that meet the definition of a lease are classified as operating or finance leases and are recorded on the balance sheets as both a right-of-use asset ("ROU asset") and lease liability, calculated by discounting fixed lease payments over the lease term at the Company's incremental borrowing rate ("IBR"). Lease ROU assets and lease obligations are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. The Company currently does not have any finance leases.

Operating lease ROU assets are adjusted for (i) payments made at or before the commencement date, (ii) initial direct costs incurred, and (iii) tenant incentives under the lease. As the implicit rates for the operating leases are not determinable, the Company uses an IBR based on the information available at the respective lease commencement dates to determine the present value of future payments. IBR represents the interest rate that the Company would expect to incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis with similar terms and payments, in an economic environment where the leased asset is located. The Company considers a lease term to be the noncancelable period that it has the right to use the underlying asset, including any periods where it is reasonably certain the Company will exercise any option to extend the contract.

Lease costs for minimum lease payments for operating leases are recognized on a straight-line basis over the lease term. Lease liabilities are increased by interest and reduced by payments each period, and the ROU asset is amortized over the lease term. Variable lease payments that do not depend on an index or rate are recognized as lease costs when incurred. In measuring the ROU assets and lease liabilities, the Company has elected to combine lease and non-lease components. The Company does not recognize ROU assets or lease liabilities for short-term leases, if any, having initial terms of 12 months or less at lease commencement as an accounting policy election, and recognizes rent expense on a straight-line basis over the lease term for these types of leases.

Redeemable Convertible Preferred Stock Warrants

The Company's redeemable convertible preferred stock warrants were classified as liabilities as the underlying redeemable convertible preferred stock was considered contingently redeemable and the Company was obligated to transfer assets to the holders upon occurrence of a deemed liquidation event. The warrants were recorded at fair value upon issuance and subject to remeasurement to fair value at each balance sheet date, with changes in fair value recognized as other expense in the statements of operations. The warrants liability was recorded as other noncurrent liabilities in the balance sheets. The Company continued to adjust the warrant liability for changes in fair value until the conversion of redeemable convertible preferred stock into common stock. At the time of conversion, the liability associated with the redeemable convertible preferred stock warrants was converted into warrants to purchase common stock and reclassified to additional paid-in capital. As a result of the conversion in the current year, the redeemable convertible preferred stock warrant liability was settled and will no longer be subject to remeasurement.

Redeemable Convertible Preferred Stock

The Company recorded its redeemable convertible preferred stock at fair value on the dates of issuance, net of issuance costs. A redemption event will be deemed to have occurred upon the liquidation or winding-up of the Company, a greater than 50% change in control, or sale of substantially all of the assets of the Company. In the event of a change of control of the Company, proceeds received from the sale of such shares will be distributed in accordance with the liquidation preferences set forth in the Company's amended and restated certificate of incorporation, unless the holders of redeemable convertible preferred stock otherwise agree or have converted their shares into shares of common stock. Therefore, redeemable convertible preferred stock was classified outside of stockholders' equity in the balance sheets, as

events triggering the liquidation preferences are not solely within the Company's control. During the current year, the holders of the redeemable convertible preferred stock agreed to have their shares converted into shares of common stock. At the time of conversion, the balances were reclassified to common stock and additional paid-in capital.

Common Stock Warrant

The Company's common stock warrant is classified in equity as it meets all criteria for equity classification. The fair value of the common stock warrant was calculated using the BackSolve Method and is recorded at fair value upon issuance in additional paid-in capital in the consolidated balance sheets. The common stock warrant is not remeasured after the issuance date.

Revenue Recognition

The Company applies the following five steps in order to determine the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its arrangements:

- Identify the contract with a customer,
- Identify the performance obligations in the contract,
- Determine the transaction price,
- Allocate the transaction price to performance obligations in the contract, and
- Recognize revenue as the performance obligations are satisfied.

Revenue recognized during the years ended December 31, 2021 and 2020 relates entirely to the sale of the Company's products within the Surgical Glaucoma and Dry Eye segments. These sales are primarily to hospitals, medical centers, and ECPs throughout the United States through sales representatives and distributors.

The Company's revenue arrangements consist of a single performance obligation. Revenue is recognized at the point in time when control of the promised goods transfer to the Company's customers. Revenue is measured at the amount of consideration expected to be received in exchange for the transfer of goods. The amount of revenue that is recognized is based on the transaction price, which represented the invoiced amounts and includes estimates of variable consideration, such as discounted, where applicable. The Company does not offer right of return, except in the case where items are defective as manufactured, and the company does not typically provide customers with a right to a refund. The amount of variable consideration included in the transaction price may be constrained and is included only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Payment terms, typically 30 days, are offered to customers and do not include a significant financing component. The Company extends credit to customers based upon their financial condition and credit history and generally require no collateral. The Company does not have any contract balances related to product sales.

Shipping and handling costs incurred for the delivery of goods to customers are included in cost of goods sold. In cases where the Company bills shipping and handling cost to customers, the Company classifies those amounts in net revenue. As a practical expedient, the Company recognizes the incremental costs of obtaining contracts, such as sales commissions, as an expense when incurred since the amortization period of the asset we otherwise would have recognized is one year or less. Sales commissions are recorded within selling, general, and administrative expenses in the statements of operations.

Cost of Goods Sold

The Company purchases its products from third-party manufacturers. Cost of goods sold consists primarily of costs related to materials, manufacturing overhead costs, reserves for excess, and obsolete and non-sellable inventories. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs, such as shipping and handling costs.

Research and Development

The Company expenses research and development costs as incurred. Research and development expenses consist primarily of product development, clinical studies to develop and support the Company's products, regulatory expenses, medical affairs, and other costs associated with products and technologies that are in development. Research and

development expenses include employee compensation, including stock-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses, depreciation, and an allocation of facility overhead expenses.

Selling, General and Administrative

Selling, general and administrative expenses include compensation, employee benefits, and stock-based compensation for executive management, finance administration, and human resources; facility costs (including rent); bad debt costs; professional service fees; and other general overhead costs, including depreciation to support the Company's operations.

Advertising Expense

The Company expenses advertising costs as incurred. Advertising expenses for fiscal years 2021 and 2020 were $2.1 million and $0.8 million, respectively, included in selling, general, and administrative expenses in the statements of operations and comprehensive loss.

Accounting for Payroll Protection Program

In March 2020, Congress established the Paycheck Protection Program ("PPP") to provide relief to small businesses during COVID-19 as part of the Coronavirus Aid, Relief, and Economic Security ("CARES") Act. The legislation authorized the U.S. Treasury to use the Small Business Association's ("SBA's") small business lending program to fund forgivable loans that qualifying businesses could spend to cover payroll, mortgage interest, rent, and utilities during the "Covered Period" defined as the 8-week period starting on the date the PPP loan proceeds are received. Upon meeting certain criteria as specified in the PPP program, the loans are eligible for partial or total forgiveness. In May 2020, the Company applied for and received a PPP loan for the amount $2.2 million from SBA. The PPP loan was fully forgiven in June 2021.

U.S. GAAP does not contain authoritative accounting standards for forgivable loans provided by governmental entities to a for-profit entity. Absent authoritative accounting standards, interpretative guidance issued and commonly applied by financial statement preparers allows for the selection of accounting policies amongst acceptable alternatives. The Company determined it most appropriate to account for the PPP loan proceeds as an in-substance government grant by analogy to International Accounting Standards 20 ("IAS 20") *Accounting for Government Grants and Disclosure of Government Assistance*. Under this guidance, a forgivable loan from government is treated as a government grant when there is reasonable assurance that the entity will meet the terms for forgiveness of the loan. While IAS 20 does not define "reasonable assurance", this concept in practice is analogous to "probable" as defined in Financial Accounting Standards Board ("FASB") ASC 450-20-20 under U.S. GAAP, which is the definition the Company has applied to its expectations of PPP loan forgiveness. Under IAS 20, government grants are recognized in earnings on a systematic basis over the periods in which the Company recognizes costs for which the grant is intended to compensate (i.e. qualified expenses). Further, IAS 20 permits for the recognition in earnings either separately under a general heading such as other income, or as a reduction of the related expenses.

The Company has elected to recognize this government grant income as a reduction of the related expenses, and recognized $0.1 million, $0.3 million and $1.8 million as a reduction of cost of revenue, research and development and selling, general and administrative expenses, respectively for the year ended December 31, 2020.

Stock-Based Compensation

The Company measures and records the expense related to stock-based payment awards based on the fair value of those awards as determined on the date of grant. The Company recognizes stock-based compensation expense over the requisite service period of the individual grant, generally equal to the vesting period and uses the straight- line method to recognize stock-based compensation, and accounts for forfeitures as they occur. The Company selected the Black-Scholes-Merton ("Black-Scholes") option-pricing model as the method for determining the estimated fair value for stock options. The Black-Scholes option-pricing model requires the use of highly subjective and complex assumptions, which determine the fair value of share-based awards, including the option's expected term, expected volatility of the underlying stock, risk-free interest rate and expected dividend yield.

Currency Remeasurement

Foreign currency transaction gains and losses are recorded in other expense, net in the Company's statements of operations and such amounts have not been material for all periods presented.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Management makes an assessment of the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all off a deferred tax asset will not be realized. Due to the Company's historical operating performance and the recorded cumulative net losses in prior fiscal periods, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Changes in recognition or measurement are reflected in the period in which judgment occurs. The Company's policy is to recognize interest and penalties related to the underpayment of income tax as a component of provision for income taxes.

Comprehensive Loss

Comprehensive loss represents all changes in stockholders' deficit except those resulting from distributions to stockholders. There have been no items qualifying as other comprehensive income (loss) and, therefore, for all periods presented, there was no difference between comprehensive loss and the Company's reported net loss.

Net loss per share attributable to common stockholders

Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities. The Company considers all series of its redeemable convertible preferred stock and restricted stock awards to be participating securities as the holders are entitled to receive dividends on a pari passu basis in the event that a dividend is paid on common stock. Under the two-class method, the net loss attributable to common stockholders is not allocated to the redeemable convertible preferred stock or restricted stock awards as the holders of the Company's redeemable convertible preferred stock and restricted stock awards do not have a contractual obligation to share in losses.

Basic and diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period without consideration of potentially dilutive securities. The Company's potentially dilutive shares, which consist of outstanding common stock options, restricted stock awards, common stock warrants, redeemable convertible preferred stock and redeemable convertible preferred stock warrants were excluded in the computation of diluted net loss per share for the period as the result would be anti-dilutive.

Emerging growth company and smaller reporting company

The Company is an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as well as a "smaller reporting company, as defined by the Securities and Exchange Commission per Rule 12b-2 of the Exchange Act. As such the Company is eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including reduced reporting and extended transition periods to comply with new or revised accounting standards for public business entities. The Company has elected to avail themselves of this exemption and, therefore, will not be subject to the timeline for adopting new or revised accounting standards for public business entities that are not emerging growth companies, and will follow the transition guidance applicable to private companies.

Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. The guidance is effective for the Company beginning in the first quarter of 2023. The Company is evaluating the impact of adopting this guidance and does not expect to have a material impact on the Company's financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, that simplifies the accounting for income taxes by eliminating certain exceptions related to the approach for intra-period tax allocation and modified the methodology for calculating income taxes in an interim period. It also clarifies and simplifies other aspects of the accounting for income taxes. The guidance is effective for the Company for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022 with early adoption permitted. The Company is evaluating the effect of this new guidance and does not expect it to have material impact on the Company's financial statements.

In March 2020, the FASB issued ASU No. 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. The new guidance provides optional expedients and exceptions for applying generally accepted accounting principles to contract modifications and hedging relationships, subject to meeting certain criteria, that reference LIBOR or another reference rate expected to be discontinued. The guidance also establishes (1) a general contract modification principle that entities can apply in other areas that may be affected by reference rate reform and (2) certain elective hedge accounting expedients. The amendment is effective for all entities through December 31, 2022. LIBOR is used to calculate the interest on borrowings under the Company's term loan and revolving line of credit with MidCap Financial Services. The Company is evaluating the effect of this new guidance and does not expect it to have material impact on the Company's financial statements.

Note 3. Fair Value Measurements

The Company reports all financial assets and liabilities and nonfinancial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to measurements involving significant unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are as follows:

Level 1—Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access at 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—Inputs are unobservable inputs for the asset or liability. The level in the fair value hierarchy within which a fair value measurement in its entirety is based on the lowest-level input that is significant to the fair value measurement in its entirety.

The financial statements as of December 31, 2021 and 2020, do not include any nonrecurring fair value measurements relating to assets or liabilities.

As of December 31, 2021, there were no liabilities that are measured at fair value on a recurring basis. The following table sets forth the fair value measurements of financial liabilities as of December 31, 2020 (in thousands):

	As of December 31, 2020			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Redeemable convertible preferred stock warrants liabilities	$ —	$ —	$ 2,112	$ 2,112
Total liabilities measured at fair value	$ —	$ —	$ 2,112	$ 2,112

The Company measures the redeemable convertible preferred stock warrants using Level 3 unobservable inputs within the Black-Scholes option-pricing model. The key assumptions include the fair value of redeemable convertible preferred stock, volatility, the risk-free interest rate, expected term (remaining contractual term of the warrants) and dividend yield. The Company has limited historical volatility information available, and the expected volatility was based on actual

volatility for comparable public companies projected over the expected terms of the warrants. The Company did not apply a forfeiture rate to the warrants as there is not enough historical information available to estimate such a rate. The risk-free interest rate was based on the U.S. Treasury yield curve at the time of the grant over the expected term of the warrants. Refer to Note 9 for the assumptions used.

The Company measures the fair value of outstanding debt for disclosure purposes on a recurring basis. As of December 31, 2021 and 2020, total debt of $32.7 million and $32.0 million is reported at amortized cost, respectively. This outstanding debt is classified as Level 2 as it is not actively traded. The amortized cost of the outstanding debt approximates the fair value.

The Company determines the fair value of the redeemable convertible preferred stock warrants quarterly, with subsequent gains and losses from remeasurement of Level 3 financial liabilities recorded through other expense, net in condensed statements of operations and comprehensive loss.

A summary of the changes in the fair value of the Company's Level 3 financial instruments for the years ended December 31, 2021 and 2020, is as follows (in thousands):

	Redeemable convertible preferred stock warrants liabilities
Balance – December 31, 2019	$ 236
Issuance of redeemable convertible preferred stock warrants	1,812
Change in fair value	136
Expiration of redeemable convertible preferred stock warrants	(72)
Balance – December 31, 2020	2,112
Change in fair value	6,861
Conversion of preferred stock warrants to common stock warrants upon the closing of the IPO	(8,973)
Balance – December 31, 2021	$ —

Note 4. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consist of the following (in thousands):

	As of December 31,	
	2021	2020
Tools and equipment	$ 1,685	$ 1,523
Computer equipment and software	100	118
Furniture and fixtures	254	43
Leasehold improvements	29	30
Construction in process	590	298
	2,658	2,012
Less: Accumulated depreciation	(1,204)	(743)
Property and equipment, net	$ 1,454	$ 1,269

Depreciation expense was $0.6 million and $0.6 million for the years ended December 31, 2021 and 2020 respectively.

Accrued and Other Current Liabilities

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

	As of December 31,	
	2021	2020
Accrued expenses	$ 2,726	$ 1,971
Current portion of lease liabilities	510	395
Short term interest payable	275	274
Other accrued liabilities	655	446
Total accrued and other current liabilities	$ 4,166	$ 3,086

Other Noncurrent Liabilities

Other noncurrent liabilities consist of the following (in thousands):

	As of December 31,	
	2021	2020
Redeemable preferred stock warrants liabilities	$ —	$ 2,112
Long term interest payable	841	465
Noncurrent portion of lease liabilities	1,040	134
Other noncurrent liabilities	38	344
Total other noncurrent liabilities	$ 1,919	$ 3,055

Note 5. Debt

In January 2019, the Company entered into credit and security agreements with MidCap Financial Services, or the Lender, which provided a maximum of $25.0 million credit facility consisting of a $20.0 million senior secured term loan (the "2019 Term Loan") and a $5.0 million 2019 revolving loan (the "2019 Revolver" and collectively with the 2019 Term Loan, the “2019 MidCap Credit Facility”). In November 2020, the Company entered into amended and restated credit and security agreements with the same institution, which replaced the 2019 MidCap Credit Facility, and provided for a maximum of $40.0 million credit facility consisting of a $35.0 million senior secured term loan (the "2020 Term Loan") and a $5.0 million revolving loan (the "2020 Revolver and collectively with the 2020 Term Loan, the “2020 MidCap Credit Facility”).

The obligations under the MidCap Loan Agreements are guaranteed by the Company's current and future subsidiaries, subject to exceptions for certain foreign subsidiaries. Obligations under the agreements are secured by substantially all assets of the Company, including material intellectual property. Additionally, the Company is subject to customary affirmative and negative covenants as defined in the credit agreement, including covenants that limit or restrict the ability to, among other things, incur indebtedness, grant liens, merge or consolidate, make investments, dispose of assets, make acquisitions, pay dividends or make distributions, repurchase stock and enter into certain transactions with affiliates, in each case subject to certain exceptions. The agreements also have financial covenants that relate to minimum trailing revenue targets, which began in November 2020, and are tested on a monthly basis. As of December 31, 2021, the Company was in compliance with all financial and non-financial covenants.

The MidCap Loan Agreements each contain events of default that include, among others, non-payment of principal, interest or fees, breach of covenants, inaccuracy of representations and warranties, cross-defaults and bankruptcy and insolvency events.

2020 Term Loan

The 2020 Term Loan has a five-year term and has a stated floating interest rate which equates to reserve- adjusted LIBOR + 7.00%. The effective interest rate at December 31, 2021 was 12.94%. The 2020 Term Loan is split into three tranches as follows: (i) the Tranche One Loans provide for $12.0 million in term loans which are deemed to have been converted from Tranche One Loans that were drawn and outstanding under the 2019 Term Loan immediately prior to entering into 2020 MidCap Credit Facility, (ii) the Tranche Two Loans provided for up to $2.0 million in term loans which are deemed to have been converted from Tranche Two Loans that were drawn and outstanding under the 2019 Term Loan

immediately prior to entering into 2020 MidCap Credit Facility, and (iii) the Tranche Three Loans provided for up to $21.0 million in new term loans. The Company borrowed $21.0 million under the Tranche Three Loans in November 2020.

The 2020 Term Loan requires monthly interest-only payments, which began in December 2020. Principal payments are scheduled to begin in December 2022, however, the interest-only period can be extended by an additional 24 months provided that the Company is in compliance with certain financial covenants and other terms as defined in the MidCap Loan Agreements. The Company currently has the ability to and intends to extend the interest-only period through December 2023.

In conjunction with entry into the 2020 MidCap Credit Facility, the Company issued a 10-year warrant to the Lender to purchase 300,000 shares of the Company's Series F redeemable convertible preferred stock (the "2020 Warrant") at an exercise price of $21.88 per share (see Note 9). The estimated fair value at issuance of the 2020 Warrant of $1.8 million. The 2020 Warrant was recorded at the fair value as a debt discount and as a warrant liability. In addition, the Company incurred $0.5 million of issuance costs paid to the Lender in conjunction with the 2020 Term Loan which represents a debt discount. The Company concluded that the 2020 Term Loan represented a modification of the 2019 Term Loan and accounted for the 2020 Term Loan as debt modification.

A final payment fee of 6% of the amounts borrowed is payable at the end of the term or when the borrowings are repaid in full. A long-term liability is being accreted using the effective interest method for the final payment fee over the term of the loan agreement. The borrowings are collateralized by a security interest in substantially all of the Company's assets. The Company accrued $0.9 million and $0.5 million as of December 31, 2021 and 2020, respectively, related to accretion of final payment due at maturity per the agreement using the effective interest rate method.

2020 Revolver

The 2020 Revolver has a four-year term and has a stated floating interest rate which equates to reserve- adjusted LIBOR plus 4.50%. An unused line fee of 0.5% is payable monthly based on the average unused balance and a collateral management fee of 0.5% is payable monthly based on the outstanding balance of the 2020 Revolver. The Company can request to increase the 2020 Revolver commitment amount to $15.0 million under the term of the agreement. As of December 31, 2021, $5.0 million was available to be drawn under the 2020 Revolver.

Long-term and short-term debt as of December 31, 2021 and 2020 was as follows (in thousands):

	As of December 31,	
	2021	2020
2020 Term Loan	$ 35,000	$ 35,000
Total principal payments due	35,000	35,000
Less: debt discount related to warrant liability and issuance costs	(2,344)	(3,045)
Total amounts outstanding	32,656	31,955
Less: Current portion	—	—
Total accrued and other current liabilities	$ 32,656	$ 31,955

The repayment schedule relating to the Company's principal debt as of December 31, 2021, is as follows (in thousands):

	Amount
2022	—
2023	(1,458)
2024	(17,500)
2025	(16,042)
Total repayments	$ (35,000)

Note 6. Commitments and Contingencies

Operating Lease Obligations

The Company's leases include facility leases and storage leases. In determining the present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date if the rate implicit in the lease is not readily determinable. The Company estimates its incremental borrowing rate based on qualitative factors including company specific credit offers, lease term, general economics, and the interest rate environment.

In September 2019, the Company entered into a noncancelable operating lease for approximately 10,823 square feet of primary office space, which expired on July 31, 2021, without the option to extend.

On February 5, 2021, the Company entered into a lease to renew the corporate headquarters in Menlo Park, California. The lease commenced on August 1, 2021 and is for a term of 37 months from the commencement date. The Company recorded an aggregate right-of-use ("ROU") asset and lease liability of $1.5 million. The ROU asset and corresponding lease liability were estimated using a weighted-average incremental borrowing rate of 13.59%. Total base rent is approximately $1.6 million under the lease agreement.

The Company recognizes rent expense on a straight-line basis over the noncancelable lease term. The Company's rent expense was $0.7 million and $0.7 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, the remaining lease term for the lease was 2.6 years.

Operating lease expense and supplemental cash flow information related to operating leases for the years ended December 31, 2021 and 2020 were as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Operating lease expense	$ 702	$ 663
Cash paid for operating leases	657	694
New operating lease assets obtained in exchange for operating lease liabilities	1,537	—

Aggregate future minimum lease payments at December 31, 2021 under these noncancelable operating leases was as follows (in thousands):

	As of December 31, 2021
2022	$ 693
2023	706
2024	462
Total future minimum lease payments	$ 1,861
Less: imputed interest	(311)
Present value of future minimum lease payments	$ 1,550
Less: current portion of operating lease liability	(510)
Operating lease liabilities - noncurrent	$ 1,040

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but that have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as a director may be subject to any proceeding arising out of acts or omissions of such director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director liability insurance. This insurance allows the transfer of risk associated with the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations as of December 31, 2021 and 2020.

Contingencies

From time to time, we may become involved in legal proceedings arising in the ordinary course of business. We are not currently a party to any material legal proceedings.

Note 7. Redeemable Convertible Preferred Stock

The Company's redeemable convertible preferred stock issued and outstanding at December 31, 2020 (in thousands, except share and per share data) were as follows:

	Shares Authorized	Shares Issued and Outstanding	Original Issuance Price	Liquidation Amount	Issuance Costs	Carrying Value
Series A	3,804,344	3,804,344	$ 1.38	$ 5,250	$ 9	$ 5,241
Series B	1,209,621	1,209,621	$ 5.79	7,000	106	6,894
Series C	2,372,371	2,342,857	$ 9.49	22,226	208	22,018
Series D	2,507,720	2,447,818	$ 12.56	30,750	647	30,103
Series E	1,921,902	1,899,847	$ 15.87	30,150	106	30,044
Series F	2,425,432	1,062,715	$ 21.88	23,250	219	23,031
	14,241,390	12,767,202		$ 118,626	$ 1,295	$ 117,331

Immediately prior to the closing of the IPO, all then-outstanding shares of redeemable convertible preferred stock were converted into 25,534,404 shares of common stock, resulting in the reclassification of the related redeemable convertible preferred stock of $117.3 million to common stock and APIC. There was no redeemable convertible preferred stock outstanding as of December 31, 2021.

Note 8. Common Stock Warrants

In connection with the issuance of the Company's Series A redeemable convertible preferred stock issuances in September 2011, the Company issued a warrant to purchase 129,310 shares of common stock to an investor who purchased Series A redeemable convertible preferred stock at an exercise price of $0.05 per share. The common stock warrant was exercised in December 2020 and is no longer outstanding.

Note 9. Redeemable Convertible Preferred Stock Warrants

2019 Warrants

Under the 2019 Term Loan, the Company issued the 2019 Warrants to purchase shares of its Series C redeemable convertible preferred stock. At initial recognition, the warrants were recorded at fair value and were subject to remeasurement at each balance sheet date. Subsequent to the IPO in 2021, the outstanding warrants were converted to common stock, which resulted in the re-classification of the convertible preferred stock warrant liability to additional paid-in-capital.

As of December 31, 2020, the estimated fair value of the warrants was $0.3 million. The fair value was calculated using the Black-Scholes option-pricing model with the following assumptions:

	December 31, 2020
Expected term (in years)	8.1 – 8.5
Expected volatility	42.18% – 42.63%
Risk-free interest rate	2.33% – 2.49%
Dividend yield	–

2020 Warrant

In conjunction with entering into the 2020 Term Loan agreement, the Company issued the 2020 Warrant to purchase 300,000 shares of its Series F redeemable convertible preferred stock. The warrant was immediately exercisable at an exercise price per share of $21.88 and expires 10 years from its date of issuance.

The estimated fair value of the warrant on the date of issuance was $1.8 million. As of the issuance date, the fair value was calculated using a Multi-scenario Method with Discounts for Lack of Marketability for each class of security.

At initial recognition, the warrant was recorded at its estimated fair values and was subject to remeasurement at each balance sheet date. Upon the completion of the IPO, the outstanding warrant was converted to purchase 600,000 shares of common stock, which resulted in the re-classification of the convertible preferred stock warrant liability to additional paid-in capital. In August 2021, the warrant was net exercised and the Company issued 431,708 shares of common stock.

At December 31, 2020, the estimated fair value of the 2020 Warrant was $1.8 million. The fair value of the redeemable convertible preferred stock warrants was determined using the following assumptions:

	December 31, 2020
Term (in years)	0.58 – 2.58
Expected volatility	55.9% - 65.6%
Risk-free interest rate	0.08% - 0.18%

Note 10. Common Stock

In connection with the Company's IPO in July 2021, the Company's certificate of incorporation was amended and restated to provide for 200,000,000 authorized shares of common stock with a par value of $0.001 per share and 10,000,000 authorized shares of preferred stock with a par value of $0.001 per share. The holders of common stock were also entitled to receive dividends whenever funds are legally available, when and if declared by the board of directors. As of December 31, 2021, no dividends have been declared to date. Each share of common stock is entitled to one vote.

At December 31, 2021 and December 31, 2020, the Company had reserved common stock for future issuances as follows:

	December 31,	
	2021	2020
Redeemable convertible preferred stock and warrants	—	26,193,432
Common stock options issued and outstanding	4,996,945	3,137,776
Common stock available for future grant	5,321,687	451,670
Restricted stock units outstanding	53,250	—
Shares available for future purchase under ESPP	850,000	—
	11,221,882	29,782,878

Note 11. Equity Incentive Plans

2011 Stock Option Plan and 2021 Equity Incentive Plan

In 2011, the Company established its 2011 stock option plan (the "2011 Plan") that provided for the granting of stock options to employees and nonemployees of the Company. In July 2021, the Company's Board of Directors and stockholders adopted and approved the 2021 Equity Incentive Plan, (the "2021 Plan"). Under the 2021 Plan, the Company had the ability to issue incentive stock options ("ISOs"), nonqualified stock options ("NSOs"), stock appreciation rights, dividend equivalent rights, restricted stock awards, and restricted stock unit awards. Options under the 2021 Plan could be granted for periods of up to 10 years. For incentive stock options granted to a grantee who, at the time the option is granted, owns stock representing more than 10% of the voting power of all classes of stock of the Company or any parent or subsidiary of the Company, the term of the incentive stock option may be granted for periods of up to five years. The ISOs and NSOs will be granted at a price per share not less than the fair value at the date of grant. The exercise price of an ISO granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant, as determined by the board of directors. Options granted to new hires generally vest over a four-year period, with 25% vesting at the end of one year and the remaining vesting monthly thereafter; options granted as merit awards generally vest monthly over a four-year period. The Company reserved 5,200,000 shares of common stock for future issuance under the 2021 Plan.

The Company's 2011 Stock Plan was terminated in connection with the IPO and no further grants will be made under the 2011 Plan from the date that the 2021 Plan became effective. The terms under the 2011 Plan are consistent with those described above for the 2021 Plan. The Company had the ability to issue ISOs, NSOs, stock appreciation rights, dividend equivalent rights, restricted stock awards, and restricted stock unit awards.

At December 31, 2021 and 2020, there were 5,321,687 shares and 451,670 shares, respectively, of common stock available for issuance under the 2021 and 2011 Plans, respectively.

Stock Option Awards

The following table summarizes stock option activity under the 2011 and 2021 Plans:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Term (in years)	Average Intrinsic Value (in thousands)
Outstanding, December 31, 2020	3,137,776	$ 0.94	6.8	$ 18,656
Grants	2,487,253	11.35		
Forfeited/cancelled	(150,520)	3.77		
Exercised	(477,564)	0.78		
Outstanding, December 31, 2021	4,996,945	$ 6.05	7.6	$ 58,420
Vested and exercisable as of December 31, 2021	2,098,249	$ 2.22	5.6	$ 32,268
Vested and expected to vest as of December 31, 2021	4,963,575	$ 6.09	7.6	$ 57,895

The weighted-average grant-date fair values of options granted during the year ended December 31, 2021 and 2020 was $11.35 and $2.90 per share, respectively. The aggregate intrinsic value of options exercised were $7.3 million during the year ended December 31, 2021. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying options and the estimated fair value of the common stock on the date of exercise. As of December 31, 2021, the unrecognized stock-based compensation of unvested options was $23.3 million, which is expected to be recognized over a weighted-average period of 3.29 years.

Determination of fair value

The Company estimated the fair value of stock options using the Black-Scholes option-pricing model. The fair value of stock options is recognized on a straight-line basis over the requisite service periods of the awards. The fair value of stock options was estimated using the following weighted-average assumptions:

	Years ended December 31,	
	2021	2020
Expected term (in years)	4.99 – 6.18	5.85-6.08
Expected volatility	56.74% – 61.08%	48.27%-55.64%
Risk-free interest rate	0.47% – 1.33%	0.33%-1.77%
Dividend yield	–	–

Expected Term

The expected term is calculated using the simplified method, which is available if there is insufficient historical data about exercise patterns and post vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant or for each vesting tranche for awards with graded vesting. The midpoint of the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting tranches, the time from grant until the midpoints for each of the tranches may be averaged to provide an overall expected term.

Expected Volatility

The Company used an average historical stock price volatility of a peer group of publicly traded companies to be representative of its expected future stock price volatility, as the Company did not have any trading history for its common stock. For purposes of identifying these peer companies, the Company considered the industry, stage of development, size, and financial leverage of potential comparable companies. For each grant, the Company measured historical volatility over a period equivalent to the expected term.

Risk-Free Interest Rate

The risk-free interest rate is based on the implied yield currently available on US Treasury zero-coupon issues with remaining terms equivalent to the expected term of a stock award.

Expected Dividend Rate

The Company has not paid, and does not anticipate paying, any dividends in the near future. Accordingly, the Company has estimated the dividend yield to be 0%.

Restricted Stock Units

RSUs are share awards that entitle the holder to receive freely tradable shares of the Company's common stock upon vesting. The RSUs cannot be transferred, and the awards are subject to forfeiture if the holder's employment terminates prior to the release of the vesting restrictions. The RSUs generally vest over a four-year period with straight-line vesting in equal amounts on an annual basis, provided the employee remains continuously employed with the Company. The fair value of the RSUs is equal to the closing price of the Company's common stock on the grant date.

The following table summarizes restricted share award activity:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
Outstanding, December 31, 2020	—	$ —
Grants	53,250	22.91
Forfeited/cancelled	—	—
Vested	—	—
Outstanding, December 31, 2021	53,250	$ 22.91

There were no RSUs granted prior to 2021. During the year ended December 31, 2021, the Company recorded stock-based compensation of less than $0.1 million related to the RSUs. As of December 31, 2020, there was $1.2 million of total unrecognized compensation cost related to the RSUs that is expected to be recognized over a weighted-average period of 3.75 years.

Stock Based Compensation

The following is a summary of stock-based compensation expense by function (in thousands):

	Years Ended December 31,	
	2021	2020
Cost of goods sold	$ 71	$ 20
Research and development	495	84
Selling, general and administrative	4,517	393
Total stock-based compensation expense	$ 5,083	$ 497

2021 Employee Stock Purchase Plan

In July 2021, the Board of Directors and stockholders also adopted and approved the 2021 Employee Stock Purchase Plan (the "ESPP"). The Company reserved 850,000 shares of common stock for future issuance under the ESPP.

As of December 31, 2021, no shares of common stock have been purchased under the ESPP.

Note 12. Net Loss per Share Attributable to Common Stockholders

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period. As the Company reported a net loss for the years ended December 31, 2021 and 2020, basic net loss per share is the same as diluted net loss per share as the inclusion of potentially dilutive shares would have been antidilutive if included in the calculation.

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Year Ended December 31,	
	2021	2020
Numerator:		
Net loss attributable to common stockholders	$ (62,960)	$ (34,693)
Denominator:		
Weighted-average shares of common stock outstanding—basic and diluted	26,734,097	9,356,218
Net loss per share attributable to common stockholders—basic and diluted	$ (2.36)	$ (3.71)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the period presented because including them would have been antidilutive:

	December 31,	
	2021	2020
Redeemable convertible preferred stock	—	12,767,202
Redeemable convertible preferred stock warrants	—	329,514
Options to purchase common stock	4,996,945	3,137,776
Restricted stock units	53,250	—
Total	5,050,195	16,234,492

Note 13. Income Taxes

The Company's income tax provision for the years ended December 31, 2021 and 2020, consists of the following (in thousands):

Current

	December 31,	
	2021	2020
Federal	$ —	$ 6
Foreign	16	—
State	172	41
Provision (benefit) for income taxes	$ 188	$ 47

Deferred tax assets and liabilities reflect the net tax effect of temporary differences between carrying value of assets and liabilities for financial reporting purposes and the tax basis of these assets and liabilities as measured by income tax law. The income tax effect of temporary differences that give rise to deferred tax assets and (liabilities) consist of the following (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 35,186	$ 22,208
Deferred compensation	1,812	899
Research and development credits	1,497	1,071
Operating lease liability	405	138
Provision for bad debt	163	75
Provision for excess and obsolete inventories	28	282
Other	104	19
Gross deferred tax assets	39,195	24,692
Less: Valuation allowance	(38,804)	(24,543)
Deferred tax assets, net of valuation allowance	391	149
Operating lease right-of-use assets	(391)	(135)
Fixed Assets	—	(14)
Deferred tax liabilities:	(391)	(149)
Net deferred tax assets	$ —	$ —

Internal Revenue Code (IRC) Section 382 limits the use of federal net operating losses and income tax credit carryforwards in certain situations where changes occur in stock ownership of a company. If the Company should have an ownership change of more than 50% of the value of the Company's capital stock, utilization of the carryforwards could be restricted.

The reconciliation of the statutory federal income tax rate to the Company's effective tax rate is as follows (in thousands):

	December 31,	
	2021	2020
Tax at statutory federal rate	21%	21%
State tax, net of federal benefit	5%	5%
Research and development credit	1%	1%
Change in valuation allowance	) (24%	(27)%
Other	) (3%	—
Effective tax rate	—	—

A valuation allowance is recorded when it is more likely than not that some portion of the deferred tax assets will not be realized. As of each reporting date, the Company's management considers all evidence, both positive and negative, that could affect management's view with regard to future realization of deferred tax assets. As of December 31, 2021 and

2020, a full valuation allowance for deferred tax assets was recorded as management believes it is more likely than not that all of the deferred tax assets will not be realized in the future. At December 31, 2021, and 2020, the Company has a net operating loss carryforward for federal income tax purposes of approximately $136.8 million and $85.3 million, respectively. At December 31, 2021 and 2020, the Company has a net operating loss carryforward for state income tax purposes of approximately $126.6 million and $83.5 million, respectively. Net operating losses prior to 2018 of $14.8 million will expire, if not utilized, beginning in 2032 for federal and state income tax purposes.

As of December 31, 2021 and 2020, the Company has federal research and development income tax credit carryforwards of approximately $1.2 million and $0.8 million, respectively. As of December 31, 2021 and 2020, the Company has state research and development income tax credit carryforwards of approximately $0.9 million and $0.9 million, respectively. The Federal income tax credits begin to expire in 2032. The Company has a full valuation allowance on research and development tax credits as of December 31, 2021 and 2020. The state research and development credits can be carried forward indefinitely. The total amount of uncertain tax positions (UTP) on research and development tax credits is $0.6 million and $0.4 million as of December 31, 2021 and 2020, respectively. The Company does not expect any significant change to the UTP balances in the next 12 months.

The following table summarizes the activity related to the unrecognized tax benefits (in thousands):

	December 31,	
	2021	2020
Unrecognized tax benefits at the beginning of the year	$ 417	$ 304
Additions based on tax positions related to the current year	163	113
Additions for tax positions of prior years	—	—
Unrecognized tax benefits at the end of the year	$ 580	$ 417

The Company does not have any material uncertain tax positions as of December 31, 2021 and does not expect any significant change to such balances in the next twelve months.

The Company currently has no federal or state tax examinations in progress nor has it had any federal or state tax examinations since its inception. Due to the history of net operating losses, the Company's federal and state tax returns remain open to examination by the tax authorities.

Note 14. Segment Information

The Company has two reportable operating segments which are determined on the basis of product portfolio: Surgical Glaucoma and Dry Eye. The operating and reportable segments were determined based on how the Company's Chief Executive Officer, its Chief Operating Decision Maker ("CODM"), views and evaluates the Company's operations. The CODM allocates resources to and evaluates the financial performance of each operating segment primarily based on gross profit and gross profit margin.

Surgical Glaucoma segment includes sales of the Company's OMNI® Surgical System for use in minimally invasive glaucoma procedures. Dry Eye segment includes sales of the Company's TearCare® System and related components.

The following table summarizes select operating results information for each reportable segment (dollars in thousands):

	Year Ended December 31,	
	2021	2020
Revenue		
Surgical Glaucoma	$ 46,496	$ 26,000
Dry Eye	2,460	1,640
Total	48,956	27,640
Cost of goods sold		
Surgical Glaucoma	6,473	7,069
Dry Eye	2,137	2,140
Total	8,610	9,209
Gross profit		
Surgical Glaucoma	40,023	18,931
Dry Eye	323	(500)
Total	40,346	18,431
Operating expense	91,824	50,619
Loss from operations	(51,478)	(32,188)
Interest income	—	30
Interest expense	(4,366)	(2,403)
Other expense, net	(6,928)	(71)
Loss before income tax	$ (62,772)	$ (34,632)

The Company does not allocate any income and expenses beyond revenue and cost of goods sold to the reportable operating segments in its reporting to the CODM. No asset information is provided for reportable operating segments because they are not reviewed by the CODM on segment basis. Substantially all of the Company's revenue is generated from sales in the United States.

Note 15. Subsequent Events

The Company evaluated subsequent events through March 24, 2022, the date on which the condensed consolidated financial statements were available for issuance.

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

None.

Item 9A. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our management, with the participation and supervision of our principal executive officer and our principal financial officer, evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and our principal financial officer concluded that as a result of the material weaknesses in our internal control over financial reporting described below, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were not effective. However, our management, including our principal executive officer and our principal financial officer, has concluded that, notwithstanding the identified material weaknesses in our internal control over financial reporting, the condensed consolidated financial statements in this Annual Report on Form 10-K fairly presented, in all material respects, our financial position, results of operations, and cash flows for the periods presented in conformity with GAAP.

Remediation efforts on previously reported material weaknesses

In connection with the preparation of our financial statements in connection with our IPO, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness related to a lack of sufficient full-time accounting personnel with requisite experience and deep technical accounting knowledge to (i) identify and resolve complex accounting issues under GAAP, and (ii) enable appropriate segregation of duties and reviews over the financial reviews over the financial close and reporting process.

We have implemented and are in process of implementing additional measures to improve our internal control over financial reporting to remediate this material weakness, including (i) the hiring of personnel with technical accounting and financial reporting experience and (ii) the implementation of improved accounting and financial reporting procedures and systems to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including the assessment of more judgmental areas of accounting. We are committed to continuing to improve our internal control processes and we will continue to diligently and vigorously review our financial reporting controls and procedures.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. While we believe that our efforts have improved our internal control over financial reporting, remediation of the material weaknesses will require further validation and testing of the design and operating effectiveness of internal controls over a sustained period of financial reporting cycles, and we cannot assure you that we have identified all, or that we will not in the future have additional material weaknesses.

Changes in internal control over financial reporting

Other than the changes intended to remediate the material weakness noted above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Paul Badawi is a co-founder of our Company and has served as our Chief Executive Officer and a member of our Board since the Company was founded in 2011. Prior to launching Sight Sciences, Paul led the U.S. healthcare venture capital practice for 3i Group, a global private equity firm.

David Badawi, M.D. is a co-founder of our Company and has served as our Chief Technology Officer and a member of our Board since the Company was founded in 2011. Since 2012, Dr. Badawi has also served as the president and a practicing ophthalmologist at Central Eye Care Ltd, an ophthalmology practice.

Jesse Selnick has served as our Chief Financial Officer since January 2018. From March 2012 to March 2017, Mr. Selnick served as the Chief Financial Officer and a member of the board of Electric Lightwave (previously known as Integra Telecom), a telecom infrastructure company, until its purchase by Zayo Group Holdings, Inc. in March 2017. Prior to that, Mr. Selnick worked at The Blackstone Group from 2003 to February 2012, where he most recently served as Managing Director.

Shawn O'Neil has served as our Chief Commercial Officer since October 2017. From October 2003 to October 2017, Mr. O'Neil held various leadership positions at Alcon, Inc., a global leader in eye care, where he most recently served as the Head of Sales and Marketing, Surgical Glaucoma.

Sam Park has served as our Chief Operating Officer since March 2020. From March 2016 to May 2019, Mr. Park served as the founder and Chief Executive Officer of Park Medical, a medical device company.

Jeremy Hayden has served as our Chief Legal Officer since April 2020. From August 2017 to April 2020, Mr. Hayden served as General Counsel of Endologix, Inc. Prior to that, Mr. Hayden served as General Counsel and Vice President, Business Development at Cytori Therapeutics, Inc. from July 2015 to August 2017 and from May 2012 to July 2015 he served as Assistant General Counsel at Volcano Corporation, a publicly traded medical device company that was acquired by Royal Phillips in 2015.

Staffan Encrantz has served as a member of our Board since 2017. Mr. Encrantz is the President of Allegro Investment Inc., the investment manager of Allegro Investment Fund, L.P. Mr. Encrantz holds a law degree from Uppsala University, Sweden.

Mack Hicks has served as a member of our Board since 2011. Since 2007, Mr. Hicks has been a Partner of Hicks Holdings LLC, an investment company. Prior to that, Mr. Hicks served as a research analyst at Halcyon Asset Management from 2005 to 2006 and worked at Credit Suisse in 2004.

Brenda Becker has served as a member of our Board since March 2022. Since 2007, Ms. Becker has served as Senior Vice President of Global Government Affairs at Boston Scientific. Prior to joining Boston Scientific, Ms. Becker served in the Bush administration for six years where she held the position as Assistant to the Vice President for Legislative Affairs and held various leadership positions over 20 years at Blue Cross Blue Shield.

Erica Rogers has served as a member of our Board since November 2019. Since October 2012, Ms. Rogers has served as President and Chief Executive Officer and a member of the board of Silk Road Medical, a medical device company. Ms. Rogers is also a director of Lucira Health, a diagnostics company, and currently serves as an advisor to Alydia Health and Venture Investors.

Valeska Schroeder, Ph.D. has served as a member of our Board since 2019. Since 2016, Dr. Schroeder has served as a Managing Director of KCK Medical Technologies, a single family evergreen fund that invests in medical technologies. From March 2014 to July 2016, Dr. Schroeder served as Senior Vice President, Product Management of Vital Connect, Inc., a wearable biosensor technology company.

Donald Zurbay has served as a member of our Board since July 2020. Since June 2018, Mr. Zurbay has served as the Chief Financial Officer of Patterson Companies, a global medical device company. Before that, from March 2004 to February 2017, Mr. Zurbay held various leadership positions at St. Jude Medical, Inc., where he most recently served as Vice President and Chief Financial Officer from August 2012 to January 2017.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics, or the Code of Business Conduct and Ethics, that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Our Code of Business Conduct and Ethics is available on our website at *www.sightsciences.com* in the "Corporate Governance" section of the "Investors" page. In addition, we intend to post on our website all disclosures that are required by law concerning any amendments to, or waivers from, any provision of our Code of Business Conduct and Ethics

The remaining information required by this item will be included in our definitive proxy statement for our 2022 Annual Meeting of Stockholders, or the 2022 Proxy Statement, to be filed with the SEC no later than 120 days after December 31, 2021, and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be included in the 2022 Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be included in the 2022 Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be included in the 2022 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be included in the 2022 Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) (1) Financial Statements

Report of Independent Registered Public Accounting Firm

Balance Sheets

Statements of Operations and Comprehensive Loss

Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

Statements of Cash Flows

Notes to Financial Statements

(2) Financial Statement Schedules

All financial statement schedules are omitted because they are not applicable or the amounts are immaterial or the required information is presented in the financial statements and notes thereto.

(3) Exhibits: see Exhibit Index submitted as a separate section of this report

(b) Exhibits

See Exhibit Index submitted as a separate section of this report

(c) Not applicable

Item 16. Form 10-K Summary

None.

Exhibit Index

Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
3.1	Restated Certificate of Incorporation of Sight Sciences, Inc.	8-K	001-40587	3.1	07/19/2021	
3.2	Amended and Restated Bylaws of Sight Sciences, Inc.	8-K	001-40587	3.2	07/19/2021	
3.3	Form of Restated Certificate of Incorporation of the Registrant	S-1/A	333-257936	3.3	07/08/2021	
4.1	Third Amended and Restated Investors' Rights Agreement, dated as of November 23, 2020, as amended	S-1/A	333-257320	4.1	07/08/2021	
4.2	Specimen Stock Certificate evidencing the shares of common stock	S-1/A	333-257320	4.2	07/08/2021	
4.3	Form of Warrant to Purchase Stock	S-1	333-257320	4.3	06/23/2021	
4.4	Description of Capital Stock					*
10.1	2011 Stock Incentive Plan, as amended, and U.K. sub-plan and forms of agreements thereunder	S-1	333-257320	10.1	6/23/2021	
10.2	2021 Incentive Award Plan and form of option agreements thereunder	S-1/A	333-257320	10.2	07/08/2021	
10.3	Non-Employee Director Compensation Program	S-1/A	333-257320	10.3	07/08/2021	
10.4	2021 Employee Stock Purchase Plan	S-1/A	333-257320	10.4	07/08/2021	
10.5#	Form of Indemnification Agreement for Directors and Officers	S-1/A	333-257320	10.5	07/08/2021	
10.6#	Employment Agreement between Sight Sciences, Inc. and Paul Badawi, dated July 7, 2021	S-1/A	333-257320	10.11	07/08/2021	
10.7#	Employment Agreement between Sight Sciences, Inc. and Shawn O'Neil, date July 7, 2021	S-1/A	333-257320	10.12	07/08/2021	
10.8#	Employment Agreement between Sight Sciences, Inc. and Sam Park, dated July 7, 2021	S-1/A	333-257320	10.13	07/08/2021	
10.9#	Employment Agreement between Sight Sciences, Inc. and David Badawi, M.D., dated July 7, 2021	S-1/A	333-257320	10.14	07/08/2021	
10.10	Multi-Tenant Space Lease, dated as of February 5, 2021, between Sight Sciences and Deerfield Campbell, LLC.	S-1	333-257320	10.7	06/23/2021	
10.11	First Amendment to the Amended and Restated Credit and Security Agreement (Revolving Loan), dated October 5, 2021	10-Q	001-40587	10.1	11/10/2021	
10.12	First Amendment to the Amended and Restated Credit and Security Agreement (Term Loan), dated October 5, 2021	10-Q	001-40587	10.2	11/10/2021	
10.13	Second Amendment to the Amended and Restated Credit and Security Agreement (Revolving Loan), dated November 15, 2021					*
10.14	Second Amendment to the Amended and Restated Credit and Security Agreement (Term Loan), dated November 15, 2021					*
10.15	First Amendment to Supply Agreement by and between Sight Sciences, Inc. and Peter's Technology (Suzhou) CO. LTD. dated as of January 28, 2022					*
21.1	Subsidiaries of Sight Sciences, Inc.					*
23.1	Consent of Deloitte & Touche, LLP					*
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a)					*

31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a)	*
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350	**
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350	**
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	*
101.SCH	Inline XBRL Taxonomy Extension Schema Document	*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	*

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* Filed herewith.

** Furnished herewith.

# Indicates a management or compensatory plan

SIGNATURES

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

SIGHT SCIENCES, INC.

Date:

By: /s/ Paul Badawi
Paul Badawi
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name and Signature	Title	Date
/s/ Paul Badawi **Paul Badawi**	President, Chief Executive Officer and Director (principal executive officer)	March 24, 2022
/s/ Jesse Selnick **Jesse Selnick**	Chief Financial Officer (principal financial officer and principal accounting officer)	March 24, 2022
/s/ Staffan Encrantz **Staffan Encrantz**	Chairman of the Board of Directors	March 24, 2022
/s/ David Badawi **David Badawi, M.D.**	Director	March 24, 2022
/s/ Mack Hicks **Mack Hicks**	Director	March 24, 2022
/s/ Brenda Becker **Brenda Becker**	Director	March 24, 2022
/s/ Erica Rogers **Erica Rogers**	Director	March 24, 2022
/s/ Valeska Schroeder **Valeska Schroeder, Ph.D.**	Director	March 24, 2022
/s/ Donald Zurbay **Donald Zurbay**	Director	March 24, 2022