UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

OR

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

For the transition period from to

Commission File Number 001-40690

RxSight, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**94-3268801**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
100 Columbia Aliso Viejo, California	**92656**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (949) 521-7830

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value per share	RXST	The Nasdaq Stock Market LLC

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

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

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

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

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

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

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

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

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

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

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

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

As of June 30, 2022, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $310 million based upon the closing price of $14.08 on the Nasdaq Global Market on such date.

The number of shares of registrant's Common Stock outstanding as of February 15, 2023 was 33,775,718.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with the registrant's 2023 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2022. Except with respect to information specifically incorporated by reference, the Proxy Statement is not deemed to be filed as part of this Annual Report on Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The following discussion and analysis should be read together with our consolidated financial statements and the notes to those statements included elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are based on our management's beliefs and assumptions and on information currently available to our management. In this Annual Report on Form 10-K, "we," "us" and "our" refer to RxSight, Inc.

The forward-looking statements are contained principally in the section entitled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of this Annual Report on Form 10-K. Forward-looking statements include, but are not limited to, statements concerning the following:

- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements, including our expectation that we do not anticipate the need to raise additional capital or incur additional debt in order to reach profit from operations, as disclosed in the Company's future Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q as filed with the Securities and Exchange Commission ("SEC"), provided that we may opportunistically access our at-the-market ("ATM") facility under advantageous circumstances;
- our plans to conduct further clinical trials and any expectations related to such trials;
- our plans and expected timeline related to our products, or developing new products, to address additional indications or otherwise;
- the expected acceptance and use of our products by doctors;
- our ability to obtain, maintain and expand regulatory clearances for our products and any new products we create;
- the expected growth of our business and our organization;
- our intentions regarding investment in our business as we pursue growth;
- our expected uses of our existing resources;
- our ability to retain and recruit key personnel, including the continued development of a sales and marketing infrastructure;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers, including single- and sole-source suppliers;
- our ability to manufacture sufficient quantities of our products with appropriate quality;
- our ability to obtain, maintain and enforce intellectual property protection for our products and protect our intellectual property rights;
- our ability to expand our business into new geographic markets;
- our ability to comply with applicable SEC rules and Nasdaq continued listing requirements;
- our ability to comply with existing and future government laws, rules and regulations both in the U.S. and internationally;
- our expectations regarding allocation of resources toward expenses associated with being a public company;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing;

- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") and a smaller reporting company under the Exchange Act;
- the volatility of the trading price of our common stock;
- our ability to identify and develop new and planned products and/or acquire new products;
- development and projections relating to our competitors or our industry, including anticipated growth rates for the conventional and premium intraocular lens ("IOL") markets;
- the impact of local, regional, national or political conditions and events;
- the impact of the COVID-19 pandemic, including currently known and unknown coronavirus variants, on our business or personnel; and
- the impact of worldwide political and economic conditions and unknown future events could have a material adverse impact on our business, financial condition and results of operations.

Forward-looking statements include statements that are not historical facts and can be identified by terminology such as "may," "will," "should," "could," "would," "expects," "plans," "intends," "anticipates," "believes," "estimates," "predicts," "projects," "potential," or "continue," or the negative of such terms and other same terminology.

Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in Part I, Item 1A, "Risk Factors," elsewhere in this Annual Report on Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for us to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Annual Report on Form 10-K may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking 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. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

DISCUSSION AND ANALYSIS OF OUR FINANCIAL CONDITION

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates including those related to revenue recognition, the realization of income tax assets and estimates of tax liabilities, and obsolete, excess and slow-moving inventory. We base our estimates on historical experience and on various other assumptions we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ materially from these estimates.

INDUSTRY, BUSINESS AND MARKET DATA

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and market opportunity, including data regarding the estimated size of the market. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

TRADEMARKS, SERVICE MARKS AND TRADE NAMES

This Annual Report on Form 10-K contains references to trademarks and service marks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that the applicable licensor will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of it by, any other companies.

PART I

Item 1. Business

Overview

We are a commercial-stage medical technology company dedicated to improving the vision of patients following cataract surgery. Our proprietary RxSight® Light Adjustable Lens system ("RxSight system") is the first and only commercially available premium cataract technology that enables doctors to customize and optimize visual acuity for patients after surgery. The RxSight system is comprised of our RxSight Light Adjustable Lens® ("LAL®"), RxSight Light Delivery Device ("LDD™") and accessories. Our LAL is a premium intraocular lens ("IOL") made of proprietary photosensitive material that changes shape in response to specific patterns of ultraviolet ("UV") light generated by our LDD.

We designed our RxSight system to address the shortcomings of competitive premium IOL technologies and provide a solution that doctors can trust to improve visual outcomes and achieve high levels of patient satisfaction. Competitive premium IOLs require patients to specify their visual priorities before surgery and be willing to accept various optical trade-offs associated with those choices. Once a patient has selected a competitive premium IOL, the surgeon must rely on a series of preoperative diagnostic tests and predictive formulae to choose the appropriate lens power. If the doctor's prediction is suboptimal, then the patient may experience suboptimal results that could necessitate a subsequent corneal refractive procedure or certain other compromises in order to reach vision targets.

In contrast, with the RxSight system, the surgeon implants the LAL as they would in any other cataract procedure, determines refractive error with patient input several weeks following surgery and then uses the LDD to modify the LAL with the precise visual correction needed to achieve the patient's desired vision outcomes. We believe our RxSight system provides doctors and patients increased confidence and peace of mind by eliminating the high-stakes preoperative guesswork common to competitive premium IOLs and allowing patients to iterate their final vision characteristics with customized post-surgical adjustments.

A cataract is the loss of transparency in the eye's natural lens, which causes blurry or hazy vision and can eventually lead to blindness. Approximately 50% of all individuals develop some form of cataracts by age 60, usually in both eyes, and prevalence increases with age. Among the world's most commonly performed procedures, cataract surgery involves removing the cloudy natural lens and replacing it with a clear IOL. Prior to surgery, patients can opt for either a spherical monofocal IOL, which usually results in improved vision but requires glasses for best vision, or a premium IOL, which also corrects for astigmatism and/or presbyopia, thereby reducing spectacle dependence. In the United States, Medicare and private insurers typically cover the full cost of spherical IOL procedures, while premium IOL procedures require patients to pay an incremental out-of-pocket fee, typically ranging from $1,000 to $4,000 per eye depending on the specific premium IOL used. In the United States, the world's largest premium IOL market, 2022 premium procedures represented about 25% of all cataract procedures and generated approximately $760 million in revenue, a figure that is projected to grow at a 12% compound annual growth rate ("CAGR") by 2027, according to the Market Scope 2022 Premium Cataract Surgery Market Report.

We believe that the premium cataract surgery market remains underpenetrated due to both doctors' reluctance to recommend competitive premium IOLs to the full universe of eligible patients and patients' confusion in assessing the associated trade-offs and side effects with competitive premium IOLs. We believe competitive premium IOLs often fail to deliver on patients' expectations for quality vision across a range of distances without glasses. In our most recent Phase IV commercial data over 90% of patients were able to achieve 20/20 or better at distance without glasses, which is approximately twice the rate of any of the alternative IOLs. In addition, over 90% of patients were also able to read 5-point font at near vision, which is typically the size of footnotes on a page.

We believe our RxSight system offers doctors and patients a significantly more reliable approach that can consistently deliver optimal, fully customized visual outcomes with few compromises, ultimately driving broad adoption and establishing it as the standard of care for premium cataract procedures. The key benefits of our solution include:

- **Allowing full customization and optimization of patient vision after surgery.** Our LAL uses a proprietary silicone formulation that enables changing the mechanical and optical properties of the lens following implantation. Our LDD uses proprietary software and algorithms to deliver a short UV light exposure treatment that polymerizes specific portions of the lens and allows doctors to adjust spherical and cylindrical refraction in 0.25 diopter increments, similar to the adjustment increments used to refract patients for glasses or contact

lenses, as well as in other refractive procedures like LASIK. All other premium IOLs are fixed-power lenses that cannot be adjusted following surgery;

- **Delivering superior visual outcomes with low risk of side effects.** In our Food and Drug Administration ("FDA") clinical trial, 70% of LAL patients achieved 20/20 or better uncorrected visual acuity without glasses, while in similar trials of other premium IOLs, only about 40% of patients achieved this performance level. Additionally, LAL patients do not experience increased incidence of glare or halos that are common with other premium IOLs;

- **Providing accuracy and precision to optimize vision with both eyes.** Most LAL patients choose minor differences in the refractive correction of each eye, resulting in glasses-free vision across a full range of distances. In our most recent Phase IV commercial study data over 90% of patients were able to achieve 20/20 or better at distance without glasses, which is approximately twice the rate of any of the alternative IOLs. In addition, over 90% of patients were also able to read 5-point font at near vision, which is typically the size of footnotes on a page;

- **Enabling patients to preview and compare possible vision outcomes.** LAL patients are the only premium IOL patients able to test-drive their vision after surgery but before selecting a final refractive outcome. With up to three possible UV light treatments to adjust the LAL, patients direct their optimal visual acuity through an interactive and iterative process; and

- **Empowering doctors to grow their practices with a premium IOL they can trust and confidently recommend.** Our RxSight system has been shown to deliver excellent visual outcomes across a broad range of patient types and preferences. In our 2022 RxSight customer survey, 89% of respondents said they thought our RxSight system delivered the highest quality vision, 98% said they would recommend the LAL to others and 75% said they would select it for their own eyes.

Our commercial efforts began in 2019 and have been primarily focused in the United States, where we are building a "razor and razor blade" business model to drive new customer adoption and ongoing LAL volume growth. Our U.S. commercial organization includes a direct sales team of LDD sales personnel and LAL account managers, as well as clinical specialists, field service engineers and marketing personnel. Our sales efforts are concentrated on the roughly 3,000 U.S. cataract surgeons that perform 70%-80% of all premium IOL procedures. As of December 31, 2022, we had established an installed base of 400 LDDs in ophthalmology practices and, since our inception though December 31, 2022, surgeons have implanted over 42,000 LALs.

We plan to grow our business primarily by expanding the size of our LDD installed base and driving increased utilization of our LAL through heightened awareness of the superior clinical outcomes our RxSight system provides patients. To continue to strengthen our competitive position in the premium IOL market, our research and development activities are focused primarily on programs that improve clinical outcomes, improve customer experience, expand our indications for use, reduce manufacturing costs and lifecycle management.

Our market and industry

Cataracts and other common vision conditions

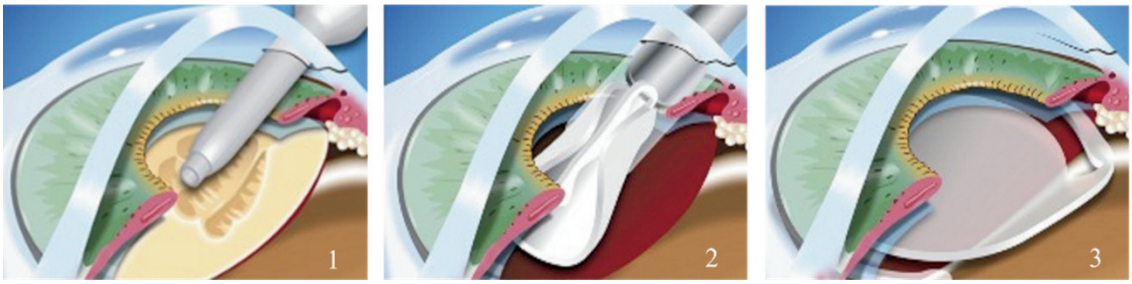
Common vision conditions can be roughly divided by two defining factors: 1) the typical age of onset and 2) whether the condition is more closely linked to the cornea, the front surface of the eye that controls about two-thirds of its focusing ability, or the natural lens, which sits behind the iris and is responsible for the eye's remaining focusing power. From childhood through the fourth decade of life, refractive conditions related primarily to the cornea – myopia, hyperopia and astigmatism – typically have the greatest impact on visual acuity and are usually addressed with glasses and contact lenses. In adults with these conditions, corneal procedures like LASIK can reduce dependence on glasses and contact lenses.

By age 50, most people also experience presbyopia, which manifests itself as increased difficulty seeing at near and intermediate distances without glasses or contact lenses. Presbyopia occurs because the natural lens is losing its elasticity and, therefore, its ability to focus light rays on near objects. By age 60, approximately half of all individuals also develop some form of cataracts, in which the normally clear lens loses its transparency and increasingly obstructs or otherwise interferes with the passage of light to the retina. The result is blurry or hazy vision and increased sensitivity to light, particularly at night, that cannot be treated with glasses or contact lenses. Cataracts are irreversible, progressive and usually affect both eyes. Cataracts can significantly interfere with daily activities, affect quality of life and eventually cause

blindness. According to the National Eye Institute, despite the availability of effective surgical treatment, cataracts are the leading cause of blindness worldwide.

Cataract surgery

Cataract surgery is among the most common surgical procedures performed in the world and involves replacement of the patient's natural cloudy lens with a clear artificial IOL. In the United States, the procedure is commonly performed in an outpatient setting, such as an Ambulatory Surgery Center ("ASC"), by an ophthalmologist specializing in cataract surgery and often requires only 5 to 15 minutes to complete. In most cases, surgery begins with removal of the cataractous lens through a process known as phacoemulsification. During phacoemulsification, the ophthalmic surgeon makes a small surgical incision in the cornea and inserts an ultrasonic probe that breaks up, or emulsifies, the lens while a hollow needle removes the pieces of the lens (see image 1 below). After the cataract is removed, the surgeon inserts the replacement IOL through the same surgical incision (see image 2 below). Following implantation, the IOL sits firmly in place just behind the iris (see image 3 below).



Conventional vs. premium cataract surgery

Cataract surgery is often bifurcated into two categories based on IOL type, as follows:

- ***Conventional:*** The patient receives a monofocal IOL, which is designed to provide vision at one pre-defined distance without correction for other visual problems that often affect cataract surgery patients such as corneal astigmatism and presbyopia. Nearly all patients undergoing conventional cataract surgery will need to rely on glasses following cataract surgery to achieve the best distance, intermediate and near vision.

- ***Premium:*** The patient receives a premium IOL, which is designed to address the shortcomings of conventional monofocal lenses by also correcting for the additional visual problems of astigmatism and/or presbyopia. Premium IOLs reduce the need for glasses relative to conventional IOLs but may impose trade-offs related to their ability to provide glasses-free near, intermediate and distance vision, as well as the potential for increased incidence of halos, glare and other side effects related to monofocal IOLs.

Healthcare payors typically cover the full cost of conventional cataract procedures. In the United States, a healthcare payor (primarily Centers for Medicare and Medicaid Services ("CMS")) typically provides reimbursement for a conventional cataract procedure of approximately $500 for a surgeon fee and approximately $1,000 for a facility fee, which includes the cost of a conventional monofocal IOL. Accounting for reductions in CMS reimbursement and for inflation, reimbursement

rates have decreased by two thirds since 1991. The surgeon fee covers all pre-operative cataract testing, the cataract operation and follow-up care for three months.

For U.S. premium cataract procedures, the healthcare payor (primarily CMS) reimburses the same surgeon and facility fees, but the patient pays the surgeon an additional fee between $1,000-$2,000 for implantation of a toric IOL and an average between $2,000-$4,000 for implantation of other premium lenses, which includes the cost of the premium IOL. Consequently, premium cataract procedures are between 10 and 15 times more profitable for the doctors and ophthalmology practices than conventional cataract procedures and are less impacted by changes in reimbursement rates. At the same time, because premium cataract patients pay an additional out-of-pocket fee, they tend to have high expectations that the surgeon will satisfy their desire for quality, glasses-free vision.

Our market opportunity

According to the Market Scope 2022 Premium Cataract Surgery Market Report and 2022 Market Scope IOL Report:

- Approximately 28 million cataract surgeries were performed globally in 2022, including 4.6 million in the United States. The number of procedures worldwide is projected to grow at a CAGR of 6.3% to over 38 million by 2027. In the United States, procedures are expected to grow at a CAGR of 4.3% to 5.3 million by 2027;
- The United States is the world's largest premium IOL market. In 2022, premium IOL procedures represented approximately 25% and 12% of cataract surgeries in the United States and worldwide, respectively;
- In 2022, premium IOL revenue was approximately $2.1 billion globally and $760 million in the United States, and is expected to grow at a CAGR of 13% and 12%, respectively, through 2027. Key growth drivers include the increasing number of patients who prefer to be glasses-free, technological innovations, increased access to healthcare and rising disposable income; and
- In the United States, there are approximately 10,000 ophthalmic surgeons that perform cataract surgery, including approximately 3,000 that perform roughly 70%-80% of premium IOL cataract procedures.

We believe there is an opportunity to gain market share in the premium IOL market segment and also increase the penetration of premium IOLs in the broader market by converting doctors and patients currently electing for conventional cataract surgery. We believe that the premium cataract surgery market remains underpenetrated due to both doctors' reluctance to recommend premium IOL offerings to the full universe of eligible patients and patients' confusion in assessing the trade-offs associated with the wide range of commercially available premium IOL offerings. Furthermore, we believe current non-adjustable premium IOL offerings often cannot deliver on patient expectations regarding their desire to see at near, intermediate and far distances without reliance on glasses and to avoid troubling side effects such as glare, halos and loss of contrast sensitivity.

We are currently focused on driving awareness and penetration of our RxSight system in the premium cataract market, and primarily concentrating our near-term commercial efforts on the United States. We believe the United States is the most compelling market given the large population of individuals over the age of 60 that are covered by health insurance, the concentrated base of cataract surgeons experienced with premium IOL offerings, the high gross domestic product per capita and the favorable U.S. healthcare reimbursement system, which has a well-established history of covering a portion of the cost for cataract surgery.

Non-adjustable premium IOLs and their limitations

Prior to the commercial availability of our RxSight system, doctors and patients chose from two primary types of premium IOLs, as follows:

- **Multifocal Lenses.** Multifocal lenses have two or more corrective zones, which allow the patient to receive focused light from different distances. Although multifocal lenses provide patients with a wider range of vision compared to the standard monofocal IOLs, multifocal lenses split light across the multiple corrective zones on the lens, sometimes impacting visual quality. For example, approximately two to three times as many patients who choose a multifocal lens over a monofocal lens experience side effects such as glare and halos, as well as reduced contrast vision, which are especially problematic in low light situations such as driving at night. For some patients these become more pronounced and can lead to explantation (removal of the IOL and replacement with another type of IOL). Extended-depth-of-focus ("EDOF") lenses are similar to multifocals, except they have

only one corrective zone. They create an elongated focal point that allows for a broader range of vision, although patients will still often require glasses for distance and near vision. EDOF lenses will still typically result in glare and halos, as well as reduced contrast vision, although generally less severe than those experienced with multifocal lenses; and

- **Astigmatism-Correcting or Toric Lenses.** Toric lenses correct for astigmatism, a condition in which the cornea is not uniformly curved leading to distortion of near and distance vision. According to the 2022 Market Scope IOL Report, approximately 70% of the population has clinically significant astigmatism of 0.5 diopters or more. Corrective toric lenses can provide additional distance, intermediate or near vision correction depending on the power of the lens selected and if their optical design incorporates either multifocal or EDOF features.

When preparing patients for premium cataract surgery, surgeons must have a comprehensive understanding of available premium IOL options and how to best match a patient to the technology that fits their priorities. Patient decisions are based on several factors and tend to be heavily influenced by surgeon recommendations, as well as the patient's motivation for independence from glasses and willingness to tolerate side effects. During an initial consultation, surgeons often ask patients to fill out a survey regarding their vision experiences and expectations to determine if the patient is a good premium IOL candidate. If so, the surgeon helps select the appropriate premium IOL based on the patient's lifestyle and the type of vision they most value (i.e., near, intermediate or distance). Significant time is often required to educate patients on the various trade-offs with respect to the visual outcomes associated with each type of premium IOL. Following this consultation, surgery is usually scheduled within several weeks or months.

Prior to surgery, the patient's eyes are measured using one or more diagnostic devices to help the surgeon predict the lens focusing power best suited to achieve the optimal postoperative outcome. Focusing power, expressed in diopters (D), refers to how a lens focuses light to a point (spherical power) or a line (cylindrical or astigmatic power). Accurately predicting lens power is critical to reducing postoperative residual refractive error and delivering the best possible visual outcomes. Because the lens power of competitive premium IOLs cannot be changed after implantation, doctors rely on a series of preoperative diagnostic tests and predictive formulae to determine the lens power. Typically, the patient returns a day after surgery to have their eye evaluated and ensure healing is underway. After approximately one month, premium cataract patients that are dissatisfied with their results may be fitted for glasses or elect to undergo a secondary, remedial procedure to meet desired vision targets. A separate LASIK procedure is the most common surgical procedure to correct any residual visual errors following the cataract procedure.

A key limitation of these competitive premium IOLs is that they cannot be adjusted after the surgery and, as such, require the patient to commit to a desired visual outcome prior to the procedure. However, in discussing vision optimization options with patients ahead of the procedure, it can be difficult to effectively demonstrate different visual outcomes. Once a premium IOL is selected, another key limitation is the ability of the surgeon to precisely predict the correct lens power and then implant the IOL with the level of accuracy required to deliver the patient's expected outcome. Additionally, the incision made to remove the cloudy lens and insert the IOL along with the resultant healing process often creates additional levels of astigmatism, which cannot be predicted with precision before cataract surgery.

We believe that the need to commit to a visual outcome before surgery combined with the limited ability to make adjustments following the procedure are key factors contributing to the low levels of premium IOL penetration. When expectations regarding postoperative visual acuity and independence from glasses are not met, patients are often disappointed. As a result, even though 60% of cataract patients rate "being glasses free after cataract surgery" as extremely important, surgeons are often hesitant to recommend existing premium IOLs to their patients.

Our solution

We designed our RxSight system to address the shortcomings of existing premium IOL technologies and provide a solution that doctors can trust to improve visual outcomes and achieve high levels of patient satisfaction. We began commercializing our solution in the United States in 2019 and are focused on establishing the RxSight system as the standard of care for premium IOL procedures. As of December 31, 2022, we had an installed base of 400 LDDs in ophthalmology practices, and since our inception over 42,000 surgeries have been performed with our RxSight system.

Overview of the RxSight system

Our RxSight system is the first and only FDA-approved IOL technology that enables doctors to customize and optimize visual acuity for patients after cataract surgery. With the RxSight system, the doctor performs a standard cataract procedure to implant the LAL, determines refractive error with patient input after healing is complete, then uses the LDD to reshape the

LAL to achieve the patients' desired vision outcomes. Our RxSight system is comprised of two key components, along with other intraoperative and postoperative accessories:

- **RxSight Light Adjustable Lens:** The LAL is our proprietary IOL that can be adjusted postoperatively to improve uncorrected visual acuity. Our IOL is made of special photosensitive material that changes shape and power when a specific pattern of UV light is delivered from the LDD.
- **RxSight Light Delivery Device:** The LDD is our proprietary office-based light treatment device that delivers UV light in a precisely programmed pattern to induce a predictable change in the shape and refractive properties of the LAL, enabling surgeons to precisely modify the LAL based on the visual correction needed to achieve the patient's desired vision after cataract surgery.

Light Adjustable Lens (LAL)

Light Delivery Device (LDD)

Our foundational technology

We have developed our RxSight system over the last 20 years, incorporating expertise and proprietary technologies across multiple disciplines, including optics, material science, chemistry, software and hardware engineering. The proprietary RxSight technology that enables post-operative adjustability is based on the principles of photochemistry. The LAL is made of a photosensitive material that changes shape and power when a specific pattern of UV light is delivered to the LAL.

Our LAL, which we manufacture using our proprietary silicone formulation, leverages the unique material properties of silicone. A silicone molecule consists of an inorganic silicon-oxygen backbone, which is a chain of alternating silicon and oxygen atoms with an attached side group, which is a pair of organic molecules bonded to each silicon atom in the chain. Through a process called polymerization, silicone monomers (short chain molecules) are reacted together to form silicone polymers (long chain molecules), which may be cross-linked at multiple points resulting in three-dimensional, rather than linear, structures. By varying chain length, attached side group and cross-linking design, silicone polymers can be tailored to have unique properties, leading to their broad use across a wide array of applications. We have developed a novel application of silicone to optimize the mechanical and optical properties of IOLs in order to improve vision in patients following cataract surgery.

To create the LAL, we use a composition of silicone polymers and monomers, the latter which we call "macromers" mixed with photo-active molecules and other compounds. The initial composition of our lens material is a viscous liquid that is thermally cured in a lens mold. Thermal curing and photopolymerization use temperature and ultraviolet light, respectively, to initiate and propagate a polymerization reaction. To avoid polymerizing the macromers in the composition, the thermal curing is performed at a low temperature. The partial polymerization of the LAL results in a solid but soft silicone lens, leaving the photosensitive macromers unpolymerized and distributed throughout the lens. While the resulting lens is optically clear, the macromers and photo-active molecules remain free to continuously move within the lens.

After packaging and sterilization, the LAL is ready to be implanted as part of a standard cataract surgical procedure to replace the patient's natural lens. Once wound healing is complete, a short exposure of UV light is applied to the LAL to adjust the refractive properties of the lens. When the UV light is directed to a specific portion of the lens, the exposed macromers in that portion of the lens are polymerized and become stationary. This creates an excess concentration of free macromers in the unexposed portion of the lens and sets up a diffusion gradient over which the unpolymerized macromers move from the concentrated area to the less concentrated area. Over the next one to two days, the unpolymerized macromers

redistribute across the lens to achieve a uniform distribution. The redistribution of the macromers causes the exposed portion of the lens to swell relative to the unexposed portion of the lens, enabling refractive power change.

The movement of the macromers causes a highly predictable change in the curvature of the lens. If the central portion of the lens is exposed to UV light, unpolymerized macromers in the periphery of the lens move into the central portion. As a result, the central portion of the lens swells, creating a lens shape for correction of hyperopia. Conversely, if the periphery of the lens is exposed to UV light, unpolymerized macromers in the central portion of the lens migrate into the periphery. As a result, the periphery of the lens swells, creating a lens shape for correction of myopia. In addition to spherical correction for myopia or hyperopia, customized cylinder adjustments along any axis of the lens can be targeted to correct for astigmatism.

To achieve the desired refractive change in the LAL, our LDD uses proprietary software and algorithms to deliver a short UV exposure treatment that polymerizes specific portions of the lens according to a predefined pattern of light, called a nomogram. Nomograms allow for adjustment of spherical and cylindrical refraction in 0.25 diopter increments, like the adjustment increments used to refract patients for glasses or contact lenses, as well as in other refractive procedures like LASIK, which has similar refractive accuracy. Designed for placement in the doctor's office, the LDD is a combination of a standard slit lamp and a digital light projector. The slit lamp portion allows the doctor to see inside the patient's eye and align the light beam with the LAL. The digital light projector portion projects an image onto the LAL using DLP technology that has approximately 250,000 micro mirrors that are electronically activated to represent an image stored in memory.

Each UV light treatment consumes only a portion of the macromers in the lens, allowing the LAL to be adjusted multiple times. This process can be repeated up to three times over a period of several weeks, until the patient and doctor are satisfied. The entire lens is then polymerized to provide a stable correction. After adjustment light treatments are completed, one or two lock-in light treatments are applied to consume all remaining macromers and photo-active compounds. After the final lock-in treatment, the lens power can no longer be adjusted.

Our approach

With the RxSight system, the surgeon performs a standard IOL implant procedure, replacing the patients' natural lens with the LAL. Two to three weeks following surgery, the patient visits the doctor's office for a standard postoperative refraction, which is similar to the eye test used to create a prescription for eye glasses. Using a traditional phoropter and vision chart, a clinician determines the refractive error and prescription required and inputs the information into the LDD's graphical user interface. The patient's eye is dilated and a contact lens is applied to the eye as the patient is seated in front of the LDD for a light treatment. Based on the prescription input, the LDD generates a programmed, predetermined exposure of UV light. For approximately 100 seconds, the light painlessly and non-invasively reshapes the implanted LAL to correct the measured refractive error. The entire treatment takes less than five minutes. The patient returns approximately three to five days later for additional light treatments to further adjust their vision, if desired, or to lock-in the lens. While patients can receive up to three adjustments, the average number of adjustments in our FDA clinical trial was 1.6.

The RxSight system enables a fully interactive and iterative process to optimize visual acuity with patients able to test drive their vision, comparing possible outcomes before selecting a final prescription for their LAL. In clinical practice since our FDA approval, roughly 60% of patients undergoing multiple adjustments have requested a change from their original spherical target, underscoring the value of adjustability and customization. From the time of surgery until 24 hours after the LAL is locked in, the patient wears UV light protective glasses as unprotected exposure to light can cause uncontrolled changes in the LAL. Since late 2021, we have included ActivShield technology on all LALs, which provides an extra layer of UV protection on the lens surface and reduces dependence on patient compliance with protective glasses.

Key benefits of RxSight system for patients

- **Superior vision outcomes.** In the pivotal study that formed the basis for our FDA approval, the observed rate of eyes with 20/20 or better uncorrected distance visual acuity for our LAL was 70.1%. This compares favorably to the results of pivotal studies with similar study designs and patient populations that supported FDA approval of Alcon's Acrysof Toric (38.4%) and J&J's Tecnis Toric (43.6%). Most LAL patients choose minor differences in the refractive correction of each eye, resulting in glasses-free vision across a full range of distances. In our most recent Phase IV commercial study data over 90% of LAL patients who chose to optimize vision with both eyes, achieved 20/20 distance vision and were also able to read 5-point font without glasses;
- **Postoperative customization.** Our RxSight system enables patients to preview and compare possible vision outcomes after surgery based on their unique preferences and lifestyle requirements before they select a final

prescription for their LAL. With up to three possible adjusting light treatments, patients can dial-in their optimal visual acuity through an interactive and iterative process;

- **No increase in glare and halo.** Our LALs do not induce higher rates of glare and halos compared to monofocal IOLs. In contrast, multifocal IOLs, generally relied upon to improve near vision, are associated with a higher incidence of unwanted side effects including reduced contrast sensitivity and increased glare and halos around bright lights. These problems can lead to explants, in which patients undergo another procedure to remove the multifocal IOL and replace it with another type of IOL. In FDA studies for the Alcon Panoptix, J&J Symfony and Alcon Vivity lenses, 48.8%, 59.2% and 17.0% of subjects, respectively, reported being bothered by halos postoperatively; and
- **Corrects residual refractive error**. The RxSight system can reduce the potential for secondary surgical procedures by correcting residual refractive error after surgery using our office based LDD to shape the LAL. With other premium IOLs, a separate LASIK procedure is generally the only way to correct for residual visual errors following the primary cataract procedure.

Key benefits of RxSight system for doctors

- **Clear value proposition for patients, helping doctors to build their premium cataract practices.** Rather than explaining the complicated trade-offs with respect to visual outcomes and predicting refraction before surgery, the surgeon may simply tell patients that their vision will be corrected postoperatively via a painless, in-office process similar to being prescribed glasses. The doctor can also share the LAL's clinical results with the patient to provide reassurance that the procedure will deliver desired results;
- **Increased confidence.** The clinical benefit of "dialing-in" to achieve superior visual outcomes postoperatively increases doctors' confidence that the LAL can meet patients' expectations. The doctor does not need to decide prior to surgery whether the patient will be particularly sensitive to suboptimal visual outcomes or side effects (such as glare, halo and loss of contrast). The patient is also unlikely to need a postoperative adjustment such as LASIK to improve their outcome;
- **Fewer intraoperative measurements.** With other premium IOLs, the lens power is fixed and cannot be changed after surgery, requiring doctors to spend considerable time on preoperative and intraoperative measurements to estimate the most suitable lens power to implant and lens position. With our RxSight system, surgeons are not as dependent on preoperative and intraoperative equipment for measurements. Instead, they can focus on the surgical procedure, knowing refractive error will be corrected postoperatively with the LDD, and with the patient's active involvement;
- **Broad application across different patients' needs.** We offer a single IOL that can address a broad range of patient types and needs, while providing a solution that doctors can trust to improve visual outcomes, eliminating the need for extensive preoperative discussions with patients about which IOL may best fit their lifestyle and visual preferences. Moreover, the superior outcomes and patient-centered approach of the RxSight system helps drive patient referrals and grow premium cataract volumes, which generally produce higher practice revenue and profit margin than conventional procedures; and
- **Economic benefits that drive practice growth.** A recent economic impact survey by Haffey & Company of almost 50 practices using the RxSight system revealed that LAL procedures were sourced from all other categories of other IOLs. For example, respondents indicated that approximately 40% of their LAL patients would have otherwise selected a conventional monofocal IOL, which is far less profitable for a practice than a LAL procedure. In addition, based on an average of 9 LALs implanted per month at these practices, doctors observed a payback period of approximately nine months for the LDD, based on the current list purchase price. Following this payback period, practices continue to reap the financial benefit of converting patients to the RxSight system.

Our growth strategies

We are leveraging the tangible and compelling benefits of our RxSight solution to achieve broad adoption of our technology and establish it as the standard of care for premium cataract surgery. Our growth strategies include:

- **Establishing new customers and growing our installed base of LDDs.** We believe our technology offers a differentiated value proposition to doctors and patients, providing us an opportunity to grow our share in the

premium IOL market and increase the penetration of premium IOLs in the broader cataract surgery market. To grow our installed base, we are focused primarily on converting high-volume premium cataract surgeons to the RxSight system by highlighting its clinical, economic and workflow benefits vs. competing premium IOL technologies. Secondarily, we are focused on the broader pool of cataract surgeons who may implant premium IOLs sparingly or not at all due to suboptimal visual outcomes, persistent side effects and uneven patient satisfaction sometimes associated with non-adjustable premium IOL offerings. Because our RxSight system is designed to overcome these shortcomings, we believe many of these doctors have the potential to be successful RxSight customers. We are also investing in professional education, additional clinical studies and registries that expand our evidence base, facilitating peer-to-peer dialogue and forums and communicating the benefits of our technology through marketing initiatives, tradeshows and podium presentations;

- **Increasing the utilization of our LALs by empowering doctors to grow their practices.** We work closely with every new customer to conduct a thorough training and onboarding process, providing a high level of service to help the practice succeed with the RxSight system. This support helps the practice confidently recommend the LAL to an increasing number of patients and, in turn, grow their practice. In a recent RxSight customer survey, 89% of doctors said they thought our RxSight system delivered the highest quality vision, 98% said they would recommend the LAL to others and 75% said they would select it for their own eyes. In addition to personnel support, we also provide practices with marketing materials, such as patient brochures, literature and digital content for website and social media promotions. We also provide ongoing training related to new technology features and developments, as well as education on the patient benefits of our solution;

- **Strategically expanding our commercial organization and marketing activities.** Since launching the RxSight system commercially in 2019, we have substantially increased the size and scope of our U.S. commercial organization. While we believe our current commercial organization is well built to reach our focused target of high-volume premium cataract surgeons, we will add highly qualified personnel for time to time, with a strategic mix of sales personnel and clinical specialists, to drive higher levels of awareness and penetration in certain regions. We also expect to accelerate marketing initiatives and professional education, including training on best practices and techniques;

- **Investing in RxSight system enhancements and expanding indications.** We continue to enhance our RxSight system to improve the patient and doctor experience, meet evolving customer needs and address the widest possible patient population. Since our initial FDA approval in November 2017 through December 31, 2022, we have received 20 supplemental approvals. Recent enhancements include increasing the range of available LAL powers, modifying the LAL to improve image quality, reducing the margin of residual refractive error, allowing an optional third refractive adjustment, developing new UV glasses with improved aesthetics and usability, and adding a photosensitive anterior layer (ActivShield™) to the LAL to help protect the lens from unwanted UV exposure. We believe these technological advancements help to drive increased adoption of our RxSight system;

- **Scaling our business to achieve cost and production efficiencies.** We expect to realize operating leverage through increased scale efficiencies as our commercial operations grow. We have executed a number of design and manufacturing process improvements to streamline both LAL and LDD production, and have developed a lower cost to manufacture LDD, which was approved by the FDA on January 31, 2023. We are also concurrently executing on our strategy to optimize our diverse supply chain and to develop second sources from less expensive suppliers. We anticipate that the combination of these strategies will drive margin improvement in the future when introduced into production and offered for sale; and

- **Growing our commercial operations in international markets.** While our current commercial focus is on the large opportunity within the United States, we believe the RxSight system offers compelling benefits for cataract doctors and patients in select international markets. According to the Market Scope 2022 Premium Report, over 70% of the premium IOL procedures in 2022 were outside the United States. Our RxSight system has approval in Mexico and Canada for improving uncorrected visual acuity by adjusting the LAL power to correct residual postoperative refractive error. We may selectively pursue commercial expansion outside the United States that accept these approvals in the future, with a priority on markets where we see significant potential growth opportunities. New approvals may also be sought in large cataract markets with more complex regulatory environments such as Asia.

FDA clinical studies

In July 2016, we completed our FDA Phase 3 pivotal randomized clinical study of 600 subjects, designed to evaluate the safety and effectiveness of performing light treatments to correct postoperative spherical and cylindrical refractive error. In this study, 391 subjects had the LAL implanted in one eye and the results were compared at the six-month postoperative visit against 193 subjects with a monofocal control IOL implanted in one eye. The LAL met all primary effectiveness endpoints and was approved by the FDA on November 22, 2017 as the first commercially available adjustable IOL. In the study, 70.1% of LAL subjects achieved monocular uncorrected distance visual acuity of 20/20 or better compared to 36.3% of the eyes implanted with the monofocal control IOL. In addition to being statistically significantly better than the control IOL, the observed rate of eyes with 20/20 or better uncorrected distance visual acuity was the highest reported for any approved intraocular lens and approximately twice what was observed by the two most popular astigmatism-correcting IOLs (38.4% by Alcon's Acrysof Toric, and 43.6% by J&J's Tecnis Toric) in similar patient populations in the pivotal studies that led to their approvals by the FDA. Additionally, LAL patients reported a low rate of glare or halo, visual side effects that are frequently reported with premium IOLs.

We are conducting a 500-eye prospective, randomized, controlled multicenter Post Approval Study, which was a requirement of our Premarket Approval ("PMA") approval. Subjects are randomized in a 2:1 ratio to receive either the LAL or a monofocal IOL. Study subjects will be followed for six months. The results will compare effectiveness and safety of the LAL and monofocal IOL. We anticipate completing enrollment in 2024.

Sales and marketing

We commenced commercial launch of our RxSight system in the United States in 2019 and are initially focused on the estimated 3,000 surgeons that perform 70%-80% of premium cataract surgery procedures. These surgeons are usually part of larger ophthalmology practices with multiple cataract surgeons. They typically have refractive surgery practices offering LASIK and are skilled at selling premium procedures based on delivery of better visual outcomes. Our U.S. commercial organization includes a direct sales team comprised of LDD sales personnel and LAL account managers, as well as clinical specialists and field service engineers and marketing personnel. While we believe we can effectively cover our concentrated target market with our focused commercial organization, we will add highly qualified personnel from time to time, with a strategic mix of sales personnel and clinical specialists, to drive further awareness and penetration among cataract surgeons.

Our commercial efforts are designed to create a "razor and razor blade" business model by building a sizable LDD installed base to drive ongoing growth in LAL procedure volumes. LDD sales personnel are responsible for establishing relationships with doctors and securing new customers. New customer contracts typically include sale of the LDD between approximately $115,000 - $120,000, sale of LALs for approximately $1,000 each and an LAL consignment agreement. Once the LDD is installed, our clinical specialists work closely with the practice's doctors, technicians and staff members to ensure that they are fully trained, proficient LAL providers. Our LAL account managers oversee this process and engage with practices on an ongoing basis to assist with patient awareness and education programs, development of efficient patient flow processes and other initiatives. To achieve broad awareness of the RxSight system among cataract surgeons, we also conduct various marketing programs, including promotions at industry and society conferences, podium presentations, social media, and educational webinars focused on the differentiated benefits of our RxSight system.

Our RxSight system has received regulatory approval in Mexico and Canada. We recently commenced limited sales activities in Canada through a distribution partner.

Research and development

Our research and development activities are focused on programs that improve clinical outcomes, improve customer experience, expand our indications for use, reduce manufacturing costs and lifecycle management. Since our initial FDA approval in November 2017 through December 31, 2022, we have received approximately 20 supplemental approvals that advance these objectives.

On January 31, 2023, the FDA approved our PMA supplement to our LDD for various modifications that are intended to reduce the cost to manufacture the device. We anticipate that this lower-cost-to-manufacture LDD will also require a submission for approval in countries outside the United States.

Research and development expenses were $26.0 million and $24.5 million for the years ended December 31, 2022 and 2021, respectively.

Manufacturing and supply

We currently manufacture, assemble, test, and ship our LAL and LDD, and various accessory products including a custom injector system for use with our LAL at our campus of four facilities and approximately 121,000 total square feet in Aliso Viejo, California. We have intentionally pursued a vertically integrated manufacturing strategy offering critical advantages, including control over our product quality and rapid product iteration using strong R&D and quality groups. We believe our current manufacturing capacity is sufficient to meet our current expected demand for at least the next 12 months.

We are registered with the FDA as a medical device manufacturer and are licensed by the State of California to manufacture and distribute our medical devices. We are required to manufacture our products in compliance with the FDA's Quality System Regulation ("QSR") (21 CFR 820). The FDA enforces the QSR through periodic inspections and may also inspect the facilities of our suppliers. We moved to our current Aliso Viejo, California facilities starting in April 2016, all of which have been registered with the FDA, the State of California, and the European Notified Body (British Standards Institution) for the manufacture and distribution of medical devices.

We have received International Organization for Standardization ("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 have also received quality system certification to the Medical Device Single Audit Program ("MDSAP") to cover the jurisdictions of United States, Canada, Brazil, Japan, and Australia from the British Standards Institution. The MDSAP certification follows the ISO 13485:2016 certification schedule. The most recent recertification and surveillance audit was conducted in July 2022.

The LAL is a silicone intraocular lens made from a proprietary blend of custom chemical components. Chemical component vendors produce the raw materials, which we inspect, blend, further purify, and process, and formulate into uncured silicone blend. Using this uncured silicone, we mold the lens in one of our two Class 7 clean rooms. After curing, the molded lens is inspected and packaged and then sent to a third-party ethylene oxide sterilization vendor. After sterilization, the lens is returned to us for final inspection, packaging, and shipment to customers.

Our LDD is a UV projector medical device, which consists of an anterior segment biomicroscope, computer controllers for performing light treatments, and a biometrically designed patient interface and table. The optics are bonded into their mounts using epoxies, which are then oven cured, assembled into the main optical housing and optimized on a proprietary precision alignment station. The completed optical head is integrated into the table, along with a computer, power supplies and other electro-mechanical parts. We outsource the cables and circuit boards used in the LDD to certified specialty contract manufacturers. The fully assembled LDD is put through an electrical safety and final acceptance test process, and then reviewed by quality control, packaged and shipped directly to our customers for installation.

In addition, to aid the doctor in implanting the LAL, we provide several accessories including a custom insertion system and a contact lens. The insertion system consists of a disposable cartridge and a reusable injector handpiece. The disposable cartridge is processed, inspected, and packaged by us while having ethylene oxide sterilization performed by a third-party vendor. The reusable injector handpiece is manufactured by a third-party vendor and is inspected and packaged by us. We also manufacture, inspect, and package a reusable contact lens for administering UV light treatments. The end user is responsible for performing cleaning and sterilization of the injector handpiece and the contact lens following directions for use and hands on training provided by us. We also provide custom UV glasses that are manufactured by third party vendors, and then inspected and shipped by us from our facilities to our customers.

We use a combination of internally manufactured and externally sourced components to produce the LAL, LDD, custom insertion system, and other accessory products. Externally sourced components include off-the-shelf chemical, materials, microchips integrated into printed circuit boards and cables, sub-assemblies, and custom parts that are provided by qualified and approved suppliers. We also employ a third-party sterilization vendor. Some components are provided by single-source or sole source suppliers. While there are other suppliers that could make or provide any one of our single sourced components, we seek to manage single-source supplier risk by regularly assessing the quality and capacity of our suppliers, implementing supply and quality agreements where appropriate and actively managing lead times and inventory levels of sourced components. In addition, we are currently in the process of identifying and approving alternative suppliers to dual or multi-source certain of our LAL raw materials and LDD components. We generally seek to maintain sufficient supply levels to help mitigate any supply interruptions and enable us to find and qualify another source of supply. Order quantities and lead times for externally sourced components are based on our forecasts, which are derived from historical demand and anticipated future demand. Lead times for components may vary depending on the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the materials, sub-assemblies, and

parts. In addition, COVID-19 has resulted in manufacturing interruptions at single and sole source suppliers in the United States, European Union, the U.K. and China, which we have been able to mitigate, to date, with selected pre-payment for product, expedite fees, sourcing from alternative suppliers, placing orders for specific chip sets separate from third party suppliers to ensure supply and longer-term orders.

Our suppliers are evaluated, qualified, and approved as part of our supplier quality program, which includes verification and monitoring procedures to ensure that our suppliers comply with FDA and ISO standards, as well as our own specifications and requirements. We inspect and verify externally sourced components under strict processes supported by internal policies and procedures. We maintain a rigorous change control policy to assure that no product or process changes are implemented without our prior review and approval.

Third-party reimbursement and patient billing

Dual aspect payment model

In the United States, the CMS has determined that the additional refractive correction provided by astigmatism correcting and presbyopia correcting (premium) IOLs is not a covered benefit. As described in two CMS rulings (CMS 05-01 and CMS 1536-R), premium IOLs have both a covered and non-covered aspect, providing the framework for the "dual-aspect payment model." In effect since 2005, this model means that CMS does not reimburse the physician or the facility for the additional costs associated with a premium IOL, while still covering the cost of the conventional IOL procedure. Instead, the patient selecting a premium IOL is responsible for the additional charges from the physician and from the facility that exceed the regular charges for insertion of a conventional IOL that are submitted to CMS by each of these providers. As of 2017, CMS has recognized the LAL as an astigmatism correcting (premium) IOL, making it eligible for the dual aspect payment model. Most commercial payers mirror the Medicare rulings, but this can vary by payor.

Procedure coding and payment

In the United States, we primarily sell our LAL products to ambulatory surgical centers ("ASCs") and occasionally to hospitals. These customers in turn bill various third-party payors, such as commercial payors and state and government payors, as well as patients and doctors directly for the services provided to each patient.

Third-party payors require physicians and hospitals to identify the service for which they are seeking reimbursement by using Current Procedural Terminology, or CPT, codes, which are created and maintained by the American Medical Association, or AMA. For cataract surgery, the most common specific CPT codes are 66984 (Cataract surgery with IOL, on stage) and 66982 (Cataract surgery, complex). The facility fees associated with these codes include payment for a conventional IOL of up to $150. A specific HCPCS code is listed on the CMS claim by the facility to indicate use of premium IOL for tracking purposes only (V2787 or V2788 for astigmatism-correcting or presbyopia-correction function of IOL, respectively). Similarly, the physician includes HCPCS code A9270 (non-covered item or service) on their claim to Medicare (or another third party) to indicate charges for extended care related to the correction of refractive error.

While an Advanced Beneficiary Notice ("ABN") or Notice of Exclusion from Medicare Benefits ("NEMB") is not required, most providers issue an ABN or NEMB to alert patients that CMS (or non-Medicare payers) do not cover the additional charges associated with a premium IOL and to get the patient's agreement to pay these charges. Patients are then billed directly by the physician and the ASC for these charges. In some cases, the physician bills the patient exclusively and then reimburses the ASC for the additional cost of the premium IOL.

Commercial payor and government program coverage

While the dual aspect payment model has been in use for over 15 years, the extent to which this model will be used by non-government third-party payors, such as commercial insurance, and managed healthcare organizations may vary. One third-party payor's decision does not ensure that other payors will also follow this model. As a result, the coverage determination process can require manufacturers to provide additional support for the use of a product to each payor separately. This can be a time-consuming process, with no assurance that the dual aspect model will be applied consistently.

Reimbursement outside of the United States

In international markets, reimbursement and healthcare payment systems also vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In many countries, analogous determinations to the dual aspect CMS ruling have been made, allowing for partial coverage of the cataract procedure by national health systems, with patients paying out of pocket for refractive services associated with the premium IOL. In other countries, such dual

billing is not allowed, forcing patients to pay for the entire cost of the cataract surgery and IOL when a premium IOL is used. In such markets, it may be possible for doctors to charge separately for the cost of light treatments, which are not part of the cataract procedure. This method would require a different billing methodology by us than is currently used in the United States, where light treatments are included with the purchase of the LAL. There is no assurance that these methodologies will be allowed or that an adequate level of payment will be established, or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

Intellectual Property, License Agreements, and Other Material Agreements

Our success depends in part on our ability to obtain, maintain, protect, and enforce our intellectual property rights, including our patent rights, preserve the confidentiality of our trade secrets, operate without infringing, misappropriating or otherwise violating the intellectual property rights of others and prevent others from infringing, misappropriating or otherwise violating our intellectual property rights. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to protect the products and technology that we consider important to our business. We also rely on know-how and continuing technological innovation to develop and maintain our competitive position.

Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our technology, inventions, improvements and products that are important to the development and implementation of our business. Our patent portfolio covers various aspects of our LDD, LAL and related devices and methods.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. Generally, in the United States, issued patents are granted a term of 20 years from the earliest claimed non-provisional or Patent Cooperation Treaty ("PCT") filing date. In certain instances, a patent term can be adjusted to recapture a portion of delay by the U.S. Patent and Trademark Office ("USPTO"), in examining the patent application (patent term adjustment, or PTA) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension, or PTE), or both. Additionally, a patent term may be shortened if a patent is terminally disclaimed over an earlier filed patent. However, the life of the patent, and the protection it affords, is limited. In addition, we cannot provide any assurance that any patents will be issued from our pending or future applications or that any issued patents will adequately protect our current and future products. We also cannot predict the breadth of claims that may be allowed or enforced in our owned or in-licensed patents or whether such claims, if issued, will cover our products, provide sufficient protection from competitors or otherwise provide any competitive advantage. Any issued patents that we may own or in-license in the future may be challenged, invalidated, narrowed, held unenforceable, infringed or circumvented.

As of December 31, 2022, our patent estate is directed to various aspects of our programs and technology, including our LAL and our LDD as well as lens adjustment procedure and other technology. Any U.S. or foreign patents issued or pending would be scheduled to expire on various dates from 2023 and 2041, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity, and other governmental fees. Further details on certain segments of our patent portfolio, including our owned and exclusively in-licensed issued patents and patent applications, are included below.

- Our current LAL: Some of the patents directed to our current LAL include, for example, U.S. Pat. No. 9,119,710, which is expected to expire in 2026, U.S. Pat. No. 10,470,874, which is expected to expire in 2026, and U.S. Pat. No. 10,874,505, which is expected to expire in 2033.
- Our LDD: Some of the patents directed to our LDD include, for example, U.S. Pat. No. 10,864,075, which is expected to expire in 2038, and U.S. Pat. No. 10,932,864, which is expected to expire in 2039.
- Our lens adjustment procedure: Some of the patents directed to our lens adjustment procedure include, for example, U.S. Pat. No. 10,010,406, which is expected to expire in 2032, and U.S. Pat. No. 10,166,731, which is expected to expire in 2036.
- Our RxSight system accessories: A patent directed to our RxSight system accessories includes, for example, U.S. Pat. No. 10,456,240, which is expected to expire in 2038.

Pursuant to the agreement with QAD, Inc. ("QAD") dated October 29, 2015 (the "QAD Agreement"), we received a nonexclusive, non-transferable, perpetual license to use certain QAD software at the physical location where we install the software. Under the agreement, we purchase such QAD software through individual orders ("Purchase Orders"), and each

Purchase Order has a respective payment fee and maintenance fee. We use the software licensed under the QAD agreement for inventory, shipping, receiving, sales order, work order, planning and financial transactions for the business. Maintenance for the software is offered by QAD and available for purchase by us on an annual basis, and such purchase was compulsory for the first year of the agreement. After the first year, maintenance purchased under the agreement automatically renews for successive one-year periods unless terminated by us or QAD 60 days prior to the effective date of any renewal term. Further, we grant QAD audit rights to verify our usage of QAD software, and if following such audit our use of the QAD software is in excess of our license, we are obligated to pay to QAD the amounts necessary to become compliant. QAD provides limited warranties to the software and retains all intellectual property ownership rights in the QAD software including any modifications made by us, however we receive a license to use any modifications made by us. Unless earlier terminated, the term of the QAD agreement is perpetual. Both parties have the right to terminate the agreement for convenience by giving the other party 90 days prior written notice and such termination does not affect the license granted. Either party to the agreement may terminate the agreement with notice, if the other materially breaches the agreement, and the breach is not cured within specified time periods. In addition, either party may terminate if the other party is adjudicated bankrupt or an official is appointed to manage its financial affairs. Upon termination for cause, we must immediately discontinue all use of the software.

We believe that we have certain know-how and trade secrets relating to our technology and current and future products. We rely on trade secrets to protect certain aspects of our technology related to our current and future products. However, trade secrets and know-how can be difficult to protect. We seek to protect our trade secrets and know-how, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, service providers, and contractors but these agreements may not provide meaningful protection, and we cannot guarantee that we have executed such agreements with all applicable counterparties. These agreements may also be breached, and we may not have an adequate remedy for any such breach. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we take steps to protect our trade secrets and know-how, third parties may independently develop or otherwise gain access to our trade secrets and know-how.

For more information regarding risks related to our intellectual property, please see “Risk Factors-Risks related to Intellectual Property” in Part I, Item 1A of this Annual Report.

Competition

Competition in the surgical ophthalmology market is intense and is primarily driven by technological innovation and the regulatory approval required to commercialize products in the key markets around the world. The development of new or improved products may make existing products less attractive, reduce them to commodity status or even make them obsolete. We believe the principal competitive factors in our markets include:

- the quality of patient outcomes, oftentimes measured by visual acuity, and adverse event rates;
- patient experience, including patient recovery time and level of discomfort;
- acceptance by treating doctors and referral sources;
- doctor learning curves and willingness to adopt new technologies;
- ease-of-use and reliability;
- economic benefits and cost savings;
- strength of clinical evidence;
- effective distribution and marketing to surgeons and potential patients; and
- product price and qualification for coverage and reimbursement.

From a commercial perspective, we believe our primary competitors in the cataract IOL market are alternative premium IOL providers, including Alcon, Johnson & Johnson and Bausch + Lomb. According to Market Scope, the global cataract IOL market is highly concentrated, with these top three players accounting for approximately 78% of the total U.S. premium cataract surgery market and approximately 61% of the global manufacturer market revenue. Our competitors are significantly larger than us with greater financial, marketing, sales and personnel resources, greater brand recognition and

longer operating histories. We believe our ability to compete effectively will be dependent on our ability to build the commercial infrastructure necessary to effectively and cost-efficiently drive awareness of the unique value of our RxSight system.

In addition, patients who receive an LAL will be required to wear UV protective glasses until final lock-in which is approximately 4-5 weeks after surgery. They will also be required to return for an additional two to three clinic visits compared to traditional cataract surgery. The additional clinic visits are non-surgical but do require the patient's eyes to be dilated. Due to these additional requirements, market acceptance of the LAL may be impacted.

The three most popular premium IOLs approved for cataract treatment are PanOptix by Alcon, Vivity by Alcon and Tecnis by Johnson & Johnson. According to the Market Scope 2022 Premium Report Alcon, Johnson & Johnson, Bausch + Lomb are three of the top IOL manufacturers, with an estimated 2022 revenue share of the world-wide premium IOL market of approximately 51%, 25%, and 2% respectively. The PanOptix and Tecnis families of IOLs are available in a monofocal Toric, multifocal Toric and EDOF Toric versions. The PC and Toric versions of these lenses represented over half of all premium multifocal IOLs sold in 2022. The rest of the market is shared between several smaller companies each with under 5% market share. From a technology perspective, we believe the LAL competes with nearly all of the existing IOLs, including conventional, premium astigmatism correcting and premium presbyopia correcting lenses.

Government regulation

Our products and operations are subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, (the "FDCA") and its implementing regulations, as well as other federal, state and local regulatory authorities in the United States, as well as foreign regulatory authorities. The FDA regulates, among other things, product design and development, pre-clinical and clinical testing, manufacturing, packaging, labeling, storage, record keeping and reporting, clearance or approval, marketing, distribution, promotion, import and export, and post-marketing surveillance in the United States to assure the safety and effectiveness of medical products for their intended use.

FDA regulation of medical devices

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a PMA application. Both the 510(k) clearance and PMA processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

FDA classifies medical devices 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 control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I devices are those for which safety and effectiveness can be reasonably 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 of the Quality System Regulation, or QSR, establishment registration and device listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling 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 products are exempt from the premarket notification requirements.

Class II devices are those that 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, patient registries, product-specific FDA guidance documents, special labeling requirements and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. 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 generally 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 into 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.

Investigational device process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE once certain requirements are addressed, and IRB approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the 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.

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's good clinical practice regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA.

The results of clinical testing may be unfavorable, or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, 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 we 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.

The 510(k) clearance process

Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, 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 Class I, or a device that was previously 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. Clinical data is sometimes, but not always, required to support substantial equivalence.

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 additional 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 not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the de novo process. A manufacturer can also submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

Medical devices can only be marketed for the indications 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 new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application or de novo classification. The determination as to whether or not a modification constitutes such a change is initially left to the manufacturer using available FDA guidance; however, 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 recall the modified device until new 510(k) clearance or PMA approval is obtained. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

The PMA approval process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the substantive review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (e.g., major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- The device may not be shown safe or effective to the FDA's satisfaction;
- The data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- The manufacturing process or facilities may not meet applicable requirements; and
- Changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also require post-market surveillance for certain devices cleared under a 510(k) notification, such as implants or life-supporting or life-sustaining devices used outside a device user facility. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. Significant modifications to the manufacturing process, labeling and design for a device which has received approval through the PMA process may require submission of a new PMA application or PMA supplement prior to marketing.

Ongoing regulation by the FDA

Even after the FDA permits a device to be marketed, numerous regulatory requirements apply, including but not limited to:

- establishment registration and device listing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation, and other quality assurance procedures during the manufacturing process;
- labeling regulations, advertising and promotion requirements, restrictions on sale distribution or use of a device, each including the FDA general 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 (“MDR”) regulation, which requires that manufactures report to the FDA if their device may have caused or contributed to a death or serious injury or if their device malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;
- medical device corrections and removal reporting regulations, which require that manufactures report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FDCA Act 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 affect 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. Further, the FDA requires us to comply with various FDA regulations regarding labeling. Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

- warning or untitled letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, voluntary or mandatory recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- delay in processing, clearing or approving submissions or applications for new products or modifications to existing products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- suspension or withdrawal of FDA approvals or clearances that have already been granted; and
- criminal prosecution.

Newly discovered or developed safety or effectiveness data may require changes to a product's labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory clearance or approval of our products under development.

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.

When the FDA conducts an inspection, the inspectors will identify any deficiencies they believe exist in the form of a notice of inspectional observations, or Form FDA 483. If we receive a notice of inspectional observations or deficiencies from the FDA following an inspection, we would be required to respond in writing, and would be required to undertake corrective and/or preventive or other actions in order to address the FDA's or other regulators' concerns. Failure to address the FDA's concerns may result in the issuance of a warning letter or other enforcement or administrative actions.

International medical device premarket authorization process

The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Our products are regulated in the European Union as medical devices per European Union Directive 93/42/EEC, also known as the Medical Device Directive ("MDD"). The MDD sets out the basic regulatory framework for medical devices in the European Union. The system of regulating medical devices operates by way of a certification for each medical device. Each certified device is marked with the CE mark which shows that the device has a Certificat de Conformité. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the MDD within their jurisdiction. The means for achieving the requirements for

the CE mark vary according to the nature of the device. Devices are classified in accordance with their perceived risks, similarly to the U.S. system. The class of a product determines the conformity assessment required before the CE mark can be placed on a product. Conformity assessments for our products are carried out as required by the MDD. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of a one-member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states. The CE mark is contingent upon continued compliance with the applicable regulations and the quality system requirements of the ISO 13485 standard.

The new European Union Medical Devices Regulation 2017/745, or EU MDR, which was published in May 2017 with a transition period of three years, replaces the MDD and will expand and modify the pre-market and post-market obligations of the MDD. The date of application of the EU MDR has been postponed to May 26, 2024 with implementation dates based off of risk classification of the medical device. Recently, the European Commission proposed legislative amendments, including amendments to extend the transition period to the new rules from May 26, 2024 to December 31, 2027 for higher risk devices and until December 31, 2028 for medium and lower risk devices. The EU MDR will impose additional requirements on clinical evaluation process, safety, classification and performance of medical device products. The EU MDR will have no impact on our current and future products as registrations to the EU MDR are in process and are scheduled for completion prior to the implementation dates. The company has passed the MDR upgrade assessment with no observations and a recommendation for certification by the European Notified Body in December 2021. In addition to inspections by the FDA and other regulatory entities, we are also subject to periodic inspections by applicable European Notified Body with respect to regulatory requirements that apply to medical devices designed and manufactured by us and clinical trials sponsored by us. We are also certified to the Medical Device Single Audit Program ("MDSAP") for the jurisdictions of the United States, Canada, Japan, Brazil, and Australia which allows for one single audit performed by Notified Body to cover those jurisdictions with respect to quality systems. All registrations and certifications due to Great Britain leaving the European Union (Brexit) and Switzerland ending a joint agreement with the European Union (Swexit) have been done to the timelines as required for these countries and will continue to be performed to the updated timelines as published during these processes.

Other U.S. regulatory matters

Medical device companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Manufacturing, sales, promotion and other activities following product clearance or approval are subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the CMS, other divisions of the Department of Health and Human Services, the Department of Justice, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. For example, in the United States, sales, marketing and scientific and educational programs also must comply with state and federal fraud and abuse, anti-kickback false claims, transparency, government price reporting, anti-corruption, and health information privacy and security laws and regulations. Internationally, other governments also impose regulations in connection with their healthcare reimbursement programs and the delivery of healthcare items and services. These laws include the following:

- U.S. federal healthcare fraud and abuse laws generally apply to our activities because our products are covered under federal healthcare programs such as Medicare and Medicaid. The Anti-Kickback Statute is particularly relevant because of its broad applicability. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription medical device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular medical device, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Almost any financial arrangement with a healthcare provider, patient or customer could implicate the Anti-Kickback Statute. Statutory exceptions and regulatory safe harbors protect certain arrangements if specific requirements are met. The government can exercise enforcement discretion in taking action against arrangements that do not fit within a safe harbor. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it. 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 civil False Claims Act. Penalties for violations of the Anti- Kickback Statute include, but are not limited to, criminal, civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from Medicare, Medicaid

and other federal healthcare programs. Our exclusion would mean that procedures using our products would no longer be eligible for reimbursement under federal healthcare programs;

- Another development affecting the healthcare industry is the increased use of the federal Civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. In recent years, the number of suits brought against healthcare companies by private individuals has increased dramatically. The federal civil and criminal false claims acts, including the civil FCA, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. No specific intent to defraud is required under the civil FCA. The criminal FCA provides for criminal penalties for submitting false claims, including imprisonment and criminal fines;

- The Civil Monetary Penalty Act of 1981 and implementing regulations impose penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or 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;

- Federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- The FDCA, which prohibits, among other things, the adulteration or misbranding of medical devices;

- Additionally, there has been a recent trend of increased federal and state regulation of payments made to doctors. The federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, medical devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;

- The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls for international operations;

- Analogous state and foreign laws and regulations, such as state anti-kickback, anti-referral, and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require certain biotechnology, pharmaceutical, and medical device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require applicable manufacturers to disclose or report certain information related to payments and other transfers of value to doctors and entities or sales, marketing, pricing, clinical trials, marketing expenditures and activities, and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus

complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our activities, such as stock-option compensation paid to doctors that have entered into consulting agreements with us, could be subject to challenge under one or more of such 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. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to various interpretations. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Also, we may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments. 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 penalties, including significant civil, criminal and administrative penalties, including damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, injunctions, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

United States health care reform

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage for the procedures associated with the use of our products or result in lower reimbursement for those procedures. The cost containment measures that payers and providers are instituting and the effect of any healthcare reform initiative implemented in the future could significantly reduce our revenues from the sale of our products. Changes in healthcare policy, including changes in the implementation or the repeal of the ACA in the United States, could increase our costs, decrease our revenue and impact sales of and reimbursement and coverage for our current and future products. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. In particular, on December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and held oral arguments in November 2020. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. It is unclear how this Supreme Court decision, future litigation, and healthcare measures of the Biden administration will impact the ACA and our business. Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers, which will remain in effect through 2031 absent additional congressional action, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional action is taken by Congress. Under current legislation, the actual reduction in Medicare payments can vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. Moreover, there recently has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

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.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our current and future products from governmental agencies or third-party payors. Current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

Data privacy and security

Medical device companies may be subject to U.S. federal and state health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information.

HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to the United States Department of Health and Human Services ("HHS") affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, or PHI, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

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

In addition, certain state laws govern the privacy and security of health 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. Actual or perceived failure to comply with these laws, where applicable, can result in private claims, demands and litigation, regulatory investigations and other proceedings, and the imposition of significant civil and/or criminal penalties and other relief. For example, California enacted the California Consumer Privacy Act, ("CCPA"), which went into effect January 1, 2020. The CCPA, among other things, created new data privacy obligations for covered companies and provided new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also created a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach.

Additionally, in November 2020, California voters passed the California Privacy Rights Act of 2020 ("CPRA"). The CPRA, which became effective January 1, 2023 created additional obligations with respect to certain data relating to consumers, significantly expands the CCPA, including by introducing additional obligations such as data minimization and storage limitations, granting additional rights to consumers, such as correction of personal information and additional opt-out rights, and creates a new entity, the California Privacy Protection Agency, to implement and enforce the law. The CCPA and CPRA may increase our compliance costs and potential liability. In addition to the CCPA, numerous other states' legislatures have passed or are considering similar laws that will require ongoing compliance efforts and investment.

The EU also has laws and regulations dealing with the collection, use and processing of personal data obtained from individuals in the EU, including the EU General Data Protection Regulation, or GDPR. These laws and regulations are often more restrictive than those in the United States and restrict transfers of personal data to the United States unless certain requirements are met. The GDPR provides that EU member states may make their own further laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition. Further, the United Kingdom's exit from the EU has

created uncertainty with regard to data protection regulation in the United Kingdom. We are subject to the UK General Data Protection Regulation and UK Data Protection Act of 2018, which retains the GDPR in the United Kingdom's national law and provides for a penalty structure similar to the GDPR. Because the interpretation and application of laws, regulations, standards and other obligations relating to data privacy and security are still uncertain, it is possible that these laws, regulations, standards and other obligations may be interpreted and applied in a manner that is inconsistent with our data processing practices and policies. If our practices are not consistent, or are viewed as not consistent, with changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may also become subject to fines, audits, inquiries, whistleblower complaints, adverse media coverage, investigations, lawsuits, loss of export privileges, severe criminal or civil sanction or other penalties.

Employees and human capital

As of December 31, 2022, we had 292 full-time employees. All of our employees are full-time and none of our employees are represented by a labor union or covered under a collective bargaining agreement.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

Our corporate headquarters is in Aliso Viejo, California where we lease four facilities housing our headquarters, manufacturing, research and development and administrative offices. The facility leases are for approximately 121,000 square feet in the aggregate. The leases terminate on (a) September 30, 2024, with one option to extend for five years; (b) January 31, 2026, with three options to extend for five years each; (c) March 31, 2023, with two options to extend for five years each; and (d) August 31, 2024, with one option to extend for five years. We believe that our existing facilities are adequate for our near-term needs but expect to need additional space as we grow. We believe that suitable additional or alternative space would be available in the future as required on commercially reasonable terms.

Legal proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Corporate information

We were incorporated in California on March 5, 1997 as Calhoun Vision, Inc. and changed our name to RxSight, Inc. in October 2016. We reincorporated in Delaware on July 6, 2021.We maintain a website at www.rxsight.com. Information contained on our website is not incorporated by reference into this Annual Report on Form 10-K or any other filings we make with the SEC.

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves numerous uncertainties and risks. In addition to the other information included in this Annual Report on Form 10-K, the following risks and uncertainties may have a material and adverse effect on our business, financial condition, results of operations, or stock price. You should consider these risks and uncertainties carefully, together with all of the other information included or incorporated by reference in this Annual Report on Form 10-K. The risks and uncertainties described below may not be the only ones we face. If any of the risks or uncertainties we face were to occur, the trading price of our securities could decline, and you may lose all or part of your investment. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. See the section titled "Special Note Regarding Forward-Looking Statements" appearing elsewhere in this Annual Report. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

Summary Risk Factors

Our following risks and uncertainties are among the most significant we face, however, the risks and uncertainties identified in this subsection are not the only ones we face and are qualified in their entirety by reference to all of the risk factors described herein:

Risks related to our business and products:

- We have a limited operating history, and if we fail to effectively train our sales force, increase our sales and marketing capabilities, or develop broad brand awareness in a cost-effective manner, our growth will be impeded, and our business will suffer.
- We have a history of net operating losses, and we expect to continue to incur losses in the future. If we ever achieve profitability, we may not be able to sustain it.
- Our success depends in large part on our RxSight system. If we are unable to successfully market and sell our RxSight system, our business prospects will be significantly harmed, and we may be unable to achieve revenue growth.
- We face significant competition, and if we are unable to compete effectively, we may not be able to achieve or maintain significant market penetration or improve our results of operations.
- Global economic, political and market conditions, including downgrades of the U.S. credit rating, may adversely affect our business, results of operations and financial condition, including our revenue growth and profitability.

Risks related to intellectual property:

- If we are unable to obtain, maintain, protect and enforce patent and other intellectual property protection for our technology and products, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- If we are unable to protect the confidentiality of our trade secrets and other proprietary information, our business and competitive position may be harmed.
- We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Risks related to government regulation:

- If we fail to obtain and maintain necessary regulatory clearances or approvals for our products, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations may be harmed.

Risks related to reliance on third parties:

- We depend upon third parties, including single and sole source suppliers, to manufacture certain components and subcomponents of the RxSight system, making us vulnerable to supply disruptions and price fluctuations.

Risks related to our common stock:

- The price of our stock may be volatile, and you could lose all or part of your investment.
- We do not know whether an active, liquid and orderly trading market will exist for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

General risk factors:

- We must recruit, retain, manage and motivate qualified executives as we build out the management team, and we are highly dependent on our management team.
- Future litigation proceedings could adversely affect our business.

Risks related to COVID-19:

- Our business, financial condition, results of operations and growth have been harmed by the effects of the COVID-19 pandemic and may continue to be harmed.

Risks related to our business and products

We have a limited operating history and if we fail to effectively train our sales force, increase our sales and marketing capabilities or develop broad brand awareness in a cost-effective manner, our growth will be impeded, and our business will suffer.

We were incorporated in March 1997 and began commercializing our products in the second half of 2019, when we initiated a full launch of our LAL and LDD. Accordingly, our limited commercialization experience and limited number of approved or cleared products make it difficult to evaluate our current business and assess our prospects. We also currently have limited sales and marketing experience. If we are unable to establish or scale effective sales and marketing capabilities, or if we are unable to commercialize any of our products, we may not be able to generate sufficient product revenue, sustain revenue growth and compete effectively. In order to generate future growth, we plan to continue to expand and leverage our sales and marketing infrastructure to increase our customer base and grow our business.

Identifying and recruiting qualified sales and marketing personnel and training them on our products, applicable federal and state laws and regulations, and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, or in the event we are unable to reduce costs in the face of an unexpected decline in demand for our products. Any failure to hire, develop and retain talented sales and marketing personnel, to achieve desired productivity levels in a reasonable timeframe or timely leverage our fixed costs could have a material adverse effect on our business, financial condition and results of operations. Moreover, the members of our direct 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 technical expertise and qualifications, or if we are unable to successfully instill technical expertise in replacement personnel, our revenue and results of operations could be materially harmed.

Our ability to increase our customer base and achieve broader market acceptance of our products will also depend to a significant extent on our ability to expand our marketing efforts. Our business may be harmed if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand in a cost-effective manner is critical to achieving broad acceptance of our products and penetrating new customer accounts. Brand promotion activities may not generate patient or doctor awareness or increased 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 doctor acceptance

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

These factors also make it difficult for us to forecast our financial performance and growth, and such forecasts are subject to a number of uncertainties, including our ability to successfully develop additional products that add functionality, reduce the cost of products sold, and broaden our commercial portfolio offerings and our ability to obtain the required regulatory approvals and clearances under applicable law both domestically and internationally, including FDA 510(k) clearance or pre-market approval, or PMA, for, and successfully commercialize, market and sell, our planned or future products in the United States or in international markets. 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.

We have a history of net losses, and we expect to continue to incur losses in the future. If we ever achieve profitability, we may not be able to sustain it.

We have incurred losses from operations since our inception and expect to continue to incur losses from operations in the future. We reported losses from operations of $63.3 million and $52.8 million for the years ended December 31, 2022 and 2021, respectively. As a result of these losses, as of December 31, 2022, we had an accumulated deficit of $546.0 million. We expect to continue to incur significant sales and marketing, research and development, regulatory and other expenses as we expand our marketing efforts to increase adoption of our products, expand existing relationships with our customers, obtain regulatory clearances or approvals for our planned or future products, conduct clinical trials on our existing and planned or future products and develop new products or add new features to our existing products. In addition, we expect our general and administrative expenses to increase due to the costs associated with being a public company.

The net losses that we incur may fluctuate from period to period. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time.

In order to support our continued operations and the growth of our business, we may seek to raise additional capital, which may not be available to us on acceptable terms, or at all.

We expect capital expenditures and operating expenses to increase over the next several years as we continue to operate our business and expand our infrastructure, commercial operations and research and development activities. Our primary uses of capital are, and we expect will continue to be, investment in our commercial organization and related expenses, clinical research and development services, laboratory and related supplies, legal and other regulatory expenses, general administrative costs and working capital. In addition, we may in the future seek to acquire or invest in additional businesses, products, services or technologies that we believe could complement or expand our product portfolio, enhance our technical capabilities or otherwise offer growth opportunities.

Because of these and other factors, we expect to continue to incur net losses and negative cash flows from operations in the future. Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our sales growth;
- our research and development efforts;
- our sales and marketing activities;
- our success in leveraging future strategic partnerships;
- working capital investments, primarily in inventories and accounts receivable;
- debt service and debt covenant requirements;
- our ability to borrow on our credit facility or raise additional funds through our at-the-market offering to finance our operations;

- the outcome, costs and timing of any clinical trial results for our current or future products;
- the emergence and effect of competing or complementary products;
- the availability and amount of reimbursement for procedures using our products;
- our ability to maintain, expand, enforce and defend our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management, sales, research and development, scientific and customer support personnel;
- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- operating and finance lease payments for our facilities;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the impact of the COVID-19 pandemic.

If we determine that we need to raise additional funds, we may do so through equity or debt financings, which may not be available to us when needed or on terms that we deem to be favorable. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected, including potentially requiring us to delay, limit, reduce or terminate certain of our product discovery and development activities or future commercialization efforts.

Moreover, in the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third party on unfavorable terms our rights to products or technologies we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic, the conflicts in Eastern Europe, and otherwise.

As of December 31, 2022 and 2021, we had $105.8 million and $159.3 million, respectively, in cash, cash equivalents and short-term investments. While we believe that our existing cash, cash equivalents and short-term investments and anticipated cash generated from sales of our products will be sufficient to meet our anticipated cash needs for at least 12 months following the date of this Annual Report on Form 10-K, we cannot assure you that we will be able to generate sufficient liquidity as and when needed. Further, although we do not anticipate the need to raise additional capital or incur additional debt in order to reach profit from operations, as the same may be disclosed in the Company's future Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q filed with the SEC (though we may opportunistically access our ATM facility under advantageous circumstances), we have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. We cannot assure you that we will be able to generate sufficient liquidity as and when needed.

Global economic, political and market conditions, including downgrades of the U.S. credit rating, may adversely affect our business, results of operations and financial condition, including our revenue growth and profitability.

The current worldwide economic and financial environment, as well as various social and political tensions in the U.S. and around the world, may contribute to increased market volatility, may have long-term effects on the U.S. and worldwide financial markets and may cause economic uncertainties or deterioration in the U.S. and worldwide. The impact of downgrades by rating agencies to the U.S. government's sovereign credit rating or its perceived creditworthiness as well as potential government shutdowns could adversely affect the U.S. and global financial markets and economic conditions. U.S. debt ceiling and budget deficit concerns have increased the possibility of additional credit-rating downgrades and economic slowdowns, or a recession in the U.S. In addition, disagreement over the federal budget has caused the U.S. federal government to shut down for periods of time. Continued adverse political and economic conditions could have a material adverse effect on our business, financial condition, results of operations and prospects.

Deterioration in the economic conditions globally resulting in instability in global financial markets, including the following, may pose a risk to our business: inflation and rising interest rates, large sovereign debts and fiscal deficits of several countries in Europe and in emerging markets' jurisdictions, levels of non-performing loans on the balance sheets of European banks, the effect of the United Kingdom leaving the European Union, instability in the capital markets and the COVID-19 pandemic.

Various social and political circumstances in the U.S. and around the world (including wars and other forms of conflict, terrorist acts, security operations and catastrophic events such as fires, floods, earthquakes, tornadoes, hurricanes and global health epidemics) may also contribute to increased market volatility and economic uncertainties or deterioration in the U.S. and worldwide and have a material adverse effect on our business, financial conditions, results of operations and prospects.

The terms of our amended term loan place restrictions on our operating and financial flexibility, and failure to comply with covenants or to satisfy certain conditions of the agreement governing the term loan may result in acceleration of our repayment obligations and foreclosure on our pledged assets, which could significantly harm our liquidity, financial condition, operating results, business and prospects and cause the price of our securities to decline.

Our amended term loan (the "Amended Term Loan"), also referred to as our credit facility, with Oxford Finance, provides for a $60.0 million term-loan facility scheduled to mature on February 1, 2027, of which $40.0 million was fully funded as of May 3, 2022, from the original term loan. Subject to the terms and conditions of the Amended Term Loan, we may borrow up to $10.0 million during the second quarter of 2023 and up to another $10.0 million in the third quarter of 2023.

Our payment obligations under the Amended Term Loan reduce cash available to fund working capital, capital expenditures, research and development and general corporate needs. In addition, indebtedness under the Amended Term Loan bears interest at a variable rate, making us vulnerable to increases in market interest rates. If market rates increase, we will have to pay additional interest on this indebtedness, which would further reduce cash available for our other business needs.

Our obligations under the Amended Term Loan are secured by substantially all of our assets, excluding intellectual property. The security interest granted over our assets could limit our ability to obtain additional debt financing. The Amended Term Loan also requires us to comply with a number of other covenants (affirmative and negative), including restrictive covenants that limit our ability to: incur additional indebtedness; encumber the collateral securing the loan; acquire, own or make investments; repurchase or redeem any class of stock or other equity interest; declare or pay any cash dividend or make a cash distribution on any class of stock or other equity interest; dispose of a portion of our assets; acquire other businesses; and merge or consolidate with or into any other organization or otherwise suffer a change in control, in each case subject to exceptions.

In addition to other specified events of default, the lenders could declare an event of default upon the occurrence of any event that they interpret as having a material impairment on their lien on the collateral under the agreement, a material adverse change in our business, operations or condition (financial or otherwise) or a material impairment in the prospect of repayment of our obligations under the agreement. If we default under the credit facility, the lenders may accelerate all of our repayment obligations and, if we are unable to access funds to meet those obligations or to renegotiate our agreement, the

lenders could take control of our pledged assets and we would have to immediately cease operations. During the continuance of an event of default, the then-applicable interest rate on the then-outstanding principal balance will increase by 5.0%. Upon an event of default, the lenders could also require us to repay the loan immediately, together with a final payment charge of 5.0% of the total term loan advances we borrowed, together with other fees. If we were to renegotiate the agreement under such circumstances, the terms may be significantly less favorable to us. If we were liquidated, the lenders' right to repayment would be senior to the rights of our stockholders to receive any proceeds from the liquidation. Any declaration by the lenders of an event of default could significantly harm our liquidity, financial condition, operating results, business, and prospects and cause the price of our securities to decline.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness may contain provisions that are as, or more, restrictive than the provisions governing our existing indebtedness. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral or force us into bankruptcy or liquidation.

Our success depends in large part on our RxSight system. If we are unable to successfully market and sell our RxSight system, our business prospects will be significantly harmed, and we may be unable to achieve revenue growth.

Our future financial success will depend substantially on our ability to effectively and profitably market and sell our RxSight system to ophthalmic practices. The commercial success of our RxSight system and any of our planned or future products will depend on a number of factors, including the following:

- the actual and perceived effectiveness and reliability of our RxSight system, especially relative to alternative products;
- the prevalence and severity of any adverse patient events involving our RxSight system;
- the results of clinical studies and trials relating to our RxSight system;
- our ability to sustain meaningful clinical benefits for our patients;
- our ability to obtain regulatory approval to market our planned or future products for use in the United States or internationally;
- the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for conditions treated by our products;
- the degree to which treatments using our products are covered and receive adequate reimbursement from third-party payors, including governmental and private insurers, as well as patient willingness to pay for the additional costs associated with our premium intraocular lens out of pocket;
- the degree to which doctors adopt our RxSight system;
- the fact that governmental and private health care providers and payors around the world are increasingly utilizing managed care for the delivery of health care services, centralizing purchasing, limiting the number of vendors that may participate in purchasing programs, forming group purchasing organizations and integrated health delivery networks and pursuing consolidation to improve their purchasing leverage and using competitive bid processes to procure health care products and services;
- our ability to obtain, maintain, protect and enforce our intellectual property rights in and to our RxSight system;
- the degree to which patients value the customized vision delivered by the RxSight system and are satisfied with their results;
- achieving and maintaining compliance with regulatory requirements applicable to our products;
- the extent to which we are successful in educating doctors about IOLs in general, and the benefits of our RxSight system;
- our reputation among doctors;

- the strength of our marketing and commercial organization;
- the effectiveness of our marketing and sales efforts in the United States, including our efforts to build out our sales team;
- our ability to expand the commercialization of our products into international markets;
- our ability to continue to develop, validate and maintain a commercially viable manufacturing process that is compliant with the Quality Systems Regulations ("QSR"), and other applicable foreign, federal and state regulatory requirements;
- the success of our ongoing or future clinical trials; and
- whether we are required by the FDA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for current or future indications.

If we fail to successfully market and sell our products, we will not be able to grow our revenue or achieve profitability, which will have a material adverse effect on our business, financial condition and results of operations. Our ability to grow our revenue in future periods will depend on our ability to successfully penetrate our target markets and increase sales of our RxSight system and any new product or product indications that we introduce, which will, in turn, depend in part on our success in growing our user base and driving increased use of our products. New products or product indications will also need to be approved or cleared by the FDA and comparable non-U.S. regulatory agencies in any international markets we target in order to commercialize them. If we cannot achieve revenue growth or achieve or sustain profitability, it could have a material adverse effect on our business, financial condition and results of operations.

Adoption of our products depends upon appropriate training for doctors, and inadequate training may lead to negative patient outcomes, affect adoption of our products and adversely affect our business.

The success of our products depends in part on our customers' adherence to appropriate patient selection and proper techniques provided in training sessions conducted by our training faculty. For example, we train our customers to ensure correct use of our RxSight system. However, doctors rely on their previous medical training and experience, and we cannot guarantee that all such doctors will have the necessary skills or training to effectively utilize our products. We do not control which doctors use our products or how much training they receive, and doctors who have not completed our training sessions may nonetheless attempt to use our products. In addition, doctors may use our products in a manner that is not consistent with their labeled indications for which no training is available. If doctors use our products in a manner that is inconsistent with their labeled indications, with components that are not compatible with our products or otherwise without adhering to or completing our training sessions, their patient outcomes may not be consistent with the outcomes achieved by other doctors or in our clinical trials. This result may negatively impact the perception of patient benefit and safety and limit adoption of our products, which would have a material adverse effect on our business, financial condition and results of operations.

We currently require limited training in the use of our products because we market primarily to doctors who are experienced in the specific techniques required to use our devices. If demand for our products continues to grow, less experienced doctors will likely use our products, potentially leading to more injury and an increased risk of product liability claims. The use or misuse of our products may in the future result in complications and potentially lead to product liability claims.

The commercial success of our RxSight system will depend upon attaining significant market acceptance of these products among patients and doctors.

Our success will depend, in part, on the acceptance of our RxSight system as safe, effective and, with respect to doctors, cost-effective. We cannot predict how quickly, if at all, patients, doctors, or payors will accept our RxSight system or, if accepted, how frequently it will be used. Our RxSight system and planned or future products we may develop or market may never gain broad market acceptance for some or all of our targeted indications. Patients and doctors must believe that our products offer benefits over alternative treatment methods. To date, a substantial majority of our product sales and revenue have been derived from a limited number of customers who have adopted our RxSight system. Our future growth and profitability largely depend on our ability to increase doctors' awareness of our RxSight system and our products and on the willingness of patients and doctors to adopt them. These parties 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 safe, effective and, with respect to providers, cost-effective, on a stand-alone basis and relative to competitors' products. Patients and

doctors must believe that our products offer benefits over alternative treatment methods. Even if we are able to raise awareness, doctors tend to be slow in changing their medical treatment practices and may be hesitant to select our products for recommendation to their patients for a variety of reasons, including:

- long-standing relationships with competing companies and distributors that sell other products;
- competitive response and negative selling efforts from providers of alternative products;
- lack of experience with our products and concerns that we are relatively new to market;
- lack or perceived lack of sufficient clinical evidence, including long-term data, supporting safety or clinical benefits;
- time commitment and skill development that may be required to gain familiarity and proficiency with our products;
- patient confusion regarding the wide range of commercially available premium IOL offerings and their ability to deliver promised results at near, middle and far distances without reliance on glasses;
- patient reticence to select a premium IOL due to nonperformance and adverse side effects associated with competing products in the market;
- patient non-compliance with the RxSight system requirement to wear protective glasses following surgery until the LAL is locked to avoid UV exposure and an unintended change to the LAL, resulting in patient dissatisfaction with the results and possible need to remove the LAL; and
- an inability to generate patient referral due to dissatisfaction with results obtained through treatment with our products, the out-of-pocket cost of treatments using our products or otherwise.

In order for doctors to use our RxSight system, they must make a significant up-front investment to purchase the LDD. This can result in a lengthy sales cycle and require extensive negotiations and management time. If we are unsuccessful in placing LDDs with providers, our sales may decrease, and our operating results may be harmed.

Doctors play a significant role in determining the course of a patient's treatment, and, as a result, the type of treatment that will be utilized and provided to a patient. We focus our sales, marketing and education efforts primarily on doctors, and aim to educate referring doctors on the patient population that would benefit from our products. However, we cannot assure you that we will achieve broad market acceptance among doctors.

For example, some doctors may choose to utilize our RxSight system on only a subset of their total patient population or may not adopt our RxSight system at all. If we are not able to effectively demonstrate that the use of our RxSight system is beneficial in a broad range of patients, adoption of our product 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. We cannot assure you that our products will achieve broad market acceptance among doctors. Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products, procedures or technologies are considered safer or more cost-effective or otherwise superior. Any failure of our products to generate sufficient 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.

Our reputation among our current or potential customers, as well as among doctors, could also be negatively affected by safety or customer satisfaction issues involving us or our products, including product recalls. Future product recalls or other safety or customer satisfaction issues relating to our reputation could negatively affect our ability to establish or maintain broad adoption of our products, which would harm our future prospects and have a material adverse effect on our business, financial condition and results of operations.

Our RxSight system involves surgical risks and is contraindicated in certain patients, which may limit adoption.

Risks of using our products include those associated with cataract surgery and IOL implantation. There are also possible, but rare, complications due to the use of UV light from the LDD, including a temporary or long-lasting change to vision. We are aware of certain characteristics and features of our RxSight system that may prevent widespread market adoption,

including the fact that doctors would need to adopt a new procedure, and training for doctors will be required to enable them to effectively operate our products.

We face significant competition, and if we are unable to compete effectively, we may not be able to achieve or maintain significant market penetration or improve our results of operations.

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. We compete with manufacturers and distributors of premium and conventional IOLs. Our most significant competitors in the IOL field include Alcon, Johnson & Johnson Vision and Bausch + Lomb. Many of our competitors are large, well-capitalized companies with significantly greater market share and resources than we have. Therefore, they can spend more on product development, marketing, sales and other product initiatives than we can. We also compete with smaller medical device companies that have a single product or a limited range of products. In addition, patients who receive an LAL will be required to wear UV protective glasses until final lock-in which is approximately four to five weeks after surgery. They will also be required to return for an additional two to three clinic visits compared to traditional monofocal cataract surgery. The additional clinic visits are non-surgical but do require the patient's eyes to be dilated. Due to these additional requirements, market acceptance of the LAL may be impacted. We believe the principal competitive factors in our markets include:

- The quality of patient outcomes, oftentimes measured by visual acuity, and adverse event rates;
- Patient experience, including patient recovery time and level of discomfort;
- Acceptance by treating doctors and referral sources;
- Doctor learning curves and willingness to adopt new technologies;
- Ease-of-use and reliability;
- Economic benefits and cost savings;
- Strength of clinical evidence;
- Effective distribution and marketing to surgeons and potential patients; and
- Product price and qualification for coverage and reimbursement.

We compete primarily on the basis that our products are designed to enable more doctors to treat more patients more efficiently and effectively. Our continued success depends on our ability to:

- continue to develop innovative, proprietary products that address significant clinical needs in a manner that is safe and effective for patients and easy-to-use for doctors;
- obtain and maintain regulatory clearances or approvals;
- demonstrate safety and effectiveness in our sponsored and third-party clinical trials;
- expand our sales force across key markets to increase doctors' awareness;
- obtain and maintain coverage and adequate reimbursement for procedures using our products;
- attract and retain skilled research, development, sales and clinical personnel;
- cost-effectively manufacture, market and sell our products;
- provide doctors with a sufficient return on investment as compared to alternative premium IOL procedures that justifies the upfront cost of our LDD; and
- obtain, maintain, enforce and defend our intellectual property rights and operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others.

We can provide no assurance that we will be successful in developing new products or commercializing them in ways that achieve market acceptance. If we develop new products, sales of those products may reduce revenue generated from our existing products. Moreover, any significant delays in our product launches may significantly impede our ability to enter or compete in a given market and may reduce the sales that we are able to generate from these products. We may experience delays in any phase of a product development, including during research and development, clinical trials, regulatory review, manufacturing and marketing. Delays in product introductions could have a material adverse effect on our business, financial condition and results of operations.

In addition, many medical device companies are consolidating to create new companies with greater market power. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for our products. If we reduce our prices because of consolidation in the healthcare industry, our revenue may decrease, which could have a material adverse effect on our business, financial condition and results of operations.

If our facilities become damaged or inoperable, or if we are required to vacate a facility, we may be unable to manufacture our products or we may experience delays in production or an increase in costs, which could adversely affect our results of operations.

We currently maintain our research and development, manufacturing and administrative operations in Aliso Viejo, California, and we do not have redundant facilities. We operate in four separate facilities, designated as a single manufacturing facility, and should any one of these facilities be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires (both of which are prevalent in California) or other events, it could take months to relocate or rebuild, during which time our employees may seek other positions, our research, development and manufacturing would cease or be delayed and our products may be unavailable. A major interruption in the manufacturing operations at this facility would materially impact our ability to operate. Because of the time required to authorize manufacturing in a new facility under federal, state and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity. While we maintain property and business interruption insurance, such insurance has limits and would not cover all damages, including losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. The inability to perform our research, development and manufacturing activities if our facilities become inoperable, combined with our limited inventory of materials and components and manufactured products, may cause doctors to discontinue using our products or harm our reputation, and we may be unable to re-establish relationships with such doctors in the future. Consequently, a catastrophic event at our current facility or any future facilities could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, the current leases on our four facilities expire, respectively, on (i) September 30, 2024, with one option to extend for five years; (ii) January 31, 2026, with three options to extend for five years each; (iii) March 31, 2023 with two options to extend for five years each, and (iv) August 31, 2024, with one option to extend for five years. We may be unable to renew our leases or find a new facility on commercially reasonable terms, or at all. If we were unable or unwilling to renew at the proposed rates, relocating our manufacturing facility would involve significant expense in connection with the movement and installation of key manufacturing equipment and any necessary recertification with regulatory bodies, and we cannot assure you that such a move would not delay or otherwise adversely affect our manufacturing activities or operating results. If our manufacturing capabilities were impaired by any such move, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business.

Technological change may adversely affect sales of our products and may cause our products to become obsolete.

The medical device market is characterized by extensive research and development and rapid technological change. There can be no assurance that other companies, including current competitors or new entrants, will not succeed in developing or marketing 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. If we are unable to innovate successfully, our products could become obsolete and our revenue would decline as our customers purchase our competitors' products. Our failure to develop new products, applications or features could result from insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills, a lack of other research and development resources or other constraints. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our current or future competitors could have a material adverse effect on our business, financial condition and results of operations.

We have limited data and experience regarding the safety and efficacy of our RxSight system. Results of earlier studies may not be predictive of future clinical trial results, and planned studies may not establish an adequate safety or efficacy profile for our RxSight system and other planned or future products, which would affect market acceptance of our RxSight system.

Because our RxSight system technology is a relatively new treatment to optimize vision after cataract surgery, we have performed clinical trials only with limited patient populations. The long-term effects of using our products in a large number of patients have not been studied and the results of short-term clinical use of such products do not necessarily predict long-term clinical benefits or reveal long-term adverse effects. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials in other patient populations. 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 have nonetheless failed to replicate results in later clinical trials and subsequently failed to obtain marketing approval. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials.

If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be harmed.

Clinical development is a long, expensive and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. We are currently engaged in post-market clinical trials of our RxSight system. Completion of clinical trials may take several years or more. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a trial, in reaching an agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board approval at each site, in recruiting patients to participate in a trial or in obtaining sufficient supplies of clinical trial materials. We cannot provide any assurance that we will successfully, or in a timely manner, enroll our clinical trials, that our clinical trials will meet their primary endpoints or that such trials or their results will be accepted by the FDA or foreign regulatory authorities.

We may experience numerous unforeseen events during, or because of, the clinical trial process that could delay or prevent us from receiving regulatory clearance or approval for new products, modifications of existing products, or new indications for existing products, including:

- successful and timely completion of nonclinical studies or clinical development of our products, as well as the associated costs, including any unforeseen costs we may incur as a result of clinical trial delays due to the COVID-19 pandemic or other causes;
- enrollment in our clinical trials may be slower than we anticipate, or we may experience high screen failure rates in our clinical trials, resulting in significant delays;
- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing which may be expensive and time-consuming;
- trial results may not meet the level of statistical significance required by the FDA or other regulatory authorities;
- the FDA or similar foreign regulatory authorities may find that one or more of our products is not sufficiently safe for investigational use in humans;
- the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;
- there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities;
- there may be delays in obtaining institutional review board approvals or governmental approvals to conduct clinical trials at prospective sites;

- the FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory;
- the FDA or similar foreign regulatory authorities may change their review policies or adopt new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications;
- we may have trouble in managing multiple clinical sites;
- we may have trouble finding patients to enroll in our trials;
- we may experience delays in agreeing on acceptable terms with third-party research organizations and trial sites that may help us conduct the clinical trials; and
- we, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks.

Failures or perceived failures in our clinical trials will delay and may prevent our product development and regulatory approval process, damage our business prospects and negatively affect our reputation and competitive position.

Unauthorized third parties may seek to access our devices or other products and services, or related devices, products, and services, and modify or use them in a way inconsistent with our FDA clearances and approvals, which may create risks to users.

Medical devices are increasingly connected to the internet, hospital networks, and other medical devices to provide features that improve healthcare and increase the ability of healthcare providers to treat patients and patients to manage their conditions. While currently bidirectional connectivity and interoperability of our RxSight system with other devices, local networks and the internet is not enabled, this may change in the future. Enablement of such features may increase cybersecurity risks and the risks of unauthorized access and use by third parties. For example, unauthorized third parties may seek to access our devices or other products and services, or related devices, products, and services, and modify or use them in a way inconsistent with our FDA clearances and approvals, which may create risks to users and potential exposure to the company.

We may expend our limited resources to pursue a particular product or indication and fail to capitalize on products or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific products and indications. As a result, we may forgo or delay pursuit of other opportunities with others that could have had greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications or enhancements may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular potential product, we may relinquish valuable rights to that potential product through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such potential product.

We may not be able to develop, license or acquire new products, enhance the capabilities of our existing products to keep pace with rapidly changing technology and customer requirements or successfully manage the transition to new product offerings, any of which could have a material adverse effect on our business, financial condition and results of operations.

Our success depends on our ability to develop, license or acquire and commercialize additional products and to develop new applications for our technologies in existing and new markets, while improving the performance and cost-effectiveness of our existing products, in each case in ways that address current and anticipated customer requirements. We intend to develop and commercialize additional products through our research and development program and by licensing or acquiring additional products and technologies from third parties. Our success is dependent upon several factors, including functionality, competitive pricing, ease of use, the safety and efficacy of our products and our ability to identify, select and acquire the rights to products and technologies on terms that are acceptable to us.

The medical device industry is characterized by rapid technological change and innovation. New technologies, techniques or products could emerge that might offer better combinations of price and performance or better address customer requirements as compared to our current or future products. Competitors, who may have greater financial, marketing and sales resources than we do, may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. Any new product we identify for internal development, licensing or acquisition may require additional development efforts prior to commercial sale, including extensive clinical testing and approval or clearance by the FDA and applicable foreign regulatory authorities. Due to the significant lead time and complexity involved in bringing a new product to market, we are required to make a number of assumptions and estimates regarding the commercial feasibility of a new product. These assumptions and estimates may prove incorrect, resulting in our introduction of a product that is not competitive at the time of launch. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies. Our ability to mitigate downward pressure on our selling prices will be dependent upon our ability to maintain or increase the value we offer to doctors as well as payors. All new products are prone to the risks of failure inherent in medical device product development, including the possibility that the product will not be shown to be sufficiently safe and effective for approval or clearance by regulatory authorities. In addition, we cannot assure you that any such products that are approved or cleared will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace. The expenses or losses associated with unsuccessful product development or launch activities, or a lack of market acceptance of our new products, could adversely affect our business, financial condition and results of operations.

Our ability to attract new customer accounts depends in large part on our ability to enhance and improve our existing products and to introduce compelling new products. The success of any enhancement to our products depends on several factors, including adoption and continued use by doctors, competitive pricing and overall market acceptance. Any new product that we develop may not be introduced in a timely or cost-effective manner, may contain defects or may not achieve the market acceptance necessary to generate significant revenue. If we are unable to successfully develop, license or acquire new products, enhance our existing products to meet customer requirements or otherwise gain market acceptance, our business, financial condition and results of operations would be harmed.

The typical development cycle of new medical device products can be lengthy and complicated and may require complex technology and engineering. Such developments may involve external suppliers and service providers, making the management of development projects complex and subject to risks and uncertainties regarding timing, timely delivery of required components or services and satisfactory technical performance of such components or assembled products. If we do not achieve the required technical specifications or successfully manage new product development processes, or if development work is not performed according to schedule, then such new technologies or products may be adversely impacted, and our business and operating results may be harmed.

If we fail to identify, acquire and develop other products, we may be unable to grow our business.

As a significant part of our growth strategy, we intend to develop and commercialize additional products through our research and development program or by licensing or acquiring additional products and technologies from third parties. The success of this strategy depends upon our ability to identify, select and acquire the right to products and technologies on terms that are acceptable to us.

Any product we identify, license or acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval or clearance by the FDA and applicable foreign regulatory authorities. All products are prone to the risks of failure inherent in medical device product development, including the possibility that the product will not be shown to be sufficiently safe and effective for approval or clearance by regulatory authorities. In addition, we cannot assure you that any such products that are approved or cleared will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace.

Proposing, negotiating and implementing an economically viable product or technology acquisition or license is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition or license of approved or cleared products. We may not be able to acquire or license the rights to additional approved or cleared products on terms that we find acceptable, or at all.

If we are unable to develop suitable potential products through internal research programs or by obtaining rights from third parties, it could have a material adverse effect on our business, financial condition and results of operations.

We may acquire other companies or technologies, which could fail to result in a commercial product or increased revenue, divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results.

Although we currently have no agreements or commitments to complete any such transactions, 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. 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 operating results, business and financial condition may suffer.

Coverage and adequate reimbursement and/or the ability of patients to pay for the difference between the price charged by practices and the reimbursement amount may not be available for our products in sufficient markets, which could diminish our sales or affect our ability to sell our products.

In both U.S. and non-U.S. markets, our ability to successfully commercialize and achieve market acceptance of our products depends, in significant part, on the availability of adequate financial remuneration to doctor practices and surgical centers. This remuneration can come from a combination of sources, including third-party payors, such as Medicare and Medicaid programs in the United States, managed care organizations and private health insurers. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments. They also can preclude patients from paying extra to receive additional services, such as those associated with placement of premium IOLs. Our products are purchased by doctors who will then seek reimbursement from third-party payors and patients for the procedures performed using our products. Reimbursement systems and patient billing rules in international markets vary significantly by country and by region within some countries, and reimbursement and/or non-reimbursement approvals must be obtained on a country-by-country basis. In certain international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Furthermore, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures, as well as the ability to charge patients directly for non-reimbursed devices and procedures. In most markets there are private insurance systems as well as government-managed systems.

While third-party payors currently cover and provide reimbursement for a portion of the cost of the procedures performed using our currently cleared or approved products, we can give no assurance that these third-party payors will continue to provide coverage and adequate reimbursement or permit patient payment for the non-reimbursed portion sufficient to permit doctors to offer procedures using our products to patients requiring treatment. If sufficient coverage and reimbursement or flexibility to enable patient payment is not available for the procedures performed using our products, in either the United States or any international markets we enter, the demand for our products and our revenue will be adversely affected.

Furthermore, the overall amount of reimbursement available for products and procedures intended to treat cataract and refractive conditions of the eye could remain at current levels or decrease in the future. Failure by doctors to obtain and maintain coverage and adequate reimbursement as well as patient charges for the procedures performed using our products would materially adversely affect our business, financial condition and results of operations.

Third-party payors are also increasingly examining the cost effectiveness of products, in addition to their safety and efficacy, when making coverage and payment decisions. Third-party payors have also instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures.

Additionally, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. It is uncertain whether our current products or any planned or future products will be viewed (or continue to be viewed) as sufficiently cost effective to warrant coverage and adequate reimbursement levels for procedures using such products in any given jurisdiction.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products. The expense and potential unavailability of insurance coverage for liabilities resulting from our products could harm us and our ability to sell our products.

We face an inherent risk of product liability as a result of the marketing and sale of our products. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable during manufacturing, marketing or sale. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on doctors in connection with the use of our products on patients. If these doctors are not properly trained or are negligent, the capabilities of our products may be diminished, or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to market and sell our products.

We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition and results of operations. In addition, 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 in the industry, significantly increase our expenses and reduce product sales.

Some of our customers and prospective customers may also have difficulty in procuring or maintaining liability insurance to cover their operations and use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our

products and potential customers may opt against purchasing our products due to the cost or inability to procure insurance coverage.

We intend to expand sales of our products internationally in the future, but we may experience difficulties in obtaining regulatory clearance or approval or in successfully marketing our products internationally even if approved. A variety of risks associated with marketing our products internationally could materially adversely affect our business.

Sales of our products outside of the United States would be subject to foreign regulatory requirements governing clinical trials and marketing approval. We will incur substantial expenses in connection with our international expansion. Additional risks related to operating in foreign countries include:

- differing regulatory requirements and reimbursement regimes in foreign countries, including changes to regulatory requirements and implementation of new regulations in foreign countries;
- difficulties in compliance with non-U.S. laws and regulations;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- trade protection measures, import or export licensing requirements, or other restrictive actions by U.S. or non-U.S. governments;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations in international markets, which would have a material adverse effect on our business, financial condition and results of operations.

Further, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, where applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international

operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

In addition, there can be no guarantee that we will receive approval to sell our products in the international markets we target, nor can there be any guarantee that any sales would result even if such approval is received. Even if the FDA grants marketing approval for a product, comparable regulatory authorities of foreign countries must also approve the manufacturing or marketing of the product in those countries. Approval in the United States, or in any other jurisdiction, does not ensure approval in other jurisdictions. Obtaining foreign approvals could result in significant delays, difficulties and costs for us and require additional trials and additional expenses. Regulatory requirements can vary widely from country to country and could delay the introduction of our products in those countries. Clinical trials conducted in one country may not be accepted by other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. If we fail to comply with these regulatory requirements or to obtain and maintain required approvals, our target market will be reduced and our ability to generate revenue will be diminished. Our inability to successfully enter all our desired international markets and manage business on a global scale could negatively affect our business, financial results and results of operations.

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

Manufacturers of medical devices 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 doctors performing cataract procedures, or any reduction in the flexibility to charge patients for non-reimbursed procedures could make it difficult for us to convince our customers to make the up-front investment in our LDD and could create additional pricing pressure with respect to the patient's decision to pay the additional cost associated with our LALs and potentially a reduction in the number of procedures performed using the RxSight system and corresponding sales of LDDs, LALs, accessories and services. If we are forced to lower the price we charge for our products, our revenue and 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 will continue to be subject to significant pricing pressure, which could harm our business, financial condition and results of operations.

The sizes of the markets for our current and future products have not been established with precision and may be smaller than we estimate.

Our estimates of the annual total addressable markets for our current products and products under development are based on a number of internal and third-party estimates, including, without limitation, the number of patients who have undergone cataract surgery, and the assumed prices at which we can sell our RxSight system. 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. In addition, our estimates of the sizes of the cataract surgery patient population include patients who might never be likely candidates for treatment with our products. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell future products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business.

Changes to state regulations and interpretation of the practice of optometry, for public health insurance coverage and government reimbursement rates for our products and related procedures and/or medical or professional malpractice insurance coverage for doctors who perform procedures using our products could affect the adoption of our products and our future revenue.

States regulate the practice of optometry, including the types of procedures optometrists are authorized to perform in each state. To the extent states change or narrow the scope of the practice of optometry or their interpretation of the scope of optometry with respect to those who are qualified to perform LDD procedures involving our RxSight system, such state regulation or policy can have a material impact on which doctors may use our RxSight system, our customer base and market share, and the adoption of our RxSight system. Additionally, payor restrictions on the coverage and/or reimbursement levels for procedures using our RxSight system can negatively impact the adoption of our products and the pricing of our products, which can have a material impact on our profitability. Changes to medical or professional malpractice insurance coverage policies for doctors who perform procedures using our products, including refusal to cover malpractice liability insurance related to the use of our products can have a material impact on the adoption of our products and our business operations. We

can provide no assurance on the impact of current and future federal and state legislative, executive, and administrative actions, including measures implemented by state boards of examiners in optometry, as well as policies of malpractice insurance carriers and payors on us, our business operations, and the business of our customers. The implementation of cost containment measures or other policy and regulatory changes may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

The federal government is considering ways to change, and has changed, the manner in which healthcare services are paid for in the United States. Individual states may also enact legislation that impacts Medicaid payments to doctors. In addition, CMS establishes Medicare payment levels for doctors on an annual basis, which can increase or decrease payment to such entities. 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. In addition, the ability to charge patients directly for premium IOLs and associated services also varies widely across different countries and could become more restricted. Even if we succeed in bringing our products to market internationally, 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.

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, profitability and cash flow, 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. 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. 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.

We expect to significantly expand our organization, including expanding our sales and marketing capability and creating additional infrastructure to support our operations as a public company, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We have and expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of sales and marketing and finance and accounting. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and our limited experience in managing such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert or stretch our management and business development resources in a way that we may not anticipate. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Certain of our operating results and financial metrics may be difficult to predict as a result of seasonality.

While we have not yet experienced significant seasonality in our results, it is not uncommon in our industry to experience seasonally weaker revenue during the summer months and end-of-year holiday season. We may be affected by other seasonal trends in the future, including severe weather (which can impact the number of elective procedures performed), particularly as our business matures. Additionally, this seasonality may be reflected to a much lesser extent, and sometimes may not be immediately apparent, in our revenue. To the extent we experience this seasonality, it may cause fluctuations in our operating results and financial metrics and make forecasting our future operating results and financial metrics more difficult.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be subject to certain limitations.

As of December 31, 2022, we had federal net operating loss carryforwards ("NOLs") of approximately $300.4 million, which will begin to expire in various years ranging from 2023 to 2037. Our NOLs could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Under the Tax Cuts and Jobs Act ("Tax Act"), as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, our federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020 is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act, as modified by the CARES Act.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), if a corporation undergoes an "ownership change" (generally defined as a cumulative change in our ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience an ownership change in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in our stock ownership. Our ability to utilize those NOLs could be limited by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations.

Risks related to intellectual property

If we are unable to obtain, maintain, protect and enforce patent and other intellectual property protection for our technology and products, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

Our success depends in large part on our ability to obtain, maintain, protect and enforce patent and other intellectual property protection in the United States and other countries with respect to our products and technology we develop. If we fail to obtain, maintain, protect and enforce our intellectual property, third parties may be able to compete more effectively against us, we may lose our technological or competitive advantage, or we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We seek to protect our position by in-licensing intellectual property relating to our products and filing patent applications in the United States and abroad related to our technologies and products that are important to our business. We also rely on a combination of contractual provisions, confidentiality procedures and copyright, trademark, trade secret and other intellectual property rights to protect the proprietary aspects of our brands, products, 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 obtaining and maintaining patents, copyrights, trademarks, trade secrets, data and know-how and other intellectual property rights.

We may not be able to obtain and maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage. For example, our trade secrets, data and know-how could be subject to unauthorized use, misappropriation or disclosure to unauthorized parties, despite our efforts to enter into confidentiality agreements with our employees, consultants, contractors, clients and other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. In addition, the patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications 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 intellectual property at all. Despite our efforts to protect our intellectual property, unauthorized parties may be able to obtain and use information that we regard as proprietary.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our owned and in-licensed issued patents may be challenged in courts or patent offices in the United States and abroad. For example, we may be subject to a third-party submission of prior art to the USPTO, challenging the validity of one or more claims of our owned

or in-licensed issued patents. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our owned or in-licensed pending patent applications.

It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, consultants, contractors, collaborators, vendors 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. We may not be able to obtain or maintain patent applications and issued patents due to the subject matter claimed in such patent applications and issued patents being in disclosures in the public domain, and we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with our technologies. In addition, 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 our owned or in-licensed issued patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or in-licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable.

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and in-licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged, narrowed or invalidated by third parties. Additionally, our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Third parties may also 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 compete 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, in which case, our competitors and other third parties 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.

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

In addition, given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed 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.

Our other intellectual property, including our trademarks, could also be challenged, invalidated, infringed and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks, in which case 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 suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion.

We may in the future also be subject to claims by our former employees, consultants or contractors asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants, contractors 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.

Failure to obtain and maintain patents, trademarks and other 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 may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, this could arise if the research resulting in certain of our owned or in-licensed patent rights and technology was funded in part by the United States government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to United States industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects.

Moreover, a portion of our intellectual property has been acquired from one or more third parties. While we have conducted diligence with respect to such acquisitions, because we did not participate in the development or prosecution of much of the acquired intellectual property, we cannot guarantee that our diligence efforts identified and/or remedied all issues related to such intellectual property, including potential ownership errors, potential errors during prosecution of such intellectual property, and potential encumbrances that could limit our ability to enforce such intellectual property rights.

Patent terms may be inadequate to protect our competitive position on technology for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest claimed U.S. non-provisional or Patent Cooperation Treaty application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent life has expired for a product, we may be open to competition. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products

might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours for a meaningful amount of time, or at all.

Obtaining and maintaining our 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 noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patents and patent applications are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of such issued patents and patent applications. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse 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. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. We are dependent on our licensors to take the necessary action to comply with these requirements with respect to certain of our in-licensed intellectual property, and if we or any of our current or future licensors fail to maintain the patents and patent applications covering our RxSight system or any future products, our competitors may be able to enter the market, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

Our future reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we expect to rely on a third party to manufacture our RxSight system, and any future products, and we expect to collaborate with third parties on the continuing development of our RxSight system, and any future products, we must, at times, share trade secrets with them. We also expect to conduct R&D programs that may require us to share trade secrets under the terms of our partnerships or agreements with CROs. We seek to protect our proprietary technology in part by entering into agreements containing confidentiality and use restrictions and obligations with our advisors, employees, contractors, CMOs, CROs, other service providers and consultants prior to disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors, CMOs, CROs, other service providers and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

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

Many of our employees and consultants were previously employed at or engaged by other medical device, 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. Litigation may be necessary to defend against these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. In addition, we may lose personnel as a result of such claims. Any such litigation, or the threat thereof, may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

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.

In addition, we or our licensors may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or in-licensed issued patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technology. Such challenges may also result in our inability to develop, manufacture or commercialize our technology without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or in-licensed issued patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future products. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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.

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

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. It is possible that U.S. and foreign patents and pending patent applications, copyrights, or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. 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, copyrights, trademarks and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents, copyrights, or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use product names. Because patent applications can take years to issue and are often afforded confidentiality for some period of time, there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our owned or in-licensed patent portfolio may therefore have no deterrent effect. We may in the future become party to adversarial proceedings or litigation where our competitors or other third parties may assert claims against us, alleging that our products or services infringe, misappropriate or otherwise violate their intellectual property rights, including patents and trade secrets. 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. 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, or any indemnification granted by such vendors may not be sufficient to address any liability and costs we incur as a result of such claims. Additionally, we may be obligated to indemnify our customers or business partners in connection with litigation and to obtain licenses or refund subscription fees, which could further exhaust our resources.

Even if we believe a third party's intellectual property claims are without merit, there is no assurance that a court would find in our favor, including on questions of infringement, validity, enforceability or priority of patents. The strength of our defenses will depend on the patents asserted, the interpretation of these patents, and our ability to invalidate the asserted patents. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any products or technology we may develop, and any other products or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such United States 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 United States patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such United States patent. Conversely, the patent owner need only prove infringement by a preponderance of the evidence, which is a lower burden of proof.

Further, if patents, trademarks, copyrights, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from developing, manufacturing, marketing or selling our products, or result in obligations to pay license fees, damages, attorney fees and court costs, which could be significant. 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, copyright, 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. We may be unable to obtain necessary licenses on satisfactory terms, if at all. In addition, if any license we obtain is non-exclusive, we may not be able to prevent our competitors and other third parties from using the intellectual property or technology covered by such license to compete with us. If we do not obtain necessary

licenses, we may not be able to redesign our products to avoid infringement. Any of these events could materially and adversely affect our business, financial condition and results of operations.

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, patent applications, trademarks or trademark applications. 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. 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, 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. Competitors may infringe our issued patents or other intellectual property, which we may not always be able to detect. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property or alleging that our intellectual property is invalid or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise challenges to the validity of certain of our owned or in-licensed patent 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, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). In any such lawsuit or other proceedings, a court or other administrative body may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or products that we may develop. If our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Any of these events could materially and adversely affect our business, financial condition and results of operations.

Even if resolved in our favor, litigation or other proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. 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 such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. Uncertainties resulting from the initiation and continuation of patent and other intellectual property litigation or other proceedings could have a material adverse effect on our business, financial condition and results of operations.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing, misappropriating or otherwise violating our owned or in-licensed patents, any patents that may be issued as a result of our future patent applications, or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Our rights to develop and commercialize our products are subject, in part, to the terms and conditions of licenses granted to us by others.

We rely, in part, upon licenses to certain patent rights, proprietary technology and other intellectual property from third parties that are important or necessary to the development of our products and technology. Further development and commercialization of our current products, and development of any future products, may require us to enter into additional license or collaboration agreements. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. Additionally, patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings brought by or against our licensors or another licensee in response to such litigation or for other reasons. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. This could materially and adversely affect our business, financial condition and results of operations.

The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement. In spite of our best efforts, our licensors might also conclude that we have materially breached our license agreements and terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain other licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected products. Any of these events could materially and adversely affect our business, financial condition and results of operations.

In the future, we may enter agreements involving licenses or collaborations that provide for access or sharing of intellectual property. If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our current and future products.

We currently, and in the future may continue to, license from third parties certain intellectual property relating to our current and future products. In the event we do so, we may have certain obligations to such licensors. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by any of our future licensors and us and our partners.

If disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected products, which would have a material adverse effect on our business.

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place.

Further, we or our future licensors, if any, 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. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our future licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our future licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition, even where we have the right to control patent prosecution of patents and patent applications under future license from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or licensed in the future from various third parties may be subject to retained rights. Our predecessors or licensors may retain certain rights under their agreements with us, including the right to use the underlying

technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or future licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or future licensed technologies, or if we lose our rights to critical future in-licensed technology, we may be unable to successfully develop, out-license, market and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of acquired technologies, and possibly in the future licensed technology, into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our products.

We may not be successful in obtaining necessary rights to any products we may develop through acquisitions and in-licenses.

We may need to obtain additional licenses from our existing licensors or otherwise acquire or in-license any intellectual property rights from third parties that we identify as necessary for our products. It is possible that we may be unable to obtain any additional licenses or acquire such intellectual property rights at a reasonable cost or on reasonable terms, if 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. In that event, we may be required to expend significant time and resources to redesign our technology, products, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially and adversely affect our business, financial condition and results of operations.

Any collaboration or partnership arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our current and future products;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

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

We or our licensors may be subject to claims that former consultants, contractors or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees, consultants 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. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. If we or our licensors 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, intellectual property that is important to our products. Furthermore, individuals executing invention assignment agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. Any such events could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to protect the confidentiality of our trade secrets and 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, and 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 inside and outside the United States 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. 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 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. 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 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 could 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.

Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases we could not assert any trade secret rights against such parties or those to whom they communicate such trade secrets. 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. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, 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 individuals, organizations 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.

Changes in United States patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The United States has enacted and implemented wide-ranging patent reform legislation. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the U.S. 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. We cannot predict how decisions or actions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Depending on actions by 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 have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or 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 have licensed or that we may obtain in the future. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting, and defending patents covering our RxSight system, and any of our future products throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than those in the United States. In some cases, we or our licensors may not be able to obtain patent protection for certain technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, even in jurisdictions where we or our licensors do pursue patent protection, or from selling or importing products made using our or our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may have or obtain patent protection, but where patent enforcement is not as strong as that in the United States. These unauthorized products may compete with our products in such jurisdictions and take away our market share where we do not have any issued or in-licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our business, financial condition, results of operations and prospects could be materially and adversely affected.

No earlier than June 1, 2023, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court ("UPC"). This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. RxSight will consider its options on a case-by-case basis regarding UPC and will coordinate with foreign counsel in a timely manner.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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. The following examples are illustrative:

- others may be able to make a product that is similar to our current products and future products we intend to commercialize and that is not covered by the patents that we own or exclusively in-license and have the right to enforce;
- we and any of our current or future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own, license or may own or license in the future;
- we or any of our current or future licensors or collaborators might not have been the first to file patent applications covering certain of our 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 current or future owned or in-licensed patent applications will not lead to issued patents;
- issued patents that we own or in-license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as 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; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Our future use of "open source" software could subject our proprietary software to general release, adversely affect our ability to sell our products and subject us to possible litigation.

We intend to incorporate open source software in future products or technologies licensed, developed and/or distributed by us. Open source software is generally licensed by its authors or other third parties under open source licenses. Some open source licenses contain requirements that we disclose source code for modifications we make to the open source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open source software could require that we disclose and license some or all of our proprietary source code in that software, as well as distribute our products that use particular open source software at no cost to the user. We intend to monitor our use of open source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code; however, there can be no assurance that such efforts will be successful. Open source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our products and technologies. Companies that incorporate open source software into their products have, in the past, faced claims seeking enforcement of open source license provisions and claims asserting ownership of open source software incorporated into their product. If an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products. In addition, if we combine our proprietary software with open source software in certain ways, under some open source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise adversely affect our business. These risks could be difficult to eliminate or manage, and, if not addressed, could harm our business, financial condition and results of operations.

If our trademarks, service marks 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 rely on 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. We cannot assure you that our trademark and service mark applications will be approved. During trademark and service mark 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 and service mark applications and to seek to cancel registered trademarks and service marks. Opposition or cancellation proceedings may be filed against our trademarks and service marks, and our trademarks and service marks may not survive such proceedings. In the event that our trademarks and service marks 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, trademarks or service marks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. As a means to enforce our trademark and service mark rights and prevent infringement and other violations, we may be required to file claims against third parties or initiate opposition proceedings. This can be expensive

and time-consuming. In addition, there could be potential trademark or service mark infringement claims brought by owners of other registered trademarks, service marks, or trademarks or service marks that incorporate variations of our registered or unregistered trademarks or service marks. Certain of our current or future trademarks or service marks may become so well known by the public that their use becomes generic and they lose trademark or service mark protection. Over the long term, if we are unable to establish name recognition based on our trademarks, service marks 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.

Risks related to government regulation

If we fail to obtain and maintain necessary regulatory clearances or approvals for our products, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations would be harmed.

Our products are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we may choose to do business. Government regulations specific to medical devices are wide ranging and govern, among other things:

- product design, development and manufacture;
- laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution;
- premarketing clearance or approval;
- record keeping;
- product safety and effective;
- product changes;
- product marketing, promotion and advertising, sales and distribution; and
- post marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for an existing product, can be marketed in the United States, a company must first submit and receive either 510(k) clearance pursuant to Section 510(k) of the FDCA, or approval of a premarket approval, or PMA, application from the FDA, unless an exemption applies.

In many cases, the process of obtaining PMA approval is much more rigorous, costly, lengthy and uncertain than the 510(k) clearance process. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, in order to clear the proposed device for marketing. 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 is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based on extensive data, including technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk. Modifications to products that are approved through a PMA application generally need prior FDA approval of a PMA supplement. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k), or such modification may put the device into class III and require PMA approval. The FDA's 510(k) clearance process usually takes from three to 12 months but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals or clearances would have a material adverse effect on our business, financial condition and results of operations.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;

- the disagreement of the FDA or the applicable foreign regulatory body with the design, conduct or implementation of our clinical trials or the analyses or interpretation of data from pre-clinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our pre-clinical 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;
- an advisory committee, if convened by the applicable regulatory authority, may recommend against approval of our application or may recommend that the applicable regulatory authority require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority may still not approve the product;
- the applicable regulatory authority may identify significant deficiencies in our manufacturing processes, facilities or analytical methods or those of our third-party contract manufacturers;
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval; and
- the FDA or foreign regulatory authorities may audit our clinical trial data and conclude that the data is not sufficiently reliable to support approval or clearance.

Similarly, regulators may determine that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Moreover, the FDA and European Union regulatory authorities strictly regulate the labeling, promotion and advertising of medical devices, including comparative and superiority claims vis a vis competitors' products, that may be made about products.

As a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. Failure to conduct the post-approval study in compliance with applicable regulations or to timely complete required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business.

In addition, we are required to timely file various reports with the FDA, including MDR, that requires that we report to the regulatory authorities if our products may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not filed in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business.

If we initiate a correction or removal action for our products to reduce a significant risk to health posed by our products, we would be required to submit a publicly available correction and removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports could be used by competitors against us and cause doctors to delay or cancel procedures, which could harm our reputation.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising, promotion and labeling of our products to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there is adequate and reasonable scientific data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading,

not substantiated or not permissible, we may be subject to enforcement actions, including adverse publicity and warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- denial of our requests for 510(k) clearance or PMA of new products, new intended uses or modifications to existing products;
- withdrawal of 510(k) clearance or PMAs that have already been granted; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition could be harmed. In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, financial condition and results of operations.

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

Medical devices regulated by the FDA are subject to "general controls" which include: registration with the FDA; listing commercially distributed products with the FDA; complying with all applicable requirements under the QSR; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting certain device field removals and corrections to the FDA; and obtaining pre-market notification 510(k) clearance for devices prior to marketing. Some devices known as "510(k)-exempt" devices can be marketed without prior marketing-clearance or approval from the FDA. In addition to the "general controls," some Class II medical devices are also subject to "special controls," including adherence to a particular guidance document and compliance with the performance standard. Instead of obtaining 510(k) clearance, most Class III devices are subject to PMA.

Although our products have received regulatory approval or clearance from FDA in the United States for a particular patient population, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, effectiveness and other post-market information, including both federal and state requirements in the United States and requirements of comparable non-U.S. regulatory authorities in any international markets we choose to enter.

Any regulatory clearances or approvals that we have received for our products will be subject to limitations on the cleared or approved indicated uses for which the product may be marketed and promoted, will be subject to the conditions of approval, or will contain requirements for potentially costly post-marketing testing. We are required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing product safety issues could result in increased costs to assure compliance. The FDA and other agencies, including the DOJ, closely regulate and monitor the post-clearance or approval marketing and promotion of products to ensure that they are marketed and distributed only for the cleared or approved indications and in accordance with the provisions of the cleared or approved labeling. We have to comply with requirements concerning advertising and promotion for our products.

Promotional communications with respect to devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the products' cleared or approved labeling. As such, we may not promote our products

for indications or uses for which they do not have clearance or approval. We received a PMA for the LAL and LDD, which is indicated for the reduction of residual astigmatism to improve uncorrected visual acuity after removal of the cataractous natural lens by phacoemulsification and implantation of the intraocular lens in the capsular bag, in adult patients with pre-existing corneal astigmatism of > 0.75 diopters and without pre-existing macular disease. We also received a 510(k) clearance for our contact lens, which is indicated for visualization and treatment in the anterior segment of the eye. We train our marketing and sales force against promoting our products for uses outside of the cleared or approved indications for use, known as "off-label uses." However, doctors may use our products for off-label purposes and are allowed to do so when in the doctor's independent professional medical judgment he or she deems it appropriate. If the FDA determines that our promotional materials or training constitute promotion of an off-label or other improper use, or that our internal policies and procedures are inadequate to prevent such off-label uses, it could subject us to regulatory or enforcement actions as discussed below.

In addition, we cannot make comparative claims regarding the use of our products against any alternative treatments without conducting head-to-head comparative clinical studies, which would be expensive and time-consuming. If the FDA determines that our promotional, reimbursement or training materials for sales representatives or doctors constitute promotion of an off-label use, the FDA could request that we modify our training, promotional or reimbursement materials and/or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, disgorgement of profits, significant penalties, including civil fines and criminal penalties. Other federal, state or foreign governmental authorities also might take action if they consider our promotion, reimbursement or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Although we train our sales force not to promote our products for off-label uses, and our instructions for use in all markets specify that our products are not intended for use outside of those indications cleared or approved for use, the FDA or another regulatory agency could conclude that we have engaged in off-label promotion. For example, the government may take the position that off-label promotion resulted in inappropriate reimbursement for an off-label use in violation of the federal civil False Claims Act for which it might impose significant civil fines and even pursue criminal action. In those possible events, our reputation could be damaged, and adoption of the products would be impaired.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with our facility where the product is manufactured or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market.

If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- subject our facility to an adverse inspectional finding or Form 483, or other compliance or enforcement notice, communication or correspondence;
- issue warning or untitled letters that would result in adverse publicity or may require corrective advertising;
- impose civil or criminal penalties;
- suspend or withdraw regulatory clearances or approvals;
- refuse to clear or approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our sub-assembly suppliers' facilities;
- seize or detain products; or
- require a product recall.

In addition, violations of the FDCA relating to the promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition and results of operations.

Material modifications to our products may require new 510(k) clearances or pre-market approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.

Modifications that could significantly affect the safety and effectiveness of our approved or cleared products, such as changes to the intended use or technological characteristics of our products, will require new 510(k) clearances or PMAs or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplemental approval or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that could significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a PMA. We may not be able to obtain the required 510(k) clearances or PMAs, or PMA supplements, or similar marketing authorization in applicable foreign jurisdictions, for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our products in the past and expect to make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA or a comparable foreign regulatory authority disagrees and requires new clearances or approvals for these modifications, we may be required to recall and to stop selling or marketing such products as modified, which could harm our operating results and require us to redesign such products. In these circumstances, we may be subject to significant enforcement actions.

Obtaining and maintaining regulatory approval of our current and future products in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our current and future products in other jurisdictions. The FDA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

Obtaining and maintaining regulatory approvals or clearances of our current and future products in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval or clearance of a current or future product, comparable regulatory authorities in foreign jurisdictions must also approve or clear the manufacturing, marketing and promotion and reimbursement of a current or future product in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

The RxSight system is approved for improving uncorrected visual acuity by adjusting the LAL power to correct residual postoperative refractive error, including for -2.0 to + 2.0 diopters of sphere and -3.0 to -0.50 diopters of cylinder and by changing lens curvature to introduce controlled amounts of spherical aberration (+/- 1 micron) and center near add (up to 2.0 diopters) which is also registered with the MHRA in the United Kingdom, in Canada and in Mexico. Obtaining additional foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements in jurisdictions where we conduct business currently or in the future, such as requirements under the EU MDR, could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals or clearances, our target market will be reduced and our ability to realize the full market potential of our current and future products will be harmed.

In addition, we have conducted clinical trials in Mexico and may choose to conduct further international clinical trials. The acceptance of study data by the FDA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the U.S. population and U.S. medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to current good clinical practices regulations; and (3) audits by regulatory authorities of the clinical data do not identify significant data integrity issues. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our products not receiving approval or clearance for commercialization in the applicable jurisdiction.

Our products may be subject to recalls after receiving FDA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation and adversely affect our business.

The FDA and similar foreign governmental authorities have the authority to require the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions or other adverse events, such as serious injuries or deaths, or quality-related issues, such as manufacturing errors or design or labeling defects. Any future recalls of our products could divert managerial and financial resources, harm our reputation and adversely affect our business.

If we initiate a correction or removal for one of our devices to reduce a risk to health posed by the device, we would be required to submit a publicly available Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders and would harm our reputation.

In addition, we are subject to medical device reporting regulations that require us to report to the FDA or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction recurred. Failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to the FDA's satisfaction, can subject us to sanctions and penalties, including warning letters and recalls.

Doctors may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

If we, or our suppliers, fail to comply with the FDA's QSR or applicable foreign regulations, our manufacturing or distribution operations could be delayed or shut down and our revenue could suffer.

Our manufacturing and design processes and those of our third-party component suppliers are required to comply with the FDA's Quality System Regulation ("QSR"), which covers procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products in the United States. We are also subject to similar state requirements and licenses, and to ongoing ISO 13485 compliance in our operations, including design, manufacturing, and service, to maintain our CE Mark in Europe. In addition, we must engage in extensive recordkeeping and reporting and must make available our facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities, EU Notified Bodies, and comparable agencies in other countries. If we fail a regulatory inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take timely and adequate corrective action in response to an adverse regulatory inspection could result in, among other things, a shutdown of our manufacturing or product distribution operations, significant fines, suspension of marketing clearances and

approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Public Health ("CDPH"), and our Notified Body to determine our compliance with the QSR and other regulations at both our design and manufacturing facilities, and these inspections may include the manufacturing facilities of our suppliers.

We can provide no assurance that we will continue to remain in material compliance with the QSR. If the FDA, CDPH, or any applicable notified body in the European Union or United Kingdom inspects any of our facilities and discover compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a delay at our manufacturing facility, we may be unable to produce our products, which would harm our business.

Healthcare reform initiatives and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations and cash flows in our key markets.

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition and results of operations.

For example, in the United States, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together, the Affordable Care Act ("ACA"), was enacted. The ACA is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges and the expansion of the Medicaid program. The ACA has impacted existing government healthcare programs and has resulted in the development of new programs.

Certain provisions of the ACA have been subject to judicial and Congressional challenges. For example, various portions of the ACA have been the subject of legal and constitutional challenges, including legal proceedings in the Fifth Circuit Court of Appeals. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. It is unclear how this Supreme Court decision, future litigation, and healthcare measures promulgated by the Biden administration will impact the ACA, our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, includes reductions to Medicare payments to providers of, on average, 2% per fiscal year, which went into effect on April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments can vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our products, if approved, and accordingly, our financial operations. We cannot assure you that the ACA, as currently enacted or

as amended in the future, will not harm our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. 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 harm:

- 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.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several United States Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. While some of these measures may require additional authorization to become effective, Congress and the federal administration have each indicated that it will continue to seek new legislative and/or administrative measures to control healthcare costs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability. Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services and could have a material adverse effect on our business, financial condition and results of operations.

If we fail to comply with United States federal and state fraud and abuse and other healthcare laws and regulations, we could face substantial penalties and our business operations and financial condition could be adversely affected.

Healthcare providers and third-party payors play a primary role in the distribution, recommendation, ordering and purchasing of any medical device for which we have or obtain marketing clearance or approval. Through our arrangements with principal investigators, healthcare professionals, third-party payors and customers, we are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our marketed medical devices. We have a compliance program, a Code of Conduct and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations.

In the United States, we are subject to various state and federal anti-fraud and abuse laws, including, without limitation, the federal healthcare Anti-Kickback Statute and federal civil False Claims Act. There are similar laws in other countries. Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market, and distribute any products for which we obtain marketing approval. Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug or medical device manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce or reward referrals, including the purchase, recommendation, or order of, items or services for which payment may be made, in whole or in part, under a federal healthcare program, such as Medicare or Medicaid. Moreover, the ACA provides that 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 civil False Claims Act;

- the Federal False Claims Act, including its civil provisions that can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties prohibiting individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, and/or impose exclusions from federal health care programs and/or penalties for parties who engage in such prohibited conduct;

- the Federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations also impose obligations on covered entities such as health insurance plans, healthcare clearinghouses, and certain health care providers and their respective business associates and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, also referred to as the CMS Open Payments, which requires applicable manufacturers of covered 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 annually report to CMS information regarding certain payments and other transfers of value to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, state laws that require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require medical device manufacturers to report information related to payments and other transfers of value to doctors or marketing expenditures and require the registration of their sales representatives; state laws that require medical device companies to report information on the pricing of certain medical device products; and state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018 ("BBA"), increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies recently have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient support programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, federal civil False Claims Act and HIPAA's healthcare fraud and privacy provisions.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our activities, such as stock-option compensation paid to doctors that have entered into consulting agreements with us, could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even 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.

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. The risk of our being found in violation of these or

other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. 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 penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment of individuals, exclusion from participation in government programs, such as Medicare and Medicaid, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If we or our employees are found to have violated any of the above laws we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses and could divert our management's attention from the operation of our business. Companies settling federal civil False Claims Act, Anti-Kickback Statute or civil monetary penalties law cases also may be required to enter into a Corporate Integrity Agreement with the OIG in order to avoid exclusion from participation (i.e., loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs on companies to ensure compliance. Defending against any such actions can be costly, time-consuming and may require significant personnel resources, and may have a material adverse effect on our business, financial condition and results of operations.

Changes in the CMS fee schedules may harm our revenue and operating results.

Government payers, such as CMS as well as insurers, have increased their efforts to control the cost, utilization and delivery of healthcare services. From time to time, the United States Congress has considered and implemented changes in the CMS fee schedules in conjunction with budgetary legislation. Reductions of reimbursement by Medicare or Medicaid for procedures that use our products or changes in policy regarding coverage of these procedures, such as adding requirements for payment, or prior authorizations, may be implemented from time to time. Reductions in the reimbursement rates and changes in payment policies of other third-party payers may occur as well. Similar changes in the past have resulted in reduced payments for procedures that use medical device products as well as added costs and have added more complex regulatory and administrative requirements. Further changes in federal, state, local and third-party payer regulations or policies may have a material adverse impact on the demand for our products and on our business. Actions by agencies regulating insurance or changes in other laws, regulations, or policies may also have a material adverse effect on our business, financial condition and results of operations.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our planned or future products and to manufacture, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

Compliance with the EU Medical Device Regulation, applicable regulations in the United Kingdom, and other applicable foreign regulations, as well as any changes to existing regulations, may be costly and disruptive to our business, and expose us to increased liability.

In 2017, the European Union ("EU") published the new EU Medical Device Regulation ("MDR") (2017/745), the application of which was postponed until May 26, 2021 for class I devices (lowest risk) and May 26, 2024 for all other class devices (higher risk devices). The new regulations replace predecessor directives and emphasize a global convergence of regulations. With the transition from the Medical Devices Directive ("MDD"), to the MDR, notified bodies are required to seek designation to operate as conformity assessment authorities under the new law. While we are currently in compliance with the MDR and in process of transferring certification from MDD to MDR, compliance with any new or changing regulations in the EU or other jurisdictions where we currently commercialize our products or intend to commercialize in the future is a time consuming process that may require comprehensive quality system audits and new conformity assessment certifications for our products. Major changes include:

- reclassification of some products;
- greater emphasis on clinical data;
- data transparency, including publication of clinical trial data and safety summaries;
- defined content and structure for technical files to support registration;
- unique device identification system;
- greater burden on post-market surveillance and clinical follow-up;
- reduction of adverse event reporting time from 30 to 15 days after the event; and
- more power to notified bodies.

Implementation of the Medical Device Regulations introduces substantial changes to the obligations with which medical device manufacturers must comply in the EU. High risk medical devices will be subject to additional scrutiny during the conformity assessment procedure. For any products that we may develop in the future, complying with these new regulations may result in Europe being less attractive as a "first market" destination. Marketing authorization timelines will become more protracted and the costs of operating in Europe will increase. A significantly more costly path to regulatory compliance is anticipated.

Our clinical trials may fail to demonstrate competent and reliable evidence of the safety and effectiveness of our products, which would prevent or delay commercialization of our products in development.

We may be required to conduct clinical studies that demonstrate competent and reliable evidence that our products are safe and effective before we can commercialize our products. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our products for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our products. Even if regulatory approval is secured for any of our products, the terms of such approval may limit the scope and use of our products, which may also limit their commercial potential.

Defects or failures associated with our products could lead to recalls, safety alerts or litigation, as well as significant costs and negative publicity.

Our business is subject to significant risks associated with manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses, or inadequate disclosure of product-related information could also result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall or market withdrawal of, or issuance of a safety alert relating to, our products and result in significant costs, negative publicity and adverse competitive pressure. The

circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products could have a material adverse effect on our business, financial condition and results of operations.

We provide a limited warranty that our products are free of material defects and conform to specifications and offer to repair the LDD in the event of a defect and replace or refund the purchase price of a defective LAL. 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 such recovery, or any recovery from such vendor or supplier may be inadequate or unavailable.

The medical device industry has historically been subject to extensive litigation over product liability claims. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death, even if due to doctor error. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and raw materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, doctors or others purchasing or using our products, even if our products were not the actual cause of such injury or death. We may choose to settle any claims to avoid a determination of fault, even if we believe fault was not due to failure of our products. An adverse outcome involving one of our products could result in reduced market acceptance and demand for such products or any or all of our other products and could harm our brand and reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Although we carry product liability insurance in the United States and in other countries in which we conduct business, including for clinical trials and product marketing, 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.

We are required to file adverse event reports under Medical Device Reporting, or MDR, regulations with the FDA that are publicly available on the FDA's website. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales. If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action and impose sanctions against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require our time and capital, distract management from operating our business and may harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

Our employees, independent contractors, consultants, commercial partners, distributors and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners, distributors and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and

commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, additional integrity reporting and oversight obligations, 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 ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition and results of operations.

Environmental health and safety laws may result in liabilities, expenses and restrictions on our operations. Failure to comply with environmental laws and regulations could subject us to significant liability.

Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

Federal, state, local and foreign laws regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal and remediation of, as well as human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Using hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our on our business, financial condition and results of operations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive, and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our business, financial condition and results of operation.

We face risks related to our collection and use of data, which could result in investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices.

Our business processes personal data, including some data related to health. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations, such as the Common Rule ("GCP") guidelines, or FDA human subject protection regulations. We also face risks inherent in handling large volumes of data and in protecting the security of such data. We could be subject to attacks on our

systems by outside parties or fraudulent or inappropriate behavior by our service providers or employees. Third parties may also gain access to users' accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and may use such access to obtain users' personal data or prevent use of their accounts. Data breaches could result in a violation of applicable United States and international privacy, data protection and other laws, and subject us to individual or consumer class action litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed.

This risk is enhanced in certain jurisdictions and, as we expand our operations domestically and internationally, we may be subject to additional laws in other jurisdictions. Any failure, or perceived failure, by us to comply with privacy and data protection laws, rules and regulations could result in proceedings or actions against us by governmental entities or others. These proceedings or actions may subject us to significant penalties and negative publicity, require us to change our business practices, increase our costs and severely disrupt our business. In the United States, various federal and state regulators, including governmental agencies like the Consumer Financial Protection Bureau and the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security and have prioritized privacy and information security violations for enforcement actions. Additionally, in the United States, California adopted CCPA in January 2020, which requires certain companies that process information of California consumers to, among other things, provide new disclosures to California consumers and afford such consumers new abilities to exercise certain rights with respect to their personal information and opt out of certain sales of personal information, in addition to severely limiting our ability to use their information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. It remains unclear how various provisions of the CCPA will be interpreted and enforced. Furthermore, in November 2020, California voters passed the CPRA, which became effective January 1, 2023. The CPRA imposes additional obligations on covered companies and significantly modifies the CCPA, including by expanding California residents' rights with respect to certain sensitive personal information. Other states have passed, or plan to pass, data privacy laws that are similar to the CCPA and CPRA, further complicating the legal landscape. In addition, laws in all 50 states require businesses to provide notice to consumers whose personal information has been accessed or acquired as a result of a data breach (and, in some cases, to regulators). The effects of the CCPA, CPRA and other such privacy laws are potentially significant, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

In addition, we are subject to international laws, regulations and standards in many jurisdictions, which apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, the GDPR, which was adopted by the EU and became effective in May 2018, applies extraterritorially and imposes several stringent requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of personal data and pseudonymized (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data.

The GDPR provides that EU member states may make their own laws and regulations limiting the (i) processing of personal data, including special categories of data (e.g., racial or ethnic origin, political opinions, religious or philosophical beliefs) and (ii) profiling and automated individual decision-making of individuals, which could limit our ability to use and share personal data or other data and could cause our costs to increase, harming our business and financial condition. Non-compliance with GDPR is subject to significant penalties, including fines of up to €20 million or 4% of total worldwide revenue, whichever is greater. Interpretations of the GDPR by local data protection authorities in EU member states, along with the complexity of the regime itself, create uncertainty regarding the interpretation and enforcement of the law, with potential inconsistencies across EU member states. Other jurisdictions outside the EU are similarly introducing or enhancing laws and regulations relating to privacy and data security, which enhances risks relating to compliance with such laws. Further, the United Kingdom's decision to leave the European Union has created uncertainty with regard to data protection regulation in the United Kingdom. We are subject to the UK General Data Protection Regulation and UK Data Protection Act of 2018, which retains the GDPR in the United Kingdom's national law and provides for a penalty structure similar to the GDPR. These recent developments have required us to review and modify the legal means by which we process personal data and may require us to make other modifications. The implementation and enforcement of the GDPR and other evolving legislation may subject us to enforcement risk and requirements to change certain of our data collection, processing and other policies and practices. We could incur significant costs investigating and defending such claims and, if we are found liable, significant damages. If any of these events were to occur, our business and financial results could be adversely affected.

Additionally, we are subject to laws and regulations regarding cross-border transfers of personal data, including laws relating to transfer of personal data outside of the European Economic Area ("EEA"), Switzerland, and the United Kingdom. We rely on transfer mechanisms permitted under these laws, including EU Standard Contractual Clauses ("SCCs"). Such mechanisms have received heightened regulatory and judicial scrutiny in recent years. The Court of Justice of the European Union ("CJEU") issued a decision in 2020 invalidating a transfer of personal data from the EEA and Switzerland to the U.S. and imposing additional obligations on companies using the SCCs. The European Commission has adopted new SCCs that are required to be implemented over time, and the United Kingdom has adopted new standard contractual clauses that also are required to be implemented over time. In June 2021, the European Commission issued an adequacy decision in respect of the United Kingdom's data protection framework, enabling data transfers from EU member states to the United Kingdom to continue without requiring contractual or other additional measures. While it is intended to last for at least four years, the European Commission may revoke the adequacy decision at any point, and if this occurs it could lead to additional costs and increase our overall risk exposure. These developments and other regulatory guidance or developments may impose additional obligations with respect to the transfer of personal data from the EEA, Switzerland, and the United Kingdom, all of which could restrict our activities in those jurisdictions, limit our ability to provide our products and services in those jurisdictions, require us to modify our policies and practices, and to engage in additional contractual negotiations, or increase our costs and obligations and impose limitations upon our ability to efficiently transfer personal data from the EEA, Switzerland, and the United Kingdom to the U.S. This could adversely affect the manner in which we provide our services and thus materially affect our operations and financial results.

Because the interpretation and application of laws, regulations, standards and other obligations relating to data privacy and security are still uncertain, it is possible that these laws, regulations, standards and other obligations may be interpreted and applied in a manner that is inconsistent with our data processing practices and policies. If our practices are not consistent, or are viewed as not consistent, with changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may also become subject to fines, audits, inquiries, whistleblower complaints, adverse media coverage, investigations, lawsuits, loss of export privileges, severe criminal or civil sanction or other penalties. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any concerns about our data privacy and security practices, even if unfounded, could damage the reputation of our businesses and discourage potential users from our products and services. Any of the foregoing could have an adverse effect on our business, financial condition, results of operations and prospects.

Inadequate funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve 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, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result.

Disruptions at the FDA and other agencies, including delays or disruptions due to the COVID-19 pandemic, travel restrictions, and staffing shortages, may also slow the time necessary for new medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies such as the FDA had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. While the FDA has largely caught up with domestic preapproval inspections, it continues to work through its backlog of foreign inspections. However, the FDA may not be able to continue its current inspection pace or may be unable to complete required inspections during the review period, which can delay clinical development and result in a complete response letter. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Recently, President Biden announced that the administration intends to end the COVID-19 national and public health emergencies on May 11, 2023. The full impact of the termination of the public health emergencies on FDA and other regulatory policies and operations is unclear. If a prolonged government shutdown or other disruption occurs, 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. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our global operations can expose us to numerous and sometimes conflicting legal and regulatory requirements, including to anti-bribery and anti-corruption laws, such as the FCPA and the U.K. Bribery Act, and violation of these requirements could result in substantial penalties and prosecution and harm our business.

We have commercialized the RxSight system outside of the United States and each component is registered with the MHRA in the United Kingdom. We are subject to numerous, and sometimes conflicting, legal regimes in the countries in which we operate, including on matters as diverse as health and safety standards, marketing and promotional activities, anticorruption, import/export controls, content requirements, trade restrictions, tariffs, taxation, sanctions, immigration, internal and disclosure control obligations, securities regulation, anti-competition, data privacy and labor relations. This includes in emerging markets where legal systems may be less familiar to us. We strive to abide by and maintain compliance with these laws and regulations. Compliance with diverse legal requirements is costly, time-consuming and requires significant resources. Violations of one or more of these regulations in the conduct of our business could result in significant fines, criminal sanctions against us or our officers, prohibitions on doing business and damage to our reputation. Violations of these regulations in connection with the performance of our obligations to our customers also could result in liability for significant monetary damages, fines and/or criminal prosecution, unfavorable publicity and other reputational damage, restrictions on our ability to process information and allegations by our customers or distributors that we have not performed our contractual obligations. Due to the varying degrees of development of the legal systems of the countries in which we operate, local laws might be insufficient to protect our rights.

Our operations outside of the United States are subject to various heavily enforced anti-bribery and anti-corruption laws, such as the FCPA, U.K. Bribery Act and similar laws around the world. These laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third-party business partners and intermediaries, fail to comply with the FCPA or other anti-corruption and anti-bribery laws. Responding to any enforcement action or related investigation may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA or other applicable anti-bribery, anti-corruption or anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our business, financial condition and results of operations.

Our international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, products and solutions, pricing, reimbursement and marketing of our products and solutions, as well as by inter-governmental disputes. Any of these changes could adversely affect our business. The imposition of new laws or regulations, including potential trade barriers, may increase our operating costs, impose restrictions on our operations or require us to spend additional funds to gain compliance with the new rules, if possible, which could have an adverse impact on our financial condition and results of operations.

Risks related to reliance on third parties

From time to time, we engage outside parties to perform services related to certain of our clinical studies and trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our products.

From time to time, we engage consultants to help design, monitor and analyze the results of certain of our clinical studies and trials. The consultants we engage interact with clinical investigators to enroll patients in our clinical trials. We depend on these consultants and clinical investigators to conduct clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards, such as GCP guidelines, the Common Rule, and FDA human subject protection regulations. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely, compliant or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for other reasons, our clinical studies or trials may be extended, delayed or terminated or may otherwise prove to

be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs, in order to obtain the regulatory clearances or approvals that we need to commercialize our products.

We and our component suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have an adverse effect on our business, financial condition and results of operations.

As a medical device manufacturer, we must register with the FDA and non-U.S. regulatory agencies in jurisdictions where we commercialize our products, and we are subject to periodic inspection by the FDA and foreign regulatory agencies, for compliance with certain good manufacturing practices, including design controls, product validation and verification, in process testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA and foreign regulatory agencies. Our manufacturer, component, and sub-component suppliers are also required to meet certain standards applicable to their manufacturing processes.

We cannot assure you that we or our component suppliers comply or can continue to comply with all regulatory requirements. The failure by us or one of our component suppliers to achieve or maintain compliance with these requirements or quality standards may disrupt our ability to supply products sufficient to meet demand until compliance is achieved or, with a component supplier, until a new supplier has been identified and evaluated. Our or any of our component supplier's failure to comply with applicable regulations could cause sanctions to be imposed on us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals or clearances, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, which could harm our business. We cannot assure you that if we need to engage new suppliers to satisfy our business requirements, we can locate new suppliers in compliance with regulatory requirements at a reasonable cost and in an acceptable timeframe. Our failure to do so could have a material adverse effect on our business, financial condition and results of operations.

For products that we currently distribute or market in the EU and the United Kingdom, as well as future products for which we obtain the applicable marketing authorization, we must maintain certain International Organization for Standardization ("ISO"), certifications to sell our products and must undergo periodic inspections by notified bodies, such as BSI, to obtain and maintain these certifications. If we fail these inspections or fail to meet these regulatory standards, it could have a material adverse effect on our business, financial condition and results of operations.

We depend upon third parties, including single and sole source suppliers, to manufacture certain components and subcomponents of the RxSight system making us vulnerable to supply disruptions and price fluctuations.

We rely on third parties, including single and sole source suppliers, to manufacture certain components and subcomponents of our products. We do not have long-term supply agreements with, or guaranteed commitments from our suppliers, including single and sole source suppliers. We utilize purchase orders or blanket orders covering the medium term of 18–24 months for the majority of our supplier base. While we depend on our suppliers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements, since the start of the COVID-19 pandemic and resultant supply chain constraints, vendors will miss delivery dates, extend delivery dates or in some circumstances cancel purchase orders because these suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. The expansion of global lead times, particularly in Europe and Asia, related to the COVID-19 pandemic, and COVID related shutdowns again in China and the more recently the military conflict in Ukraine, has resulted in the lack of availability of raw materials, including semiconductors, computers, monitors electronic parts, metals, packaging, adhesives, chemicals, resins and subcontract painted components. Certain suppliers have passed on higher prices, surcharges and expedited shipping fees to defray the higher commodity prices they are paying due to short supply and pushed out delivery dates. Additionally, due to these supply chain constraints we will identify and qualify new vendors or substitute components which requires testing, validations and documentation adding to internal costs and diverting engineering resources from other projects. On January 31, 2023, the FDA approved our premarket approval supplement to our lower cost LDD for various modifications that are intended to reduce the cost to manufacture the device. However, we have deferred the introduction of our lower cost-to-manufacture LDD to the market until the second half of 2023, as it is less difficult to procure components and subcomponents for our existing LDD than the lower cost-to-manufacture LDD. Currently, we are procuring materials for both LDD's, which have the same functionality. Management's expectation is that our gross margin will be impacted by the decision to continue to produce both LDD's, which it is necessary to mitigate potential supply chain issues. While we have taken measures to mitigate business continuity risk, including increasing standard lead times, payment of expedite fees, issuance of a limited number of non-cancelable purchase orders, advance delivery of critical components ahead of normal delivery dates and

second sourcing, our suppliers may cease producing the components we purchase from them or otherwise decide to cease doing business with us. Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components or subcomponents used in our products would limit our ability to manufacture our current and new products and could 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, and other third parties to research, develop, manufacture and commercialize our products. 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, 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 have a material adverse effect on our business, financial condition and results of operations.

Risks related to our common stock

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock has been and may continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which we cannot control. From the date of our initial public offering through March 1, 2023, our common stock has traded at a low of $8.80 and a high of $19.67 on the Nasdaq Global Market. The stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Part I, Item 1A, "Risk Factors," and elsewhere in this Annual Report on Form 10-K, these factors include:

- the timing and results of preclinical studies and clinical trials of our current and future products or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the medical device sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- general economic, industry and market conditions, including global and national events, such as the conflicts in Eastern Europe, and general economic downturns; and
- the impact of the COVID-19 pandemic.

The realization of any of the above risks or any of a broad range of other risks, including those described in this Part I, Item1A, "Risk Factors," could have a dramatic and adverse impact on the market price of our common stock.

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

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

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. We will not have any control of the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

We do not know whether an active, liquid and orderly trading market will exist for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

Our common stock is currently traded on Nasdaq Global Market, but we can provide no assurance that we will be able to maintain an active trading market on Nasdaq Global Market or any other exchange in the future. If an active trading market does not develop, or is not maintained, or if we fail to satisfy the continued listing standards of the Nasdaq Global Market or applicable SEC rules for any reason and our securities are delisted, you may have difficulty selling any of our shares of common stock that you buy. The lack of an active trading market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active trading market may also reduce the fair market value of your shares. Furthermore, an inactive trading market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

As of December 31, 2022, we had 28,268,389 shares of common stock issued and outstanding. All of these shares are available for sale in the public market, subject to limitations under Rule 144 with respect to affiliates of our company.

On July 30, 2021, we filed a registration statement on Form S-8 under the Securities Act registering the issuance of 7,473,839 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans.

On March 8, 2022, we filed an additional registration statement on Form S-8 under the Securities Act registering the offer and sale of 1,094,670 additional shares of common stock under our 2021 Equity Incentive Plan (the "2021 Plan") and 273,667 additional shares of common stock under our 2021 Employee Stock Purchase Plan (the "2021 ESPP"). Shares registered under the registration statement on Form S-8 can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. The number of shares registered represent the annual increase commencing on the first day of each fiscal year beginning with the 2022 fiscal year calculated as 4% of the outstanding shares of our common stock on the last day of our immediately preceding fiscal year under our 2021 Plan and 1% of the outstanding shares of our

common stock as of the last day of the immediately preceding fiscal year under our 2021 ESPP. We anticipate filing additional Form S-8 registration statements for future annual increases under our equity plans.

On August 8, 2022, we filed a $200.0 million shelf registration statement which became effective on August 12, 2022. The shelf registration statement is effective for three years and permits us to sell, from time to time, up to $200.0 million in aggregate value of our common stock, preferred stock, debt securities, warrants, and/or units. The shelf registration statement is intended to provide us with flexibility to access additional capital when market conditions are appropriate. Included in the $200.0 million shelf registration statement, we also filed a prospectus supplement to sell up to an aggregate value of $50.0 million dollars of our common stock through an "at-the-market" ("ATM") offering. The shares are being offered through BofA Securities, Inc. as sales agent. As of the date of this Annual Report on Form 10-K, a total of 1,355,216 shares of common stock, for total net proceeds of $17.1 million, have been issued and sold through the ATM offering, of which 879,341 shares of common stock, for net proceeds of $11.1 million, were sold in January 2023.

On February 7, 2023, we entered into an underwriting agreement with BofA Securities, Inc., which we agreed to issue and sell 4,000,000 shares of our common stock in a public offering ("Public Offering"), pursuant to our shelf registration statement, which was declared effective on August 12, 2022. The shares of common stock were sold at a price to the public of $12.50 per share. Under the terms of the underwriting agreement, we also granted the underwriters an option exercisable for 30 days from the date of the underwriting agreement to purchase up to an additional 600,000 shares of common stock on the same terms and conditions. The Public Offering closed on February 10, 2023. The underwriter's option was exercised in full on February 10, 2023 and closed on February 14, 2023.

Further, concurrent with the filing of this Form 10-K, we will file on Form S-8 under the Securities Act to register the issuance of 1,130,735 shares of common stock subject to options or other equity awards issued for future issuance under the 2021 Plan. The number of shares to be registered represent the annual increase commencing on the first day of each fiscal year beginning with the 2022 fiscal year calculated as 4% of the outstanding shares of our common stock on the last day of our immediately preceding fiscal year under our 2021 Plan.

Since the offering price for our shares of common stock through the ATM and Public Offering is substantially higher than the net tangible book value per share of common stock outstanding prior to these offerings, stockholders suffered immediate and substantial dilution in the net tangible book value of the shares of common stock. If additional shares are sold through the ATM offering, shareholders will experience additional dilution.

In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, and employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2022 our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates beneficially owned approximately 48% of our voting common stock. As a result, this group of stockholders will have the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

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

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the consummation of our initial public offering (i.e. December 31, 2026); (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion; (iii) the date on which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

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.

We have incurred increased costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives and corporate governance practices. Additionally, if we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

As a public company we incur significant legal, accounting and other expenses and these expenses may increase even more after we are no longer an "emerging growth company." We will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase our operating expenses. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain

director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot accurately predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our board committees or as executive officers.

In addition, as a public company we are required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm if we are an accelerated filer or large accelerated filer. To achieve compliance with Section 404 within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

Provisions in our certificate of incorporation, bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our certificate of incorporation and bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified Board of Directors so that not all members of our board are elected at one time;
- permit only the Board of Directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a poison pill);
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;

- prohibit cumulative voting;
- authorize our Board of Directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware, ("DGCL"), prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our bylaws provide that, unless the company consents in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This Delaware forum provision may limit a stockholder's ability to bring a claim in a judicial forum that the stockholder finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. If a court were to find this Delaware forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with litigating such disputes in multiple and/or other jurisdictions, which could seriously harm our business.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended against any person in connection with any offering of the Company's securities, including but not limited to any auditor, underwriter, expert, control person, or other defendant. This federal forum provision may limit a stockholder's ability to bring a Securities Act claim in a judicial forum that the stockholder finds favorable, which may discourage lawsuits against us and our directors, officers and other employees. Any person purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to this provision. While the Delaware Supreme Court has held such provisions to be facially valid as a matter of Delaware law and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions. If a court were to find this federal forum provision to be inapplicable or unenforceable in an action, we may incur additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business.

This Delaware forum provision does not apply to actions arising under the Securities Exchange Act of 1934 because the federal courts have exclusive jurisdiction over such claims.

Taxing authorities may successfully assert that we should have collected or in the future should collect sales and use, value added or similar taxes, and we could be subject to liability with respect to past or future sales, which could adversely affect our results of operations.

We rely on third party software for state and local tax rates, updated whenever tax rates change. We also rely on state exemptions, when applicable, for medical devices and services, which are determined by management's review of each state's sales tax laws and regulations concerning prescribed medical treatments. However, as laws and regulations change from time to time, these exemptions may or may not continue to apply to our products in the various taxing jurisdictions. Certain jurisdictions in which we do not collect such taxes on sales of our products may later assert that such taxes are applicable, which could result in tax assessments, penalties and interest, and we may be required to collect such taxes in the future. Such tax assessments, penalties and interest or future requirements may adversely affect the results of our operations.

Our Board of Directors are authorized to issue and designate shares of our preferred stock in additional series without stockholder approval.

Our certificate of incorporation authorizes our Board of Directors, without the approval of our stockholders, to issue shares of our preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, as shares of preferred stock in series, to establish from time to time the number of shares to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of preferred stock may be senior to or on parity with our common stock, which may reduce its value.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

The Tax Act enacted many significant changes to the U.S. tax laws, the consequences of which have not yet been fully determined. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings and the deductibility of expenses contained in the Tax Act or other tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years and could increase our future U.S. tax expense. As an example, beginning in 2022, the Tax Act eliminates the option to immediately deduct research and development expenditures currently and requires taxpayers to capitalize and amortize them over five or fifteen years pursuant to Section 174 of the Code, which may impact our effective tax rate and our cash tax liability in 2022 or in future years. Regulatory or legislative developments may arise from the proposed U.S. tax reform under the Biden Administration, which has proposed several changes to the corporate income tax regime, which, if adopted, could result in increased taxation of our business operations. There is uncertainty regarding what changes, if any, will be enacted and the effect on our business and financial results. The foregoing items, as well as any future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition or results of operations. We will also continue to monitor and assess the impact of international tax reform, including but not limited to the 15% global minimal tax proposed by the Organisation for Economic Co-operation and Development. Finally, the Inflation Reduction Act of 2022 (the "IRA"), will become effective beginning in fiscal year 2024. We do not currently expect that the IRA will have a material impact on our income tax liability.

General risk factors

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified executives as we build out the management team, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and need to add executives with operational and commercialization experience as we plan for commercialization of our current and future products and build out a leadership team that can manage our operations as a public company. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the medical device and ophthalmology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the

future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other medical device and biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our current and future products will be limited and the potential for successfully growing our business will be harmed.

Our business and operations would suffer in the event of system failures or security breaches or incidents.

Our computer systems, as well as those of our contractors and consultants, are vulnerable to damage from computer viruses, ransomware and other malicious code, unauthorized access, natural disasters (including hurricanes), terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of the commercialization of our RxSight system and our future products. For example, the loss, corruption, or unavailability of preclinical study or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any disruption or security breach or incident resulting in, or believed or perceived to have reported in, the loss or unavailability of or damage to our data or applications, or inappropriate disclosure or other processing of personal, confidential or proprietary information, could cause us to incur liability and cause the commercialization of our RxSight system and the further development of our current and future products to be delayed.

The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or internal bad actors, or breached due to technical vulnerabilities, employee error, malfeasance or other disruptions. Although, to our knowledge, we have not experienced such material security breach to date , any security breach or security incident could compromise our networks and the information stored there could be accessed, publicly disclosed, lost, stolen, or otherwise processed without authorization. Any such actual or perceived access, disclosure or other security breach or incident, loss, or unauthorized processing of information (whether affecting us or one of our third-party service providers) could result in legal claims and proceedings, regulatory investigations, and other proceedings and liability under laws that protect the privacy of personal information, significant regulatory penalties or other fines or remedies, and such an event could disrupt our operations, damage our reputation, and cause a loss of confidence in us and our ability to commercialize our products and conduct clinical trials, which could adversely affect our reputation and delay the commercialization of our RxSight system and clinical development of our current and future products.

The techniques and sophistication used to conduct cyber-attacks and breaches of information technology systems, as well as the sources and targets of these attacks, may take many forms (including phishing, social engineering, denial or degradation of service attacks, ransomware, malware or other malicious code), change frequently and are often not recognized until such attacks are launched or have been in place for a period of time. In addition, our employees, contractors, or third parties with whom we do business or to whom we outsource business operations may attempt to circumvent our security measures in order to misappropriate regulated, protected, or personally identifiable information, and may purposefully or inadvertently cause a breach or incident involving or compromise of such information. Third parties may have the technology or know-how to breach the security of the information collected, stored, or transmitted by us, and our respective security measures, as well as those of our third-party service providers, may not effectively prohibit others from obtaining improper access to this information. Advances in computer and software capabilities and encryption technology, new tools, and other developments may increase the risk of such a breach, incident, or compromise. There is no assurance that any security procedures or controls that we or our third-party providers have implemented will be sufficient to prevent data-security related incidents from occurring.

We may be required to expend significant capital and other resources to protect against, respond to, and recover from any potential, attempted or existing security breaches, incidents, or failures and their consequences. As data security-related threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. We could be forced to expend significant financial and operational resources in responding to a security breach or incident, including investigating and remediating any information security vulnerabilities, defending against and resolving legal and regulatory claims and complying with notification obligations, all of which could divert resources and the attention of our management and key

personnel away from our business operations and adversely affect our business, financial condition and results of operations. In addition, our remediation efforts may not be successful, and we could be unable to implement, maintain and upgrade adequate safeguards.

Economic conditions may adversely affect our business.

Global economic, political and market conditions, including those related to the COVID-19 pandemic, conflicts in Eastern Europe, and general economic downturns, may negatively impact our business. A significant change in the liquidity or financial condition of our customers could cause unfavorable trends in their purchases and also in our receivable collections, and additional allowances may be required, which could adversely affect our business, financial condition and results of operations. Adverse worldwide economic conditions may also adversely impact our suppliers' ability to provide us with materials and components, which could have a material adverse effect on our business, financial condition and results of operations.

Litigation and other legal proceedings may adversely affect our business.

From time to time we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, severe weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce our products. Our ability to obtain clinical supplies of our products could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in Aliso Viejo, California, near major earthquake faults and fire zones, and the ultimate impact on us for being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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 due to the expansion of global lead times, particularly in Europe and Asia, related to the COVID-19 pandemic, has resulted in the lack of availability of raw materials, including semiconductors, computers, monitors electronic parts, metals, packaging, adhesives, chemicals, resins and subcontract painted components, limiting our ability to maintain as much inventory of components, sub-assemblies, materials and finished products on hand as would be ideal under normal circumstances. To ensure adequate inventory supply and manage our operations with our third-party manufacturers and 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, the expansion of global lead times, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance 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, including as a result of our introduction of product enhancements, may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs, which could have a material adverse effect on our business, financial condition and results of operations. Conversely, if we underestimate customer demand for our products or our own requirements for components, subassemblies and materials, our third-party manufacturers and 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 may not be available when required on terms that are acceptable to us, or at all, and our third-party manufacturers and 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.

Risks related to COVID-19

Our business, financial condition, results of operations and growth have been harmed by the effects of the COVID-19 pandemic and may continue to be harmed.

We are subject to risks related to public health crises such as the global pandemic associated with COVID-19. The COVID-19 outbreak has negatively impacted and may continue to negatively impact our operations and revenues and overall financial condition by decreasing the number of our RxSight systems sold.

The expansion of global lead times related to the COVID-19 pandemic, has resulted in the lack of availability of raw materials, including semiconductors, computers, monitors electronic parts, metals, packaging, adhesives, chemicals, resins and subcontract painted components. Certain suppliers have passed on higher prices, surcharges and expedited shipping fees to defray the higher commodity prices they are paying due to short supply. Our suppliers may cease producing the components we purchase from them or otherwise decide to cease doing business with us. Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components or subcomponents used in our products would limit our ability to manufacture our current and new products and could have a material adverse effect on our business, financial condition and results of operations.

While the potential economic impact brought by and the duration of COVID-19 may be difficult to assess or predict, the widespread 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. We expect any new shelter-in-place policies and restrictions on elective surgical procedures worldwide to have a substantial near-term impact on our revenue. During the COVID-19 pandemic, our customers, including doctors, have experienced financial hardship and some of them may not fully recover. This could lead to some of these customers temporarily or permanently shutting down, filing for bankruptcy or being acquired by larger health systems, leading to reduced procedures and/or additional pricing pressure on our products. The COVID-19 pandemic has also resulted in a significant increase in unemployment in the United States which may continue even after the pandemic. The occurrence of any such events may lead to reduced disposable income and access to health insurance which could adversely affect the number of RxSight systems sold after the pandemic has ended.

Item 1B. Unresolved Staff Comments.

None

Item 2. Properties.

We currently lease four facilities housing our headquarters, manufacturing, research and development and administrative offices in Aliso Viejo, California. The facility leases are for approximately 121,000 square feet in the aggregate. The leases terminate, respectively, on (i) September 30, 2024, with one option to extend for five years; (ii) January 31, 2026, with three options to extend for five years each; (iii) March 31, 2023 with two options to extend for five years each; and (iv) August 31, 2024, with one option to extend for five years. We believe that our facilities are adequate to meet our current needs.

Item 3. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. Except as indicated above, we are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

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 information and holders

Our common stock has been publicly traded on the Nasdaq Global Market under the symbol "RXST" since July 30, 2021. Prior to that time, there was no public market for our common stock.

Stockholders

As of February 15, 2023, there were approximately 221 registered stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend policy

We have never declared or paid any cash dividends on our common stock or any other securities. We anticipate that we will retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future. Our Amended Term Loan restricts our ability to pay dividends. In addition, future debt instruments we issue may materially restrict our ability to pay dividends on our common stock. Payment of future cash dividends, if any, will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of then-existing debt instruments and other factors our Board of Directors deems relevant.

Unregistered sales of equity securities

None.

Issuer purchases of equity securities

None.

Item 6. [Reserved]

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" in Part I, Item 1A and elsewhere in this Annual Report on Form 10-K. See "Special Note Regarding Forward-Looking Statements."

Overview

We are a commercial-stage medical technology company dedicated to providing high quality customized vision to patients following cataract surgery. Our proprietary RxSight® Light Adjustable Lens system ("RxSight system") is the first and only commercially available premium cataract technology that enables doctors to customize and optimize visual acuity for patients after surgery. The RxSight system is comprised of our RxSight Light Adjustable Lens® ("LAL"®), RxSight Light Delivery Device ("LDD"™) and accessories. Our LAL is a premium intraocular lens ("IOL") made of proprietary photosensitive material that changes shape in response to specific patterns of ultraviolet ("UV") light generated by our LDD.

We designed our RxSight system to address the shortcomings of competitive premium IOL technologies and provide a solution that doctors can trust to improve visual outcomes and achieve high levels of patient satisfaction. Competitive premium IOLs require patients to specify their visual priorities before surgery and be willing to accept various optical trade-offs associated with those choices. Once a patient has selected a competitive premium IOL, the surgeon must rely on a series of preoperative diagnostic tests and predictive formulae to choose the appropriate lens power. If the doctor's prediction isn't exact, the patient may experience suboptimal results that could necessitate a subsequent corneal refractive procedure or certain other compromises in order to reach vision targets.

In contrast, with the RxSight system, the surgeon implants the LAL during a standard cataract procedure, determines refractive error with patient input several weeks following surgery and then uses the LDD to modify the LAL with the precise visual correction needed to achieve the patient's desired vision outcomes. We believe our RxSight system provides doctors and patients increased confidence and peace of mind by eliminating the high-stakes preoperative guesswork common to competitive premium IOLs and allowing patients to iterate their final vision characteristics with customized post-surgical adjustments.

We compete in the IOL market in the U.S. The LAL is a premium IOL which is partially reimbursable under Medicare, and in some cases by private payors. Premium IOLs are sold at a higher price point than conventional IOLs, as they provide refractive correction of vision unlike a conventional IOL that only replaces the natural lens with a clear lens (which is the standard for Medicare reimbursement). Our RxSight system is approved in Mexico and Canada for improving uncorrected visual acuity by adjusting the LAL power to correct residual postoperative refractive error. We may selectively pursue commercial expansion in these or other geographies that accept these approvals in the future, with a priority on markets where we see significant potential opportunity. New approvals may also be sought in large cataract markets with more complex regulatory processes such as Asia.

We are a Delaware corporation headquartered in Aliso Viejo, California with one wholly owned subsidiary located in Amsterdam, Netherlands. The wholly owned subsidiary has a registered branch in the United Kingdom and a wholly owned subsidiary located in Germany.

Our commercial efforts began in 2019 and have been primarily focused in the United States, where we are building a "razor and razor blade" business model to drive new customer adoption and ongoing LAL volume growth. Our United States commercial organization includes a direct sales team of LDD sales personnel and LAL account managers, as well as clinical specialists, field service engineers and marketing personnel. Our sales efforts are concentrated on the roughly 3,000 U.S. cataract surgeons that perform 70%-80% of all premium IOL procedures. As of December 31, 2022, we had established an installed base of 400 LDDs in ophthalmology practices and, since our inception though December 31, 2022, surgeons have implanted over 42,000 LALs.

We believe this business model provides an attractive and concentrated market opportunity addressable with a focused sales force. We intend to continue to make significant investments in our sales and marketing organization. We believe selectively increasing the number of sales representatives, practice development personnel and clinical trainers will help facilitate further adoption of our products among existing customer accounts as well as broaden awareness of our products to new accounts. We plan to grow our business primarily by expanding the size of our LDD installed base and driving increased

utilization of our LAL through heightened awareness of the superior clinical outcomes our RxSight system provides patients. To continue to strengthen our competitive position in the premium IOL market, our research and development activities are focused primarily on programs that improve clinical outcomes, improve customer experience, expand our indications for use, reduce manufacturing costs and lifecycle management.

Our near-term research and development activities are focused on enhancements to the RxSight system to improve the patient and doctor experience, expand the range of patients that can be treated, as well as expand the RxSight system indications and drive adoption. We believe that over time, our adjustable lens solution can be used to address a broad range of cataract surgery patients, including those that would otherwise elect for a conventional cataract procedure today. Additional development and clinical studies that are designed to provide clinical evidence of the safety and effectiveness of our existing and future generations of products are also anticipated. Finally, we may in the future seek to acquire or invest in additional businesses, products or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities.

We intend to continue to make investments in our sales and marketing organization, primarily sales representatives, clinical applications specialists and technical service personnel to support new customers and upgrades and LAL account managers to facilitate adoption of use of our LALs among existing accounts. We will expand our marketing efforts with additional print and digital, social media and other customer tools to expand their local advertising. We will also continue to make significant investments in research and development and clinical expenses to make enhancements in our current products. As a public company, we will incur costs that we have not previously incurred or have previously incurred at lower rates, including increased costs for employee-related expenses, director and officer insurance premiums, audit and legal fees, investor relations fees, fees to members of our Board of Directors and expenses for compliance with public-company reporting requirements. Because of these and other factors, we expect to continue to incur net losses and negative cash flows from operations in the future.

We believe that our existing cash and cash equivalents and short-term investments, will enable us to fund our operating expenses and capital expenditure and meet our term loan covenant requirements for at least the next 12 months from the date of filing of this Annual Report on Form 10-K. Although we do not anticipate the need to raise additional capital or incur additional debt in order to reach profit from operations, as the same may be disclosed in the Company's future Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q filed with the SEC, we may be required to raise additional capital through public or private equity offerings or debt financings, credit or loan facilities or by entering into partnerships or a combination of one or more of these funding sources in order to meet our liquidity requirements. We may also opportunistically access our at-the-market ("ATM") facility under advantageous circumstances. If we raise additional funds by issuing equity securities, our stockholders may experience dilution.

Supply chain constraints, inflation and COVID-19 pandemic

We rely on third parties, including single and sole source suppliers, to manufacture certain components and subcomponents of our products. We do not have long-term supply agreements with, or guaranteed commitments from our suppliers, including single and sole source suppliers. We utilize purchase orders or blanket orders covering the medium term of 18–24 months for the majority of our supplier base. While we depend on our suppliers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements, since the start of the COVID-19 pandemic and resultant supply chain constraints, vendors will miss delivery dates, extend delivery dates or in some circumstances cancel purchase orders because these suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. The expansion of global lead times, particularly in Europe and Asia, related to the COVID-19 pandemic, and COVID related shutdowns again in China and the more recently the military conflict in Ukraine, has resulted in the lack of availability of raw materials, including semiconductors, computers, monitors electronic parts, metals, packaging, adhesives, chemicals, resins and subcontract painted components. Certain suppliers have passed on higher prices, surcharges and expedited shipping fees to defray the higher commodity prices they are paying due to short supply and pushed out delivery dates. Additionally, due to these supply chain constraints we will identify and qualify new vendors or substitute components which requires testing, validations and documentation adding to internal costs and diverting engineering resources from other projects. On January 31, 2023, the FDA approved our premarket approval supplement to our lower cost LDD for various modifications that are intended to reduce the cost to manufacture the device. However, we have deferred the introduction of our lower cost-to-manufacture LDD to the market until the second half of 2023, as it is less difficult to procure components and subcomponents for our existing LDD than the lower cost-to-manufacture LDD. Currently, we are procuring materials for both LDD's, which have the same functionality. Management's expectation is that our gross margin will be impacted by the decision to continue to produce both LDD's, which it is necessary to mitigate potential supply chain issues. While we have taken measures to

mitigate business continuity risk, including increasing standard lead times, payment of expedite fees, issuance of a limited number of non-cancelable purchase orders, advance delivery of critical components ahead of normal delivery dates and second sourcing, our suppliers may cease producing the components we purchase from them or otherwise decide to cease doing business with us. Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components or subcomponents used in our products would limit our ability to manufacture our current and new products and could have a material adverse effect on our business, financial condition and results of operations.

Uncertain macroeconomic conditions including recent inflationary pressures and the rise in interest rates have created significant uncertainty in the U.S. economy and capital markets, which is expected to continue in 2023 and beyond and could negatively impact our financial results and liquidity.

Key business metrics

We regularly review several operating and financial metrics to evaluate our business, measure our performance, identify trends affecting our business, formulate our business plan and make strategic decisions. We believe the number of LDDs installed, LALs implanted and the number of doctors performing surgery with our products are indicators of our ability to drive adoption and generate revenue. We believe these are important metrics for our business. We may not yet be able to accurately assess seasonality and other trends, and we will continue to evaluate our business in the future using these and other financial metrics as we observe trends in our business.

We believe the number of LDDs sold in each quarter and our LDD installed base at the end of each period are important metrics as they represent an installed base into which we can sell our LALs.

	2022				2021			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
LDDs Sold	40	49	49	57	13	25	31	45
Installed Base at End of Period	246	294 *	343	400	105	130	161	206

* Reduced by one LDD taken out of installed base in Q2 2022.

We believe the number of LALs sold (reported as implanted in a patient) in each quarter is an important metric indicative of adoption and utilization of our RxSight system.

	2022				2021			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
LALs Sold	4,166	5,400	6,595	9,123	1,567	1,825	1,977	2,959

During 2022, we had increased LDD sales of 81 and increased LAL sales of 16,956 when compared to 2021 from strong adoption of our RxSight system by practices and doctors combined with an increased LDD installed base.

Components of results of operations

Sales

Our sales consists of the sale of LALs used in cataract surgeries, the LDDs for delivering light to the LALs to adjust the lens post-surgery, as needed, and service and accessories. Revenue is derived from sales of products primarily in the United States. Customers are primarily comprised of ophthalmic practices (LDD sales) and ambulatory surgery centers (LAL sales). We expect revenue to increase in absolute dollars as we expand our sales organization and sales territories, add customers, expand the base of doctors that are trained to use our products, and expand awareness of our products with new and existing customers and as doctors perform more procedures using our products.

LALs are held at customer sites on consignment. The single performance obligation is satisfied, and revenue is recognized for LALs upon customer notification that the LALs have been implanted in a patient.

Our LDD contracts contain multiple performance obligations bundled into one transaction price, with all obligations generally satisfied within one year. The LDD capital asset and related components revenue is recognized upon installation and customer acceptance, training revenue is recognized upon completion of training by at least one doctor and the initial warranty and service agreement are recognized ratably over the service period. After the first year, service contracts can be purchased separately on a standalone basis. Revenue for such service agreements will be recognized over the term of each contract.

For the year ended December 31, 2022 and 2021, contract liabilities from service agreements with customers consisted of the following:

	Year Ended December 31,	
	2022	2021
Balance at beginning of period	$ 540	$ 345
Additions during the period	2,052	793
Revenue recognized during the period	(1,405)	(598)
Balance at end of period	$ 1,187	$ 540

For the year ended December 31, 2022 and 2021 we had no customers who individually accounted for more than 10% of revenue.

Cost of sales

Cost of sales consists of materials, labor and manufacturing overhead internally to produce the Company's products as well as the cost of shipping and handling. Overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management and stock-based compensation. Cost of sales also includes depreciation expense for production equipment and certain direct costs such as shipping costs and royalty and license fee expense. Shipping costs billed to customers are included in sales. We expect cost of sales to increase in absolute dollars as our revenue grows and more of our products are sold.

We calculate gross margin as gross profit/(loss) divided by sales. Our gross margin has been and will continue to be affected by a variety of factors, including average selling prices, product sales mix, production and ordering volumes, manufacturing costs, product yields, headcount and cost-reduction strategies. Our gross margin could fluctuate from quarter to quarter as we introduce new products, and as we adopt new manufacturing processes and technologies.

Our LDD, as is typical of many medical device capital equipment products, has a low gross margin, as the material cost of the LDD is significant, representing greater than 50% of the total cost to manufacture. In addition, we do not mark up our LDD substantially, as LDDs, as sold, generate LAL procedures. Our LAL gross margin is higher, with low material cost but high fixed overhead costs. As our manufacturing volume of the LAL increases, we expect the gross margin may improve significantly.

Operating expenses

Selling, general and administrative expenses

Selling, general and administrative, or SG&A, expenses consist primarily of personnel-related expenses, including wages, incentive bonuses, stock-based compensation and benefits related to administrative, selling and marketing functions, education programs for doctors, commercial operations and analytics, finance, information technology and human resource functions. Other SG&A expenses include sales commissions, travel expenses, promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, training for doctors, professional services fees such as legal, patent registration costs, accounting, audit and tax fees, board of directors' expenses, insurance costs, general corporate expenses and facilities-related expenses. We expect SG&A expenses to continue to increase in absolute dollars as we expand our sales and marketing organization and infrastructure to both drive and support the anticipated growth in revenue and due to additional legal, accounting audit and tax fees, insurance and other expenses associated with being a public company.

Research and development expenses

Research and development expenses consist of expenses incurred in performing research and development and engineering activities for new products and technology, clinical studies and regulatory submissions and compliance. The expenses include personnel-related expenses, including wages, incentive bonuses, stock-based compensation and benefits, costs incurred at clinical trial sites, regulatory and manufacturing engineering costs, including those related to various laboratory and research equipment and supplies, expense of pre-approved inventory utilized for clinical trial and research purposes, costs incurred in the development of manufacturing processes in excess of capitalizable value, fees paid to consultants and contract clinical organizations and direct FDA related costs and costs related to FDA premarket approval submission preparation. Research and development expenses are expensed as incurred. We expect research and development

expenses as a percentage of revenue to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trials and registries and other related activities.

Change in fair value of warrants

Change in fair value of warrants consists of gains and losses resulting from the remeasurement of the fair value of our preferred stock warrant liabilities at each balance sheet date. We continued to record adjustments to the estimated fair value of the preferred stock warrants until the conversion of the underlying convertible preferred stock into common stock which occurred immediately prior to the completion of our IPO in July 2021.

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 indebtedness.

Interest and other income, net

Interest and other income, net consists primarily of interest income earned on our cash and cash equivalents.

Comprehensive Loss

All components of comprehensive loss, including net loss, are reported in the consolidated financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on short-term investments and foreign currency translation adjustments.

Results of operations

Comparison of the years ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021, together with the dollar increase or decrease and percentage change in those items:

	Year-Ended December 31,		Change	
(in thousands, except percentages)	**2022**	**2021**	**($)**	**(%)**
Sales	$ 49,005	$ 22,593	$ 26,412	116.9%
Cost of sales	27,677	18,076	9,601	53.1
Gross profit	$ 21,328	$ 4,517	$ 16,811	372.2%
Operating expenses:				
Selling, general and administrative	58,665	32,805	25,860	78.8
Research and development	25,981	24,499	1,482	6.0
Total operating expenses	84,646	57,304	27,342	47.7
Loss from operations	$ (63,318)	$ (52,787)	$ (10,531)	19.9%
Other income (expense), net:				
Change in fair value of warrants	—	2,717	(2,717)	(100.0)
Expiration of warrant	—	5,018	(5,018)	(100.0)
Interest expense	(4,946)	(3,682)	(1,264)	34.3
Interest and other income	1,517	54	1,463	2,725.4
Total other (expense) income , net:	(3,429)	4,107	(7,536)	(183.5)%
Loss before income taxes	(66,747)	(48,680)	(18,067)	37.1
Income tax expense	9	8	1	19.1
Net loss	$ (66,756)	$ (48,688)	$ (18,068)	37.1%
Other comprehensive loss				
Unrealized loss on short-term investments	(66)	(7)	(59)	829.9
Foreign currency translation loss	(9)	(10)	1	(5.3)
Total other comprehensive loss	(75)	(17)	(58)	347.5
Comprehensive loss	$ (66,831)	$ (48,705)	$ (18,126)	37.2%

Sales

Sales increased by $26.4 million, or 116.9%, to $49.0 million for the year ended December 31, 2022 from $22.6 million for the year ended December 31, 2021. The increase in sales was due to sales in 2022 of 81 more LDDs and 16,956 more LALs as compared to 2021, from the growth in our installed base of LDDs and increased adoption of our LAL by doctors and patients.

Cost of sales

Cost of sales increased by $9.6 million, or 53.1%, to $27.7 million for the year ended December 31, 2022 from $18.1 million for the year ended December 31, 2021, primarily due to the increase in the number of LALs and LDDs sold during the period. Gross margin increased to 43.5% in the year ended December 31, 2022 from 20.0% in 2021 due to the increased revenue from higher margin LALs from 34% of sales in 2021 to 56% of sales in 2022 and by the recording of a $2.4 million reserve primarily for excess LAL inventory as a result of the introduction of an updated LAL with ActivShield technology for the year ended December 31, 2021.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $25.9 million, or 78.8%, to $58.7 million for the year ended December 31, 2022, from $32.8 million for the year ended December 31, 2021. This increase was primarily attributable to an increase in selling and marketing personnel costs of $15.1 million due mainly to additional headcount, $2.4 million in post market study costs as well as increased travel costs of $2.3 million, due to increased LDD sales, and increased trade show costs of $1.1 million when compared to the year ended December 31, 2021. General and administrative expenses increased by $4.9 million primarily due to an additional $3.6 million from increased personnel costs and increased stock-based compensation as well as $1.7 million of increased costs related to operating as a public company.

Research and development expenses

Research and development expenses increased by $1.5 million to $26.0 million for the year ended December 31, 2022 from $24.5 million for the year ended December 31, 2021, an increase of 6.0%. This increase was primarily attributable to $1.9 million in increased clinical study costs and $0.9 million in increased personnel costs which were partially offset by $1.2 million reduced material costs.

Other income (expense)

Other income, net, decreased by $7.5 million to expense of $3.4 million for the year ended December 31, 2022 from income of $4.1 million for the year ended December 31, 2021, due primarily to a favorable change in fair value of warrant liabilities of $2.7 million, gain on expiration of warrant of $5.0 million for the year ended December 31, 2021 and increased interest expense of $1.3 million in 2022, primarily due to rising interest rates on our amended term loan. The increase in other expense was partially offset by an increase in interest income of $1.5 million in 2022 from higher interest rates on our short-term investments.

Liquidity and capital resources

Sources of liquidity

We have incurred significant operating losses and negative cash flows from operations since our inception, and we anticipate that we will incur significant losses in the future.

As of December 31, 2022, we had cash and cash equivalents of $105.8 million, short-term investments of $94.0 million, long-term debt of $40.2 million and accumulated deficit of $546.0 million. For the years ended December 31, 2022 and 2021, our net losses from operations were $63.3 and $52.8 million, respectively. We generated sales of $49.0 million and had a net loss of $66.8 million for the year ended December 31, 2022, compared to sales of $22.6 million and net income of $48.7 million for the year ended December 31, 2021.

Prior to our IPO, which we completed in July 2021, our primary sources of capital were private placements of preferred stock, a structured transaction with a strategic partner, debt financing and from sales of our products.

On July 29, 2021, we completed our IPO, which resulted in the issuance and sale of 8,248,549 shares of common stock, including 898,549 shares sold pursuant to the exercise of the underwriters' over-allotment option at the IPO price of $16.00 per share. We received net proceeds of approximately $119.6 million from the IPO, after deducting underwriters' discounts and commissions of $9.2 million and offering costs of $3.2 million.

Term Loan

On May 3, 2022, we entered into a Second Amendment to the Term Loan (as amended through the Second Amendment, (the "Amended Term Loan"). The Amended Term Loan increased the loan and security agreement to $60.0 million, of which $40.0 million was fully funded as of May 3, 2022 from the original term loan. Under the Amended Term Loan, we may borrow an additional amount of up to $10.0 million through June 30, 2023, upon satisfaction of the applicable drawdown conditions and achievement of sufficient trailing twelve-month sales as provided in the agreement for the measurement period ending March 31, 2023. Subject to the terms and conditions of the Amended Term Loan, we may also borrow an additional amount of up to $10.0 million through September 30, 2023, upon satisfaction of the applicable drawdown conditions and achievement of sufficient trailing twelve-month sales as provided in the agreement for the measurement period ending June 30, 2023. The Amended Term Loan bears interest at a rate per annum equal to the greater of (i) 9.25% or (ii) 1-Month Term Secured Overnight Financing Rate ("SOFR") (or, if greater, 0.16%) plus an applicable margin of 9.09%. If there is an event of default under the Amended Term Loan additional interest of 5% applies. The Amended Term Loan extends the maturity date of the loan and security agreement, which was due to expire on October 1, 2025, to February 1, 2027. The Company refers to its $60.0 million Amended Term Loan as its credit facility. See Note 8 - Term Loan in the Notes to the consolidated financial statements included in this annual report.

Standby letter of credit

We also have a standby letter of credit, expiring September 30, 2024, issued by a financial institution as a required security for one operating lease. The aggregate amount of the letter of credit was $0.3 million as of December 31, 2022 and 2021, respectively.

Shelf Registration Statement

On August 8, 2022, we filed a $200.0 million shelf registration statement which became effective on August 12, 2022. The shelf registration is effective for three years and permits us to sell, from time to time, up to $200.0 million in aggregate value of our common stock, preferred stock, debt securities, warrants, and/or units. The shelf registration statement was intended to provide us with flexibility to access additional capital when market conditions are appropriate. Included in the $200.0 million shelf registration statement, we also filed a prospectus supplement to sell up to an aggregate value of $50.0 million dollars of our common stock through an ATM offering. The ATM shares were offered through BofA Securities, Inc. as sales agent. As of the date of this Annual Report on Form 10-K, a total of 1,355,216 shares of common stock, for total net proceeds of $17.1 million, have been issued and sold through the ATM offering, of which 879,341 shares of common stock, for net proceeds of $11.1 million, were sold in January 2023.

On February 7, 2023, we entered into an underwriting agreement with BofA Securities, Inc., which the we agreed to issue and sell 4,000,000 shares of our common stock in a Public Offering, pursuant to our shelf registration statement, which was declared effective on August 12, 2022. The shares of common stock were sold at a price to the public of $12.50 per share. Under the terms of the underwriting agreement, we also granted the underwriters an option exercisable for 30 days from the date of the underwriting agreement to purchase up to an additional 600,000 shares of common stock on the same terms and conditions. The Public Offering closed on February 10, 2023. The underwriters' option was exercised in full on February 10, 2023 and closed on February 14, 2023. We received net proceeds of approximately $53.7 million from the Public Offering, after deducting underwriters' discounts and commissions of $3.5 million and offering expenses of $0.3 million.

Funding requirements

Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our sales growth;
- our research and development efforts;
- our sales and marketing activities;
- working capital investments, primarily in inventories and accounts receivable;
- debt service and debt covenant requirements;
- our ability to raise additional funds or borrow on our credit facility to finance our operations;

- the outcome, costs and timing of any clinical trial results for our current or future products;
- the emergence and effect of competing or complementary products;
- our ability to maintain, expand, enforce and defend our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management, sales, research and development, scientific and customer support personnel;
- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- operating and finance lease payments for our facilities;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the impact of the COVID-19 pandemic.

In January 2023, we sold 879,341 common shares through the ATM offering for $11.1 million in net proceeds after deducting underwriting discounts and commissions. In addition, in February of 2023 we sold 4,600,000 common shares in a Public Offering and received net proceeds of approximately $53.7 million, after deducting underwriters' discounts and commissions of $3.5 million and offering expenses of $0.3 million.

We expect that our current cash, cash equivalents and short-term investments and additional capital raised, through the date of filing of this Form 10-K will be sufficient to fund our operations for at least the next 12 months. Although, based on our current planned operations, we do not anticipate the need to raise additional capital or incur additional debt in order to reach profit from operations, as the same may be disclosed in the Company's future Annual Reports on Form 10-K or Quarterly Reports on Form 10-Q filed with the SEC, we may be required to raise additional capital through public or private equity offerings or debt financings, credit or loan facilities or by entering into partnerships or a combination of one or more of these funding sources in order to meet our liquidity requirements. We may also opportunistically access our ("ATM") facility under advantageous circumstances.

See Part I, Item 1A (Risk Factors) of this Annual Report on Form 10-K for additional risks associated with our substantial capital requirements and Note 12 - Leases and Note 15 - Subsequent Events in the Notes to Consolidated Financial Statements included in Part II - Item 8 in this Annual Report on Form 10-K for additional information.

Summary statement of cash flows

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

	For the Year Ended December 31,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$ (58,850)	$ (44,708)
Investing activities	39,950	(81,907)
Financing activities	6,332	137,342
Effect of foreign exchange rate on cash, cash equivalents and restricted cash	(9)	(10)
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (12,577)	$ 10,717

Cash used in operating activities

Net cash used in operating activities for the year ended December 31, 2022 was $58.8 million, consisting primarily of a net loss of $66.8 million, a change in operating assets and liabilities of $7.4 million, partially offset by non-cash stock-based compensation of $11.4 million, and depreciation and amortization of $3.9 million.

Net cash used in operating activities for the year ended December 31, 2021 was $44.7 million, consisting primarily of loss from operations of $48.7 million, a non-cash gain on expiration of an unexercised warrant of $5.0 million, an increase in

operating assets and liabilities of $2.7 million, offset by non-cash stock-based compensation of $7.6 million, depreciation and amortization of $4.0 million and the provision for obsolete and excess inventory of $2.4 million.

Cash provided by (used in) investing activities

Net cash provided by investing activities for the year ended December 31, 2022 was $40.0 million, consisting of net maturity of short-term investments of $42.3 million and purchases of property and equipment of $2.4 million.

Net cash used in investing activities for the year ended December 31, 2021 was $81.9 million, consisting of net purchases of short-term investments of $160.0 million and purchases of property and equipment of $1.9 million which were partially offset by maturities of short-term investments of $80.0 million.

Cash from financing activities

Net cash from financing activities for the year ended December 31, 2022 was $6.3 million, consisting primarily of net proceeds from our at-the-market offering of $6.0 million and proceeds from stock options exercised and issuance of common stock under the employee stock purchase plan of $1.8 million which were partially offset by payments of employee taxes of $0.6 million and payments for offering costs of $0.6 million in connection with the filing of our shelf registration statement.

Net cash from financing activities for the year ended December 31, 2021 was $137.3 million, consisting primarily of net proceeds from the IPO of $119.6 million, a draw on the Company's term loan of $15.0 million and proceeds from stock options exercised of $1.6 million.

Critical accounting policies, significant judgments and estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP, which requires us to make estimates that affect the reported amounts of assets, liabilities, sales and expenses, and related disclosure of contingent assets and liabilities. Generally, we base our estimates on historical experience and on various other assumptions in accordance with U.S. GAAP, that we believe to be reasonable under the circumstances. Actual results may differ from these estimates and such differences could be material to the financial position and results of operations.

While our significant accounting policies are described in more detail in the "S*ummary of Accounting Polices*" in Note 2 in the Notes to Consolidated Financial Statements included in Part II - Item 8 in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue recognition

Our revenues from sales are generated from the sale of light adjustable intraocular lenses, the LAL, used in cataract surgery along with a specifically designed machine for delivering light to the eye, the Light Delivery Device ("LDD"), to adjust the lens post-surgery, as needed. Revenue from sales is recognized from products sold in the U.S. and Europe. Customers are primarily comprised of ambulatory surgery centers, hospitals, and physician private practices.

We recognize revenue from sales when promised goods or services are transferred to customers at a transaction price that reflects the consideration to which we expect to be entitled in exchange for those goods and services. Specifically, we apply the following five steps to recognize revenue from sales: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue from sales when, or as, we satisfy a performance obligation. We apply the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. At contract inception, we assess the goods promised within each customer contract to determine the individual deliverables in its product offerings as separate performance obligations and assesses whether each promised good or service is distinct. The transaction price is determined based on the consideration expected to be received, based either on the stated value in contractual arrangements or the estimated cash to be collected in non-contracted arrangements. We recognize revenue from sales as the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied, considering whether or not this occurs at a point in time or over time. We elected to account for shipping costs as fulfillment costs rather than a promised service and exclude from revenue any taxes collected from customers that are remitted to government authorities.

Our LDD contracts contain multiple performance obligations bundled for one transaction price, with all obligations generally satisfied within one year. For these bundled arrangements, we account for individual products and services as separate performance obligations if they are distinct, that is, if a product or service is separately identifiable from other items in the bundled package, and if a customer can benefit from it on its own or with other resources that are readily available to the customer. Our LDD contracts include a combination of the following performance obligations: (1) LDD capital asset and related components, (2) training and (3) device service (initial year). Each of these three performance obligations are considered distinct. The LDD capital asset is distinct because the customer can benefit from it together with other resources that are readily available to the customer. Training on the use of the machine is offered as a distinct activity after installation of the LDD to enhance the customer's ability to utilize the machine by having an industry professional provide best practices and customize training to the specific needs of the customer. Each LDD comes with a twelve-month manufacturer's warranty (service-type) that includes preventative maintenance, unscheduled service (labor and parts) and software updates. After the first year, service contracts can be purchased separately on a standalone basis. We recognize revenue as performance obligations are satisfied by transferring control of the product or service to a customer. Specifically, revenue for the LDD capital asset is recognized at a point in time at installation. Revenue for training is also recorded at a point in time, generally 60 days after installation. Revenue for the device service is recognized ratably over time after installation, generally 12 months. We have determined that the transaction price is the invoice price, net of adjustments, if any. The allocation to the separate performance obligations is based upon the relative standalone selling price. Standalone selling prices are based on observable prices at which we separately sell the products or services. We estimate the standalone selling price using the market assessment approach considering market conditions and entity-specific factors including, but not limited to, features and functionality of the products and services, geographies, type of customer and market conditions. The Company regularly reviews and updates standalone selling prices as necessary.

LALs are held at customer sites on consignment. The single performance obligation is satisfied, and revenue from sales is recognized for LALs upon customer notification that the LALs have been implanted in a patient. For the year ended December 31, 2022 and 2021, credits related to returns and rebates on list prices were not significant.

The Company adopted the practical expedient permitting the direct expensing of costs incurred to obtain contracts where the amortization of such costs would occur over one year or less, and it applied to substantially all the Company's contracts.

Indemnification agreements

We enter into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, we indemnify, hold harmless and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement, misappropriation or other violation claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments we could be required to make under these arrangements is not determinable. We have never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, we believe the fair value of these agreements is minimal.

Recent accounting pronouncements

See the section titled "*Summary of Accounting Policies—Recent Accounting Pronouncements*" in Note 2 to our Consolidated Financial Statements included in Part II - Item 8 in this Annual Report on Form 10-K for additional information.

Emerging growth company and smaller reporting company status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation, and an exemption from the requirements to obtain a non-binding advisory vote on executive compensation or golden parachute arrangements. We have elected to take advantage of certain of the reduced disclosure obligations in this Annual Report on Form 10-K and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

The JOBS Act permits an "emerging growth company" to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. However, we have chosen to irrevocably "opt out" of such extended transition period, and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

We will remain an emerging growth company until the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the consummation of our initial public offering (i.e. December 31, 2026); (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion; (iii) the date on which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

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.

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

As a smaller reporting company, we are not required to provide disclosure under this item.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of RxSight, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of RxSight, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, redeemable common stock, stock options, convertible preferred stock and stockholders' equity and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

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/ Ernst & Young, LLP

We have served as the Company's auditor since 2015.

Irvine, California

March 6, 2023

RxSIGHT, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 11,834	$ 24,361
Short-term investments	93,968	134,971
Accounts receivable, net	10,956	4,862
Inventories	14,835	8,032
Prepaid and other current assets	2,962	4,069
Total current assets	134,555	176,295
Property and equipment, net	10,138	11,217
Operating leases right-of-use assets	3,943	4,284
Restricted cash	761	811
Other assets	767	114
Total assets	$ 150,164	$ 192,721
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,595	$ 1,689
Accrued expenses and other current liabilities	12,672	7,859
Lease liabilities	1,970	1,529
Total current liabilities	17,237	11,077
Long-term lease liabilities	2,856	3,642
Term loan, net	40,169	39,760
Total liabilities	60,262	54,479
Commitments and contingencies (*Note 13)*		
Stockholders' equity:		
Common stock, $0.001 par value, 900,000,000 shares authorized, 28,268,389 shares issued and outstanding as of December 31, 2022 and 27,366,746 shares issued and outstanding as of December 31, 2021	28	27
Preferred stock, $0.001 par value, 100,000,000 shares authorized, no shares issued and outstanding	—	—
Additional paid-in capital	636,001	617,511
Accumulated other comprehensive loss	(95)	(20)
Accumulated deficit	(546,032)	(479,276)
Total stockholders' equity	89,902	138,242
Total liabilities and stockholders' equity	$ 150,164	$ 192,721

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

RxSIGHT, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2022	**2021**
Sales	$ 49,005	$ 22,593
Cost of sales	27,677	18,076
Gross profit	21,328	4,517
Operating expenses:		
Selling, general and administrative	58,665	32,805
Research and development	25,981	24,499
Total operating expenses	84,646	57,304
Loss from operations	(63,318)	(52,787)
Other income (expense), net:		
Change in fair value of warrants	—	2,717
Expiration of warrant	—	5,018
Interest expense	(4,946)	(3,682)
Interest and other income	1,517	54
Loss before income taxes	(66,747)	(48,680)
Income tax expense	9	8
Net loss	$ (66,756)	$ (48,688)
Other comprehensive loss		
Unrealized loss on short-term investments	(66)	(7)
Foreign currency translation loss	(9)	(10)
Total other comprehensive loss	(75)	(17)
Comprehensive loss	$ (66,831)	$ (48,705)
Net loss per share:		
Attributable to common stock, basic & diluted	$ (2.41)	$ (3.57)
Weighted-average shares outstanding used in computing net loss per share:		
Attributable to common stock, basic & diluted	27,661,982	13,625,044

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

RxSIGHT, INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE COMMON STOCK, STOCK OPTIONS, CONVERTIBLE PREFERED STOCK AND STOCKHOLDERS' EQUITY
(In thousands, except number of shares)

	Redeemable common stock		Notes receivable for redeemable common stock issued	Redeemable stock options	Convertible preferred stock		Common stock		Additional paid-in capital	Notes receivable for common stock issued	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Amount			Shares	Amount	Shares	Amount					
Balance at December 31, 2020	3,813,450	$ 80,780	$ (803)	$ 53,085	14,376,272	$ 353,300	1	$ -	$ -	$ -	$ (3)	$ (430,588)	$ (430,591)
Shares issued for the exercise of stock options and vesting of restricted stock units	280,545	6,922	-	(5,715)		-	83,958	-	347	-	-	-	347
Stock-based compensation expense	-	-	-	-	-	-	-	-	7,575	-	-	-	7,575
Proceeds from notes receivable	-	-	-	-	-	-	-	-		136	-	-	136
Surrender of common stock in exchange for cancellation of note receivable	-	-	-	-	-		(11,011)	-	(229)	229	-	-	-
Reclassification of 4,093,995 shares of redeemable common stock to 4,093,995 shares of common stock	(4,093,995)	(87,702)	817	-	-	-	4,093,995	4	87,698	(817)	-	-	86,885
Reclassification of redeemable common stock options to common stock options	-	-	-	(47,370)			-	-	47,370	-	-	-	47,370
Change in notes receivable for common stock issued	-	-	(14)	-	-	-	-	-	-	452	-	-	452
Exercise of preferred stock warrants, net of shares withheld for exercise price	-	-	-	-	100,261	3,912	-	-	(2,011)	-	-	-	(2,011)
Conversion of preferred stock to common stock upon initial public offering, net of fractional shares settled for $11	-	-	-	-	(14,476,533)	(357,212)	14,951,254	15	357,187	-	-	-	357,202
Issuance of common stock in connection with initial public offering, net of issuance costs of $12.4 million	-	-	-	-	-	-	8,248,549	8	119,574	-	-	-	119,582
Other comprehensive loss	-	-	-	-	-	-	-	-	-	-	(17)	-	(17)
Net loss	-	-	-	-	-	-	-	-	-	-	-	(48,688)	(48,688)
Balance at December 31, 2021	-	$ -	$ -	$ -	-	$ -	27,366,746	$ 27	$ 617,511	$ -	$ (20)	$ (479,276)	$ 138,242
Shares issued for the exercise of stock options and vesting of restricted stock units	-	-	-	-	-	-	382,506	1	840		-	-	841
Shares redeemed for employee tax withholdings	-	-	-	-	-	-	(49,456)		(643)	-	-	-	(643)
Stock-based compensation expense	-	-	-	-	-	-	-	-	11,397	-	-	-	11,397
Shares issued for the employee stock purchase plan	-	-	-	-	-	-	92,718		937	-	-	-	937
Issuance of common stock in at-the-market offerings, net of issuance costs	-	-	-	-	-	-	475,875	-	5,959	-	-	-	5,959
Other comprehensive loss	-	-	-	-	-	-	-	-	-	-	(75)	-	(75)
Net loss	-	-	-	-	-	-	-	-	-	-	-	(66,756)	(66,756)
Balance at December 31, 2022	-	$ -	$ -	$ -	-	$ -	28,268,389	$ 28	$ 636,001	$ -	$ (95)	$ (546,032)	$ 89,902

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

RxSIGHT, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31, 2022	2021
Operating Activities:		
Net loss	$ (66,756)	$ (48,688)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,884	3,975
Amortization of right-of-use lease assets	138	13
Amortization of debt issuance costs and premium	552	493
Change in fair value of warrants	—	(2,717)
Gain on expiration of warrant	—	(5,018)
Amortization of discount on short-term investments	(1,405)	(30)
Stock-based compensation	11,397	7,575
Provision for excess and obsolete inventory	752	2,367
Change in operating assets and liabilities:		
Accounts receivable	(6,094)	(1,996)
Inventories	(7,555)	(2,111)
Prepaid and other assets	789	(2,809)
Accounts payable	635	555
Accrued expenses and other liabilities	4,813	3,683
Net cash used in operating activities	(58,850)	(44,708)
Investing Activities:		
Purchase of property and equipment	(2,393)	(1,940)
Maturity of short-term investments	255,000	80,000
Purchases of short-term investments	(212,657)	(159,967)
Net cash provided by (used in) investing activities	39,950	(81,907)
Financing Activities:		
Proceeds from term loan	—	15,000
Payments of debt issuance costs	(145)	(132)
Proceeds from exercise of preferred stock warrants	—	790
Proceeds from exercise of stock options and issuance of common stock under the employee stock purchase plan	1,778	
Payments for employee taxes related to stock compensation	(643)	—
Proceeds from initial public offering, net of underwriting discounts and commissions and offering costs	—	119,582
Proceeds from issuance of common stock in at-the-market offerings	6,050	—
Principal payments on finance lease liabilities	(121)	(27)
Payments of deferred offering costs	(587)	—
Change in notes receivables for redeemable common stock issued	—	575
Proceeds from issuance of common stock	—	1,554
Net cash provided by financing activities	6,332	137,342
Effect of foreign exchange rate on cash, cash equivalents and restricted cash	(9)	(10)
Net (decrease) increase in cash, cash equivalents and restricted cash	(12,577)	10,717
Cash, cash equivalents and restricted cash - beginning of period	25,172	14,455
Cash, cash equivalents and restricted cash - end of period	$ 12,595	$ 25,172
Supplemental disclosure of cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	2,187	1,269
Cash paid for income taxes	3	20
Cash paid for interest on financing leases	18	5
Cash paid for interest on term loan	4,239	3,182
Non-cash investing and financing activities:		
Right-of-use assets obtained in exchange for lease obligations:		
Operating lease	1,090	126
Finance lease	311	—
Lease obligations recorded for right-of-use assets:		
Operating lease	1,090	126
Finance lease	311	—
Acquisition of property and equipment included in accounts payable and accrued expenses and other current liabilities	299	—
Deferred offering costs included in accounts payable and accrued liabilities	133	—
Payment-in-kind interest income added to principal of notes receivable	—	28
Reclassification from warrant liability to additional paid-in capital for warrants exercised	—	1,111
Reclassification of 4,093,995 shares of redeemable common stock to 4,093,995 shares of common stock	—	87,702
Reclassification of redeemable common stock options to common stock options	—	47,370
Conversion of preferred stock to common stock upon initial public offering	—	357,202
Deferred offering costs reclassified to additional paid in capital	90	3,156

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

RxSIGHT, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1 – Organization and Basis of Presentation

Description of Business

RxSight®, Inc. (the "Company") is a Delaware corporation headquartered in Aliso Viejo, California with one wholly owned subsidiary located in Amsterdam, Netherlands. The wholly owned subsidiary has a registered branch in the United Kingdom and a wholly owned subsidiary located in Germany. The Company is engaged in the research and development, manufacture and sale of light adjustable intraocular lenses used in cataract surgery along with capital equipment used with the lenses.

The Company's products, which include the light adjustable lens ("LAL®") and a specially designed machine for delivering light to the eye, the Light Delivery Device ("LDD™"), are approved by the United States ("U.S.") Food and Drug Administration ("FDA") primarily for sale in the U.S. and have regulatory approval in the U.S., Europe, Canada and Mexico. The Company began marketing its products in 2019. The LAL is a premium intraocular lens ("IOL") which is partially reimbursable under Medicare. The Company competes with other IOLs in the premium market in the U.S. and Europe.

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of RxSight, Inc. and its wholly-owned subsidiaries, RxSight, B.V., located in the Netherlands, and RxSight GmbH, located in Germany. The Company translates the financial statements of its foreign subsidiaries using end-of-period exchange rates for assets and liabilities and average exchange rates during each reporting period for results of operations. All significant inter-company balances and transactions have been eliminated in consolidation.

Operating Segments

The Company determined its operating segment on the same basis that it uses to evaluate its performance internally. The Company's chief operating decision-maker ("CODM"), its Chief Executive Officer, reviews its consolidated operating results for the purpose of allocating resources and evaluating financial performance.

The Company determined that it operates and manages its business (including its non-U.S. subsidiaries) in one reportable segment: the research and development, manufacture and sale of light adjustable lenses and related capital equipment.

Liquidity

Initial Public Offering ("IPO")

On July 22, 2021, the Company's Board of Directors ("Board") approved an amendment to the Company's certificate of incorporation to effect a reverse split of shares of the Company's common stock, excluding Series G and Series W common stock, and convertible preferred stock on a 1-for-10.33 basis ("Reverse Stock Split"). The par values of the common stock and convertible preferred stock were not adjusted as a result of the Reverse Stock Split. The Reverse Stock Split was effected on July 23, 2021. Accordingly, all common stock, excluding Series G and Series W common stock, options to purchase common stock, convertible preferred stock, share data, per share data and related information contained in the accompanying consolidated financial statements and notes have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented. Outstanding stock options were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased. The Reverse Stock Split resulted in an adjustment to the convertible preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion.

On July 29, 2021, the Company completed its IPO which resulted in the issuance and sale of 8,248,549 shares of its common stock at a price of $16.00 per share. The aggregate net proceeds from the offering, which included 898,549 common shares sold upon the partial exercise of the underwriters' over-allotment option, after deducting underwriting discounts and commissions of $9.2 million and other offering costs of $3.2 million, were approximately $119.6 million.

Immediately prior to the completion of the IPO, (i) 14,376,272 outstanding shares of the Company's convertible preferred stock were converted into an aggregate of 14,725,309 shares of common stock and (ii) 225,945 warrants to purchase Series H convertible preferred stock were exercised and converted into 100,261 shares of common stock.

Shelf Registration Statement

On August 8, 2022, the Company filed a $200.0 million shelf registration statement on Form S-3 ("shelf registration statement") which became effective on August 12, 2022. The shelf registration statement is effective for three years and permits the Company to sell, from time to time, up to $200.0 million in aggregate value of common stock, preferred stock, debt securities, warrants, and/or units. The shelf registration statement is intended to provide the Company with flexibility to access additional capital. Included in the $200.0 million shelf registration statement the Company also filed a prospectus supplement to sell up to an aggregate value of $50.0 million dollars of common stock through an "at-the-market" ("ATM") offering. During the year ended December 31, 2022 the Company sold 475,875 common shares "at-the-market" for $6.0 million in proceeds after deducting underwriting discounts and commissions and other offering expenses.

As of December 31, 2022 and 2021 the Company has cash, cash equivalents and short-term investments of $105.8 million and $159.3 million, respectively.

The Company began generating revenue from its principal operations in 2019. The Company has a limited operating history, and the revenue and income potential of the Company's business and market are unproven. The Company has experienced recurring net losses and negative cash flows from operating activities since its inception. For the years ended December 31, 2022 and 2021, the Company incurred losses from operations of $63.3 million and $52.8 million, respectively. The Company expects to continue to incur net operating losses into the foreseeable future. Successful transition to attaining profitable operations is dependent upon gaining market acceptance of the Company's products and achieving a level of revenues adequate to support the Company's cost structure.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company believes that existing cash resources will be sufficient to meet projected operating requirements for at least 12 months from the date of issuance of the accompanying consolidated financial statements. The Company plans to continue to fund its losses from operations using its cash, cash equivalents and short-term investments as of December 31, 2022 and meet its future capital funding needs through equity or debt financings, other third-party funding, collaborations, strategic alliances and licensing arrangements or a combination of these. There can be no assurance that the Company will be able to obtain additional financing on acceptable terms, or at all. If the Company is not able to secure adequate additional funding, the Company may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations and future prospects.

Note 2 – Summary of Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make informed estimates, judgments and assumptions that affect the reported amounts in the consolidated financial statements and disclosures in the accompanying notes as of the date of the accompanying consolidated financial statements. On an on-going basis, management evaluates the most critical estimates and assumptions for continued reasonableness. These estimates and assumptions involve judgments with respect to numerous factors that are difficult to predict. Actual results may differ materially from the estimates used in the preparation of the accompanying consolidated financial statements under different assumptions or conditions.

The Company's consolidated financial statements as of and for the year ended December 31, 2022 reflect the Company's estimates of the impact of the macroeconomic environment, including the impact of inflation, higher interest rates, foreign exchange rate fluctuations and the COVID-19 pandemic. The duration and the scope of these conditions cannot be predicted; therefore, the extent to which these conditions will directly or indirectly impact the Company's business, results of operations and financial condition, is uncertain. The Company is not aware of any specific event or circumstance that would require an update to its estimates, judgments and assumptions or a revision of the carrying value of the Company's assets or liabilities as of the date of this filing.

Cash Equivalents

Cash equivalents consist of investments in money market accounts. The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase that can be liquidated without prior notice or penalty to be cash equivalents. Cash equivalents are recorded at face value or cost, which approximates fair market value.

Short-term Investments

Short-term investments are classified based on the maturity date of the related securities. Based on the nature of the assets, the Company's short-term investments, which are government securities, are classified as available-for-sale and are recorded at their estimated fair value as determined by prices for identical or similar securities at the balance sheet date. The Company's short-term investments consist of Level 2 financial instruments in the fair value hierarchy. Unrealized gains and losses are recorded as a component of Other Comprehensive Loss within Stockholders' Equity on the consolidated balance sheets. Realized gains and losses are included as other income (expense) in the accompanying Consolidated Statements of Operations and Comprehensive Loss. The cost basis for realized gains and losses on available-for-sale securities is determined on a specific identification basis. Management determines the appropriate classification of its investments at the time of purchase and reevaluates such determination at each balance sheet date. The Company periodically reviews its investments for unrealized losses other than credit losses and whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. In determining whether the carrying value is recoverable, management considers the following factors:

- whether the investment has been in a continuous loss position for over 12 months;
- the duration to maturity of investments;
- intention and ability to hold the investment to maturity and if it is not more likely than not that the Company will be required to sell the investment before recovery of the amortized cost basis;
- the credit rating, financial condition and near-term prospects of the issuer and
- the type of investments made.

The Company recognized $75,000 and $9,000 of unrealized losses related to short-term investments as of December 31, 2022 and 2021, respectively.

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. The Company did not record an allowance for credit losses for these investments as of December 31, 2022 and December 31, 2021. For additional information see Note 3 – Short-Term Investments.

Restricted Cash

Restricted cash consists of cash held as collateral for a letter of credit as security for future facility lease payments and corporate credit cards at the Company's bank. Restricted cash decreased $50,000 during the year ended December 31, 2022 to $761,000 as required for these operating activities.

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the consolidated balance sheets to the amount reported in the Consolidated Statement of Cash Flows for the years ended December 31, 2022 and 2021 (in thousands).

	Year Ended December 31,	
	2022	2021
Cash and cash equivalents	$ 11,834	$ 24,361
Restricted cash	761	811
Cash, cash equivalents and restricted cash in the consolidated statements of cash flows	$ 12,595	$ 25,172

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments which potentially subject the Company to concentration of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company's policy is to invest cash in institutional money market funds and marketable securities of the U.S. government to limit the amount of credit exposure. The Company currently maintains a portfolio of cash equivalents and short-term investments in money market funds and U.S. treasury bills. Additionally, the Company has established guidelines regarding diversification of its investments and their maturities, which are designed to maintain principal and maximize liquidity. The Company has not experienced material losses on cash equivalents and short-term investments.

The Company's products require approval from the FDA and foreign regulatory agencies before commercial sales can commence. There can be no assurance that the Company's products will receive any of these required approvals. The denial or delay of such approvals may have a material adverse impact on the Company's business and may impact business in the future. In addition, after approval by the FDA, there is still an ongoing risk of adverse events that did not appear during the device approval process.

The Company is subject to risks common to companies in the medical device industry, including, but not limited to, new technological innovations, clinical development risk, establishment of appropriate commercial partnerships, protection of proprietary technology, compliance with government and environmental regulations, uncertainty of market acceptance of the Company's products, product liability and the need to obtain additional financing.

Accounts Receivable

Accounts receivable pertain to contracts with customers who are granted credit by the Company in the ordinary course of business and are presented net of allowances for credit losses. Accounts receivable are typically due between 30 and 90 days after invoicing. The Company maintains an allowance for credit losses resulting from the inability of its customers, including ambulatory surgery centers, to make required payments. The allowance for credit losses is calculated quarterly and is developed using an aging of receivables where receivables are segregated into various categories based upon due date, and a historical loss percentage is applied to each category that is adjusted for current receivable composition, counterparty and specific risk and prevailing economic condition and supportable forecasted economic conditions. Once a receivable is deemed uncollectible after collection efforts have been exhausted, it is written off against the allowance for credit losses. The Company closely monitors the credit quality of its customers and has yet to experience a write-off of a receivable or uncollected receivable. The Company does not generally require collateral or other security on receivables.

The Company has a diverse customer base and as of December 31, 2022, and 2021 the Company did not have any customer who individually accounted for greater than 10% of accounts receivable. After evaluation of the collectability of accounts receivable, the Company did not record any significant allowance for credit losses as of December 31, 2022 or December 31, 2021.

Fair Value of Financial Instruments

Fair value is measured as the price that would be received from the sale of an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques that are consistent with the market, income or cost

approach are used to measure fair value. The fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value into three levels:

Level 1—Observable inputs such as unadjusted quoted prices in active markets that are accessible at the measurement date for identical unrestricted assets or liabilities.

Level 2—Inputs (other than quoted prices included in Level 1) that are either directly or indirectly observable for the asset or liability, for substantially the full term of the asset or liability, through correlation with market data. These include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and inputs to valuation models or other pricing methodologies that do not require significant judgment because the inputs used in the model, such as interest rates and volatility, can be corroborated by readily observable market data.

Level 3—One or more significant inputs that are unobservable and supported by little or no market activity and reflect the use of significant management judgment and assumptions. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques and significant management judgment or estimation. These include the Black-Scholes option-pricing model which uses inputs such as expected volatility, risk-free interest rate and expected term to determine fair market valuation.

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification at each reporting date. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy. The Company did not have any transfers of assets and liabilities between the levels of the fair value measurement hierarchy during the years presented.

Cash, cash equivalents, accounts receivable and accounts payable are carried at their estimated fair value because of the short-term nature of these assets and liabilities. The Company’s short-term investments in government securities are carried at fair value, determined based on publicly available quoted market prices for identical securities at the measurement date. The Company believes the fair values of its operating lease liabilities and term loan at December 31, 2022 and 2021 approximated their carrying values, based on the borrowing rates that were available for loans with similar terms as of that date.

Inventories

Inventories consist of raw materials, work-in-process and finished goods. Raw materials are comprised of chemicals and parts used in the production of the Company's lenses, cartridges, and LDDs. Finished goods are comprised of lenses, cartridges, accessories and LDDs. Inventories are valued at the lower of cost or net realizable value. Cost is computed using standard cost, which approximates actual cost on a first-in, first-out basis. The carrying value of inventories is reviewed for potential impairment whenever indicators suggest that the cost of inventories exceeds the carrying value and management adjusts the inventories to its net realizable value. The cost of finished goods and work-in-process is comprised of raw materials, direct labor, other direct costs and related production overhead to the extent that these costs do not exceed the net realizable value of the goods produced. The Company periodically reviews inventories for potential impairment, estimated losses from obsolescence, material expirations or unmarketable inventories or excess inventories and writes down the cost of inventories to net realizable value at the time such determinations are made. Net realizable value is determined using the estimated selling price, in the ordinary course of business, less estimated costs to complete and dispose.

Long-Lived Assets

Property and equipment and leasehold improvements are recorded at cost, net of accumulated depreciation and amortization. Property and equipment are depreciated over the estimated useful lives of the related assets, generally three to five years, using a straight-line method. Leasehold improvements are amortized on the straight-line method over the shorter of the lease term or their estimated economic lives. Repairs and maintenance costs are charged directly to operations as incurred, while renewals and betterments are capitalized.

All long-lived assets are reviewed for impairment whenever circumstances such as events or changes in the business indicate that an asset or asset group’s carrying value may not be recoverable based on undiscounted future

operating cash flows to be derived from their use. Factors that are considered important that could trigger an impairment review include a current period operating or cash flow loss or a history of operating or cash flow losses and a projection or forecast that demonstrates continuing losses or insufficient income associated with the use of a long-lived asset or asset group. Other factors include a significant change in the manner of the use of the asset or a significant negative industry or economic trend. This evaluation is performed based on estimated undiscounted future cash flows from operating activities compared with the carrying value of the related assets. If the undiscounted future cash flows are less than the carrying value, an impairment loss is recognized, measured by the difference between the carrying value and the estimated fair value of the assets. Fair value is determined primarily using the discounted cash flows expected to be generated from the use of assets. Significant management judgment is required in the forecast of future operating results that are used in the preparation of expected cash flows.

Leases

Lease right-of-use assets represent the Company's right to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized when the Company takes possession of the leased property ("Commencement Date") based on the present value of lease payments over the lease term. The Company estimates the incremental borrowing rate based upon the cost of its own debt financing, current market interest rates and quoted offerings or the rate implicit in the lease. Operating lease right-of-use assets also include any lease payments made at or before lease commencement and exclude any lease incentives received. The lease terms used to calculate the right-of-use asset and related lease liability include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Rent expense on noncancelable leases containing known future scheduled rent increases is recorded on a straight-line basis over the term of the respective leases beginning on the Commencement Date. The difference between rent expense and rent paid is accounted for as a component of operating lease right-of-use assets on the accompanying consolidated balance sheets. Landlord improvement allowances and other such lease incentives are recorded as property and equipment and as reduction of the right-of-use leased assets and are amortized on a straight-line basis as a reduction to operating lease costs. Leases with an initial term of 12 months or less are expensed as incurred and are not recorded as right-of-use assets on the consolidated balance sheets.

Net Loss per Share

Basic net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average shares of common stock outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average shares of common stock and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. Diluted net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock and potential dilutive securities outstanding during the period.

The following outstanding potentially dilutive securities were excluded from the calculation of diluted net loss per share attributable to common stockholders because their impact under the treasury stock method was anti-dilutive for the periods presented:

	Year Ended December 31,	
	2022	**2021**
Stock options issued and outstanding under the Calhoun Vision, Inc. 2006 Stock Plan, Calhoun Vision, Inc. 2015 Equity Incentive Plan and the 2021 Equity Incentive Plan	1,926,226	2,144,860
Restricted stock units	543,538	223,716
Stock issuable in offering period under the 2021 Employee Stock Purchase Plan	48,594	8,248

Revenue Recognition

The Company's revenue is generated from the sale of LALs used in cataract surgery along with a specifically designed machine for delivering light to the eye, the LDD, to adjust the lens post-surgery, as needed. Revenue is recognized from sales of products in the U.S. and Europe. Customers are primarily comprised of ambulatory surgery centers, hospitals, and physician private practices.

The Company recognizes revenues when promised goods or services are transferred to customers at a transaction price that reflects the consideration to which the Company expects to be entitled in exchange for those goods and services. Specifically, the Company applies the following five steps to recognize revenue: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when, or as, the Company satisfies a performance obligation. The Company applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. At contract inception, the Company assesses the goods promised within each customer contract to determine the individual deliverables in its product offerings as separate performance obligations and assesses whether each promised good or service is distinct. The transaction price is determined based on the consideration expected to be received, based either on the stated value in contractual arrangements or the estimated cash to be collected in non-contracted arrangements. The Company recognizes revenue as the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied, considering whether or not this occurs at a point in time or over time. The Company elected to account for shipping costs as fulfillment costs rather than a promised service and excludes from revenue any taxes collected from customers that are remitted to government authorities.

The Company's LDD contracts contain multiple performance obligations bundled for one transaction price, with all obligations generally satisfied within one year. For these bundled arrangements, the Company accounts for individual products and services as separate performance obligations if they are distinct, that is, if a product or service is separately identifiable from other items in the bundled package, and if a customer can benefit from it on its own or with other resources that are readily available to the customer. The Company's LDD contracts include a combination of the following performance obligations: (i) LDD capital asset and related components, (ii) training and (iii) device service (initial year). Each of these three performance obligations are considered distinct. The LDD capital asset is distinct because the customer can benefit from it together with other resources that are readily available to the customer. Training on the use of the machine is offered as a distinct activity after installation of the LDD to enhance the customer's ability to utilize the machine by having an industry professional provide best practices and customize training to the specific needs of the customer. Each LDD comes with a twelve-month manufacturer's warranty (service-type) that includes preventative maintenance, unscheduled service (labor and parts) and software updates. After the first year, service contracts can be purchased separately on a standalone basis. The Company recognizes revenue as performance obligations are satisfied by transferring control of the product or service to a customer. Specifically, revenue for the LDD capital asset is recognized at a point in time at installation. Revenue for training is also recorded at a point in time, generally 60 days after installation. Revenue for the device service is recognized ratably over time after installation, generally 12 months. The Company has determined that the transaction price is the invoice price, net of adjustments, if any. The allocation to the separate performance obligations is based upon the relative standalone selling price. Standalone selling prices are based on observable prices at which the Company separately sells the products or services. The Company estimates the standalone selling price using the market assessment approach considering market conditions and entity-specific factors including, but not limited to, features and functionality of the products and services, geographies, type of customer and market conditions. The Company regularly reviews and updates standalone selling prices as necessary.

LALs are generally held at customer sites on consignment. The single performance obligation is satisfied, and revenue is recognized for LALs upon customer notification that the LALs have been implanted in a patient. For the years ended December 31, 2022 and 2021, credits related to returns and rebates on list prices were not significant.

The Company has adopted the practical expedient permitting the direct expensing of costs incurred to obtain contracts where the amortization of such costs would occur over one year or less, and it applied to substantially all the Company's contracts. Revenue for service agreements is recognized ratably over the term of each contract.

For the years ended December 31, 2022 and 2021, contract liabilities from sales activity recorded as liabilities on the Company's consolidated balance sheets consisted of the following (in thousands):

	Year Ended December 31,	
	2022	2021
Balance at beginning of period	$ 540	$ 345
Additions during the period	2,052	793
Revenue recognized during the period	(1,405)	(598)
Balance at end of period	$ 1,187	$ 540

For the year ended December 31, 2022 and 2021, the Company did not have any customers who individually accounted for greater than 10% of revenue.

Cost of Sales

Cost of sales consists of materials, labor and manufacturing overhead incurred to produce the Company's products as well as the cost of shipping and handling. Overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management, including stock-based compensation. Cost of sales also includes depreciation expense for production equipment and certain direct costs such as royalty and license fee expenses.

Research and Development Expenses

Research and development expenses are expensed as incurred. Research and development expenses consist of upfront fees and milestones paid to collaborators and expenses incurred in performing research and development activities for new products and technology. The expenses include personnel-related costs, including compensation and benefits and stock-based compensation, consultants hired to perform research projects, costs incurred at clinical trial sites, regulatory and manufacturing engineering costs related to FDA premarket approval submission preparation, various laboratory and research supplies, write-off of pre-approved inventory utilized for clinical trial and research purposes, costs incurred in the development of manufacturing processes in excess of capitalizable value, fees paid to contract research organizations and direct FDA related costs. The Company also accrued the costs of ongoing clinical trials associated with programs that have been terminated or discontinued for which there is no future economic benefit at the time the decision is made to terminate or discontinue the program.

Stock-Based Compensation

The Company recognizes compensation expense for equity-based awards on the date of grant to employees, board of directors and consultants based on the estimated grant date fair value of the award Equity-based payments include stock options, restricted stock units and employee stock plan purchases. The fair value of the option awards are estimated using the Black-Scholes option-pricing model and recognized in expense in the consolidated statements of operations and comprehensive loss over the requisite service period, which is generally four years. The Company amortizes the stock-based compensation for equity awards with service conditions on a straight-line basis over the vesting period of the awards. Compensation cost for stock options with performance conditions is recognized based upon the probability of that performance condition being met. Forfeitures of unvested stock option awards are recognized as reductions of expense as they occur.

The Black-Scholes option-pricing model requires the use of assumptions about a number of variables, such as the fair market value of the Company's common stock, the risk-free interest rate, dividend yield, expected term and expected volatility:

- Prior to the Company's shares being traded on the Nasdaq Global Market, the fair value of the Company's common stock was determined by the Company's Board at the time of each option grant by considering a number of objective and subjective factors. These factors included the valuation of a select group of public peer group companies within the medical device industry that focus on technological advances and development that the Board believed were comparable to the Company's operations. Operating and financial performance, the lack of liquidity of the common stock and

trends in the broader economy and medical device industry also impacted the determination of the fair value of the common stock. In addition, the Company regularly engaged a third-party valuation specialist to assist with estimates related to the valuation of the Company's common stock. For all grants subsequent to the Company's shares being traded on the Nasdaq Global Market in July 2021, the fair value of common stock was determined by using the closing price per share of common stock as reported on the Nasdaq Global Market;

- The risk-free interest rate used is based on the published U.S. Department of Treasury interest rates in effect at the time of stock option grant for zero coupon U.S. Treasury notes with maturities approximating each grant's expected term;
- The dividend yield is zero as the Company has not paid dividends and does not anticipate paying a cash dividend in the foreseeable future;
- Due to the lack of historical exercise history, the expected term for options granted is calculated using the "simplified method" and represents the average time that options are expected to be outstanding based on the mid-point between the vesting date and the end of the contractual term of the award;
- Expected volatility is derived from the historical volatilities of a select group of comparable peer companies, for a look-back period commensurate with the expected term of the stock options, as the Company has limited trading history of common stock.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The likelihood of realizing the tax benefits related to a potential deferred tax asset is evaluated, and a valuation allowance is recognized to reduce that deferred tax asset if it is more likely than not that all or some portion of the deferred tax asset will not be realized. Deferred tax assets and liabilities are calculated at the beginning and end of the year; the change in the sum of the deferred tax asset, valuation allowance and deferred tax liability during the year generally is recognized as a deferred tax expense or benefit. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the Consolidated Statements of Operations and Comprehensive Loss in the period that includes the enactment date.

Significant judgment is required in determining the Company's provision for income taxes, deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets. The Company assesses the likelihood that deferred tax assets will be recovered as deductions from future taxable income. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history and reliability of forecasting. The Company recognized a valuation allowance on deferred tax assets as of December 31, 2022 and 2021 after evaluating that it is more likely than not that deferred tax assets will not be realized as of those dates.

The Company evaluates the accounting for uncertainty in income tax recognized in the consolidated financial statements and determines whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit is recorded in its consolidated financial statements. For those tax positions where it is "not more likely than not" that a tax benefit will be sustained, no tax benefit is recognized. Where applicable, associated interest and penalties are also recorded. The Company has not accrued any liabilities for any such uncertain tax positions as of December 31, 2022 or 2021. The Company is subject to U.S. federal and state tax authority examinations for all the years since inception due to net operating loss and tax credit carryforwards. The net operating losses and tax credits are subject to adjustment until the statute closes on the year the attributes are ultimately utilized.

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations. The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcomes of examinations by tax authorities in determining the adequacy of its provision for income taxes. The Company continually assesses the likelihood and amount of potential revisions and adjusts the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known.

The Company is required to file federal and state income tax returns in the United States, United Kingdom, Germany and Netherlands. The preparation of these income tax returns requires the Company to interpret the applicable tax laws and regulations in effect on such jurisdictions, which could impact the amount of tax paid. An amount is accrued for the estimate of additional tax liabilities, including interest and penalties, for any uncertain tax positions taken or expected to be taken in an income tax return. The accrual for uncertain tax positions is updated when more definitive information becomes available.

Comprehensive Loss

All components of comprehensive loss, including net loss, are reported in the consolidated financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on marketable securities and foreign currency translation adjustments.

Operating Segments

Operating segments are defined as components for which discrete financial information is available for evaluation by the chief operating decision maker to make resource allocation decisions and conduct performance assessments. The Company determined that it operates and manages its business (including its non-U.S. subsidiaries) in one reportable segment: the research and development, manufacture and sale of light adjustable lenses and related capital equipment.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has irrevocably elected to not take this exemption and, as a result, will adopt new or revised accounting standards on the relevant effective dates on which adoption of such standards is required for other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

Changes to GAAP are established by the Financial Accounting Standards Board ("FASB") in the form of accounting standards updates ("ASU"). ASUs not listed below were assessed and determined not to be applicable or are expected to have minimal impact on the Company's consolidated financial statements.

In June 2020, the FASB issued ASU No. 2020-06, *"Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity,*" ("ASU No. 2020-06") which is intended to simplify the accounting for convertible instruments. This new guidance eliminates certain models that require separate accounting for embedded conversion features and eliminates certain of the conditions for equity classification for contracts in an entity's own equity. Accordingly, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The new guidance can be adopted through either a modified retrospective method of transition or a fully retrospective method of transition. ASU 2020-06 is effective for public business entities for

fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. The Company adopted ASU 2020-06 effective January 1, 2022 using the modified retrospective method and the adoption did not have a material impact on the Company's consolidated financial statements.

Note 3 – Short-Term Investments

Short-term investments, principally U.S. Treasury bills, are available-for-sale and consisted of the following (in thousands):

	As of December 31, 2022		
	Amortized Cost	Unrealized Loss, Net	Estimated Fair Value
U.S. Treasury securities	$ 94,043	$ (75)	$ 93,968

	As of December 31, 2021		
	Amortized Cost	Unrealized Loss, Net	Estimated Fair Value
U.S. Treasury securities	$ 134,980	$ (9)	$ 134,971

All available-for-sale securities held as of December 31, 2022 and 2021 had a maturity of less than one year. The Company has classified all marketable securities, regardless of maturity, as short-term investments based upon the Company's ability and intent to use any and all of those marketable securities to satisfy the Company's liquidity requirements.

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis, the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, and any significant deterioration in economic conditions.

The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest expense in the consolidated statements of operations through an allowance for credit losses. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive loss. Unrealized losses on available-for-sale debt securities as of December 31, 2022 and December 31, 2021 were not significant and were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. Further, the Company does not intend to sell these investments and it is not more likely than not that the Company will be required to sell these investments before recovery of their amortized cost basis. Accordingly, the Company did not record an allowance for credit losses with these investments as of December 31, 2022 and December 31, 2021.

Note 4 – Inventories

Inventories consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Finished goods	$ 6,408	$ 4,451
Raw materials	6,494	2,828
Work-in-process	2,567	868
	15,469	8,147
Less: reserve for excess and obsolete inventory	(634)	(115)
	$ 14,835	$ 8,032

At December 31, 2022 and 2021, finished goods included $2.8 million and $1.8 million of inventory held on consignment at customer sites, respectively.

Note 5 – Property and Equipment

Property and equipment consisted of the following (in thousands):

	December 31, 2022	2021
Machinery and equipment	$ 12,799	$ 12,421
Leasehold improvements	11,206	10,334
Construction in progress	1,331	1,118
Computer hardware and software	1,693	1,536
Production molds	1,873	1,268
Furniture and fixtures	928	853
Right-of-use equipment	206	32
	30,036	27,562
Less: Accumulated depreciation and amortization	(19,898)	(16,345)
	$ 10,138	$ 11,217

The Company recorded $3.9 million and $4.0 million in depreciation and amortization expense for the years ended December 31, 2022 and 2021, respectively.

Note 6 – Fair Value Measurements

The table and disclosures below (in thousands) present information about the Company's assets and liabilities measured at fair value on a recurring basis and indicate the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value.

Money market funds are liquid investments and are actively traded. The pricing information on these investment instruments is readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy. U.S. Government securities are measured at fair value using Level 2 inputs. The Company reviews trading activity and pricing for these investments as of each measurement date. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

	As of December 31, 2022		
	Level I	Level II	Total
Assets:			
Money market securities	$ 8,909	$ —	$ 8,909
U.S. Treasury securities	—	93,968	93,968
Total assets at fair value	$ 8,909	$ 93,968	$ 102,877

	As of December 31, 2021		
	Level I	Level II	Total
Assets:			
Money market securities	$ 21,390	$ —	$ 21,390
U.S. Treasury securities	—	134,971	134,971
Total assets at fair value	$ 21,390	$ 134,971	$ 156,361

During the year ended December 31, 2021, the Series W warrant expired unexercised on March 31, 2021 and the remaining fair value of $5.0 million was recorded at that time in the Consolidated Statement of Operations and Comprehensive Loss.

Upon completion of the Company's IPO in July 2021 all of the 14,376,272 issued and outstanding shares of Convertible Preferred Stock outstanding were converted to common stock and 225,945 warrants to purchase Series H convertible preferred stock were exercised and converted into 100,261 shares of common stock.

The fair value of the preferred stock warrants was determined by management, with input and assistance from a third-party valuation specialist using a probability weighted expected return model/option pricing model ("PWERM/OPM") hybrid valuation model.

The Company did not have any assets or liabilities measured at fair value on a recurring basis within Level 3 fair value measurements as of December 31, 2022 and 2021.

The following table sets forth changes in the estimated fair values for the Company's warrant liabilities measured using significant unobservable inputs (in thousands):

	Year Ended December 31, 2021
Beginning of period	$ 8,846
Exercise of preferred stock warrants	(1,111)
Expiration of common stock warrant	(5,018)
Change in fair value of preferred stock warrants	(2,717)
End of period	$ —

Note 7 – Accrued Expenses and Other Current Liabilities

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

	December 31, 2022	December 31, 2021
Employee compensation and benefits	$ 8,537	$ 5,916
Contract liabilities	1,348	618
Accrued interest	455	319
Other	2,332	1,006
	$ 12,672	$ 7,859

Note 8 – Term Loan

In October 2020, the Company entered into a loan facility ("Term Loan") with an initial draw of $25.0 million. Proceeds were used to help fund the Company's ongoing operations. As part of the Term Loan, Oxford Finance LLC, ("Oxford Finance") committed to providing further loans of up to $35.0 million to the Company at its election (or for one specific draw, upon the occurrence of a revenue milestone) during various draw periods in the future, provided the Company is not in default at the time of the additional loan draws. In March 2021, the Company drew an additional $5.0 million from the facility for the purpose of funding ongoing operations. In June 2021, the Company drew an additional $10.0 million from the facility for the purpose of funding ongoing operations.

On May 3, 2022, the Company entered into a Second Amendment to the Term Loan (as amended through the Second Amendment, the (the "Amended Term Loan")). The Amended Term Loan increased the loan and security agreement to $60.0 million, of which $40.0 million was fully funded as of May 3, 2022 from the original term loan. Under the Amended Term Loan, the Company may borrow an additional amount of up to $10.0 million through June 30, 2023, upon satisfaction of the applicable drawdown conditions and achievement of sufficient trailing twelve-month sales as provided in the agreement for the measurement period ending March 31, 2023. Subject to the terms and conditions of the Amended Term Loan, the Company may also borrow an additional amount of up to $10.0 million through September 30, 2023, upon satisfaction of the applicable drawdown conditions and achievement of sufficient trailing twelve-month sales as provided in the agreement for the measurement period ending June 30, 2023. The Amended Term Loan bears interest at a rate per annum equal to the greater of (i) 9.25% or (ii) 1-Month Term Secured Overnight Financing Rate ("SOFR") (or, if greater, 0.16%) plus an applicable margin

of 9.09%. If there is an event of default under the Amended Term Loan additional interest of 5% applies. The Amended Term Loan extends the maturity date of the loan and security agreement, which was due to expire on October 1, 2025, to February 1, 2027. The Company refers to its $60.0 million Amended Term Loan as its credit facility. The Amended Term Loan was recorded as a debt modification.

The Amended Term Loan is secured by substantially all of the Company's personal property other than its intellectual property, but includes any accounts receivable, other amounts owed and any proceeds of intellectual property. The Company also entered into a negative pledge arrangement with the collateral agent and lenders where the Company agreed not to encumber any of its intellectual property. The Amended Term Loan also includes certain customary representations and warranties, affirmative and negative covenants, and events of default, including a financial performance-to-plan covenant that requires the Company to achieve certain minimum net sales, measured on a trailing twelve-month basis. As of December 31, 2022 and 2021, the Company was in compliance with all covenants.

The Amended Term Loan requires 35 months of interest-only payments, followed by 22-months of principal and accrued interest payments. If the Company is in compliance with its performance-to-plan covenant through April 1, 2025 and has not provided an IP lien election notice before May 1, 2025, the interest-only period is extended by 12 months, and the amortization period is reduced to ten months. Payments are due on the first day of each month in arrears. All unpaid amounts under the Amended Term Loan mature on February 1, 2027. The Company may elect to prepay the loans under the credit facility at any time in full or in part; however, the Company may only elect to prepay the loans in part once, in an amount not less than $5.0 million. Any amounts prepaid may not be subsequently reborrowed. Under the Amended Term Loan, a final payment ("Final Payment") will be due at the earlier of the maturity date, acceleration of the loans, or a voluntary or mandatory prepayment of the loans, in an amount equal to (a) if the Final Payment is paid on or after January 1, 2022 through and including October 31, 2022, three percent (3.00%) of the original principal amount of the loans (or, in the case of a partial prepayment, the amount of principal to be prepaid), (b) if the Final Payment is paid on or after November 1, 2022 through and including October 31, 2023, four percent (4.00%) of the original principal amount of the loans (or, in the case of a partial prepayment, the amount of principal to be prepaid) and (c) if the Final Payment is paid on or after November 1, 2023, five percent (5.00%) of the original principal amount of the loans (or, in the case of a partial prepayment, the amount of principal to be prepaid). The Final Payment is being accreted to the carrying value of the debt as a debt premium and interest expense over the life of the loan using the effective interest method.

The Company paid $0.1 million in loan amendment fees and other closing costs that are directly attributable to execution of the Amended Term Loan transaction. These issuance costs are recorded as a discount to the carrying amount of the debt and are being amortized, along with the unaccreted portion of the Final Payment and unamortized debt issuance costs from the original Term Loan, to interest expense over the expected term of the debt using the effective interest method. The loans may be accelerated by Oxford Finance in the event of default.

As of December 31, 2022, future annual principal payments due under the Amended Term Loan were as follows (in thousands):

Year Ended December 31,	
2023	$ —
2024	—
2025	16,364
2026	21,818
2027	1,818
Total	40,000
Plus: exit fee and unamortized issuance costs	169
Term loan, net	$ 40,169

For the year ended December 31, 2022 and 2021 the cash interest paid and effective interest rate on the Amended Term Loan and Term Loan were as follows:

	For the Year Ended December 31,	
	2022	2021
Cash interest paid	10.66%	9.25%
Effective interest rate	12.19%	10.90%

Note 9 – Stock-Based Compensation Expense

The Company has three equity incentive compensation plans, the Calhoun Vision, Inc. 2006 Stock Plan, the Calhoun Vision, Inc. 2015 Equity Incentive Plan, and the 2021 Equity Incentive Plan (collectively the "Plans").

2006 Stock Plan

The Company's 2006 Stock Plan (the "2006 Plan") was originally adopted by the Company's Board and approved by the Company's stockholders in 2006. The Company's 2006 Plan was terminated in 2015 in connection with the adoption of the Company's 2015 Plan and as a result no new awards may be issued under the 2006 Plan. However, the 2006 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2006 Plan.

2015 Equity Incentive Plan

The Company's 2015 Equity Incentive Plan (the "2015 Plan") was originally adopted by the Board and approved by the Company's stockholders in 2015. The 2015 Plan was most recently amended in March 2021. In July 2021, upon completion of the IPO, the 2015 Plan terminated immediately prior to effectiveness of the 2021 Equity Incentive Plan with respect to the grant of future awards. However, the 2015 Plan will continue to govern the terms and conditions of the outstanding awards previously granted under the 2015 Plan.

2021 Equity Incentive Plan

On July 28, 2021, the Company's 2021 Equity Incentive Plan (the "2021 Plan"), was adopted and approved by the Company's Board and stockholders prior to the IPO and became effective. The 2021 Plan provides for the grant of incentive stock options to employees and any subsidiary corporations' employees, and for the grant of nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units, or ("RSUs"), and performance awards to employees, directors, and consultants and subsidiary corporations' employees and consultants. The number of shares of the Company's common stock originally available for issuance under the 2021 Plan was equal to 2,420,135 shares of common stock plus any shares subject to awards granted under the 2015 Plan and the 2006 Plan that, after the effectiveness of the 2021 Plan, expire or otherwise terminate without having been exercised in full, are tendered to or withheld by the Company for payment of an exercise price or for tax withholding obligations, or are forfeited to or repurchased by the Company due to failure to vest, with the maximum number of shares to be added to the 2021 Plan from the 2015 Plan and 2006 Plan equal to 4,569,530 shares of common stock.

Evergreen provision

The number of common shares reserved for issuance under the 2021 Plan will be increased automatically on the first day of each fiscal year beginning with the 2022 fiscal year and ending on the ten year anniversary of the date the Board approved the 2021 Plan, by a number equal to the least of: (i) 7,260,406 shares of our common stock; (ii) 4% of the outstanding shares of our common stock on the last day of our immediately preceding fiscal year; or (iii) such lesser number of shares of our common stock as the administrator may determine. The 2021 Plan is administered by the Company's Board. On January 1, 2022, under the evergreen provision, an increase of 1,094,670 shares of common stock were reserved for future issuance under the 2021 Plan.

2021 Employee Stock Purchase Plan

On July 28, 2021, the Company's Board and stockholders adopted and approved the Company's 2021 Employee Stock Purchase Plan ("2021 ESPP"). The number of shares of the Company's common stock originally available for issuance under the 2021 ESPP was equal to 664,976 shares of common stock.

The 2021 ESPP provides eligible employees of the Company and its subsidiaries with the opportunity to purchase shares of the Company's Common Stock at a purchase price equal to 85% of the common stock's fair market value on the first trading day or last trading day of each purchase period, whichever is lower. The 2021 ESPP

generally provides for two six-month purchase periods every twelve months: May 1 through October 31 and November 1 through April 30. The initial purchase period began on November 1, 2021.

Evergreen provision

The number of common shares reserved for issuance under the 2021 ESPP plan will be increased automatically on the first day of each fiscal year beginning with our 2022 fiscal year, by a number equal to the least of: (i) 1,452,081 shares; (ii) 1% of the outstanding shares of our common stock on the last day of our immediately preceding fiscal year; or (iii) such other amount as the administrator may determine. The 2021 ESPP is administered by the Board of Directors. On January 1, 2022, under the evergreen provision, an increase of 273,667 shares of common stock were reserved for future issuance under the 2021 ESPP.

Stock-Based Compensation Expense

The purpose of the 2021 Plan and 2021 ESPP is to provide a means by which eligible recipients of stock awards may be given an opportunity to benefit from increases in the value of the common stock in order to retain or procure the services of the employees, members of the Board and consultants and provide them with an incentive to promote the Company's success and accomplish corporate goals.

Stock option awards are generally granted with an exercise price of no less than 100% of estimated fair market value on the date of grant. Time based awards generally vest over four years as follows: one fourth of the total number of shares vest and become exercisable on the one-year anniversary; 1/48th of the total number of shares subject to the option vest and become exercisable on each monthly anniversary thereafter for the remaining three years.

A summary of the stock option activities related to the Plans, as of and for the year ended December 31, 2022 and 2021 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Avg Remaining Contractual Life (Years)
Options outstanding as of December 31, 2021	5,754,005	$ 11.64		$ 6.88
Granted	1,149,018	12.76	$ 7.27	
Exercised	(202,806)	4.14	2.13	
Forfeited	(196,969)	13.70	11.93	
Expired	(163,690)	17.04		
Options outstanding as of December 31, 2022	6,339,558	11.88		6.48
Exercisable as of December 31, 2022	3,891,871	$ 10.56		$ 5.06

A summary of restricted stock unit activities for the year ended December 31, 2022 and 2021 is presented below:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2021	640,479	$ 15.46
Granted	80,427	13.37
Vested	(179,700)	15.57
Forfeited	(48,344)	15.38
Unvested at December 31, 2022	492,862	$ 15.08

As of December 31, 2022 and 2021, the intrinsic value of options vested was $15.9 million and $14.7 million, respectively, and of all options outstanding was $16.4 million and $14.7 million, respectively. During the year ended December 31, 2022 and 2021, the total cash received from the exercise of stock options was $0.8 million and $1.6

million, respectively. The total fair value less strike price of these options was $1.8 million and $4.0 million, respectively.

Stock-based compensation expense was classified in the accompanying consolidated statements of operations and comprehensive income (loss) as follows (in thousands):

	Twelve Months Ended December 31,	
	2022	2021
Research and development	$ 3,064	$ 2,620
Selling, general and administrative	7,399	4,061
Cost of goods sold	934	894
	$ 11,397	$ 7,575

As of December 31, 2022 and 2021, there were 2,447,687 and 2,437,649 unvested options, respectively. Total unrecognized expense related to unvested stock options was approximately $19.1 million and $20.1 million as of December 31, 2022 and 2021, respectively. Amounts are expected to be recognized over a weighted average period of approximately 2.6 years and 3.0 years, respectively.

As of December 31, 2022 and 2021, total unrecognized expense related to unvested restricted stock units was approximately $6.1 million and $8.8 million as of December 31, 2022 and 2021, respectively. Amounts are expected to be recognized over a weighted average period of approximately 2.3 years and 3.5 years, respectively.

The following table presents the range and weighted-average assumptions, used in the Black-Scholes option pricing model to determine the fair value of stock options:

	Twelve Months Ended December 31,			
	2022		2021	
	Range	Weighted Average	Range	Weighted Average
Expected volatility	62.4% to 64.9%	63.1%	61.6% to 63.7%	63.2%
Risk-free interest rate	2.0% to 3.8%	2.7%	0.6% to 1.7%	1.0%
Expected life (in years)	6.0 to 10.0 years	6.1 years	5.5 to 10.0 years	6.1 years
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Grant date fair value	$10.74 to $15.52	$12.73	$12.08 to $19.94	$15.02

Note 10 – Stockholders' Equity

Shelf Registration Statement

On August 8, 2022, the Company filed a $200.0 million shelf registration statement which became effective on August 12, 2022. The shelf registration statement is effective for three years and permits the Company to sell, from time to time, up to $200.0 million in aggregate value of our common stock, preferred stock, debt securities, warrants, and/or units. The shelf registration statement is intended to provide the Company with flexibility to access additional capital when market conditions are appropriate. Included in the $200.0 million shelf registration statement, the Company also filed a prospectus supplement to sell up to an aggregate value of $50.0 million dollars of our common stock through an ATM offering. During the year ended December 31, 2022 the Company sold 475,875 common shares for $6.0 million after deducting underwriting discounts and commissions and other offering expenses.

Common stock reserved for future issuance consisted of the following:

	December 31, 2022	December 31, 2021
Stock options issued and outstanding under the Equity Plans	6,339,558	5,754,005
Restricted stock units	492,862	640,479
Employee stock purchase plan	664,976	484,027
Shares available for future sale under the at-the-market offering [1]	3,454,064	—
Total shares of common stock reserved	10,951,460	6,878,511

[1] Based on the closing stock price of $12.67 as reported on the Nasdaq Global Market on December 30, 2022.

Note 11 – Income Taxes

The components of loss before income taxes are as follows (in thousands):

	December 31, 2022	December 31, 2021
U.S. loss before taxes	$ (66,750)	$ (48,694)
Foreign income before taxes	3	14
Loss before income taxes	$ (66,747)	$ (48,680)

Income tax expense for the years ended December 31, 2022 and 2021 consists of the following (in thousands):

	Year ended December 31, 2022	2021
Current:		
Federal	$ —	$ —
State	8	7
Foreign	1	1
	9	8
Deferred:		
Federal	(11,366)	(9,950)
State	(3,542)	(3,241)
Foreign	—	—
	(14,908)	(13,191)
Change in valuation allowance	14,908	13,191
Income tax expense	$ 9	$ 8

The significant components that comprised the Company's net deferred taxes are as follows (in thousands):

	Year ended December 31,	
Deferred tax assets:	2022	2021
Net operating loss	$ 70,179	$ 62,347
Amortization	99	117
R&D expenditures capitalization	4,879	—
Stock-based compensation	2,960	2,829
Research and development credit	9,202	7,902
Right-of-use liability	1,204	1,290
Depreciation	779	536
Other	2,332	1,745
Gross deferred tax assets	91,634	76,766
Less: valuation allowance	(90,471)	(75,546)
Total net deferred tax assets	$ 1,163	$ 1,220
Deferred tax liabilities:		
Right-of-use asset	(1,163)	(1,220)
Total deferred tax liabilities	(1,163)	(1,220)
Net deferred tax assets	$ —	$ —

A reconciliation of the provision for income taxes with the expected income tax computed by applying the federal statutory income tax rate to loss before provision for income taxes was calculated as follows (amounts in thousands):

	December 31, 2022		December 31, 2021	
	Rate	Amount	Rate	Amount
Income tax provision at the federal statutory tax rate	21.0%	$ (14,017)	21.0%	$ (10,223)
State taxes, net of federal benefit	3.5%	(2,358)	4.1%	(1,989)
Research and development credits	1.9%	(1,269)	2.6%	(1,241)
Stock-based compensation	(2.4)%	1,625	(1.4)%	677
Other non-deductible permanent items	(0.2)%	105	2.6%	(1,252)
Expired tax attributes	(1.5)%	988	(2.0)%	960
Other	0.0%	27	0.2%	(113)
Change in valuation allowance	(22.3)%	14,908	(27.1)%	13,189
Income tax expense	0.0%	9	0.0%	$ 8

The tax effects of items that give rise to significant portions of deferred tax assets are primarily net operating loss carryforwards. The Company evaluates the recoverability of deferred tax assets and assesses all available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. Based on the weight of all the evidence, including a history of operating losses and the Company's ability to generate future taxable income to realize these assets, a full valuation allowance has been recorded to offset the net deferred tax asset as realization of such asset is uncertain. The Company's valuation allowance increased by $14.9 million and $13.2 million in 2022 and 2021, respectively.

As of December 31, 2022, the Company had federal net operating loss carryforwards of $300.4 million and state net operating loss carryforwards of $128.8 million which will not expire and will be able to offset 80% of taxable income in future years. Of the $300.4 million in federal NOLs, $188.9 million will not expire and will be able to offset 80% of taxable income in future years. Of the $128.8 million in state NOLs, $17.6 million will not expire and will be able to offset 80% of taxable income in future years. The remaining federal NOL carryforwards will expire between 2023 and 2037, and the remaining state NOL carryforwards will expire between 2025 and 2042. In addition, the Company also had federal credit carry forwards of $8.2 million and state credit carry forwards of $8.0 million as of December 31, 2022, which may be available to offset future tax liabilities. The federal credits will expire between 2037 and 2042, and the state credits do not expire.

The Inflation Reduction Act 2022 which incorporates a Corporate Alternative Minimum Tax ("CAMT") was signed on August 16, 2022. The changes will affect tax years beginning after December 31, 2022. The new tax will require companies to compute two separate calculations for federal income tax purposes and pay the greater of the new minimum tax or their regular tax liability. The Company will be monitoring the impacts of the act to determine if this will have an impact for the Company for years beginning after December 31, 2022. The CAMT act is not expected to have a material impact on the Company's consolidated financial statements.

The Creating Helpful Incentives to Produce Semiconductors ("CHIPS") Act of 2022 was signed into law on August 9, 2022 to boost domestic semiconductor manufacturing and encourage US research activities. The act provided a 25% investment credit intended to promote domestic production of semiconductors. This act is not expected to have a material impact for the Company. The CHIPS act is not expected to have a material impact on the Company's consolidated financial statements.

Utilization of the net operating loss carryforwards may be subject to substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state provisions. These ownership changes may limit the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change," as defined by Section 382 of the Code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups.

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss and R&D credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an IRC Sections 382 and 383 analysis regarding the limitation of net operating loss and R&D credit carryforwards as of December 31, 2022. The Company has not completed a formal R&D study but has estimated the federal and California credit for purposes of the tax footnote as of December 31, 2022. However, the Company has not reflected a benefit in the consolidated financial statements due to the recorded valuation allowance.

The following reconciliation of the beginning and ending amount of gross unrecognized tax benefits, excluding interest and penalties, is as follows (in thousands):

	Year ended December 31,	
	2022	2021
Beginning balance of unrecognized tax benefits	$ 3,013	$ 2,554
Additions for current year tax positions	481	459
Ending balance	$ 3,494	$ 3,013

None of the unrecognized tax benefits, if recognized, would impact the annual effective rate, due to the valuation allowance. The Company's unrecognized tax benefits are recorded as a reduction in deferred tax assets. The Company does not expect any significant increases or decreases to the Company's unrecognized tax benefits within the next 12 months. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate. The Company has not incurred any material interest or penalties as of the current reporting date with respect to income tax matters.

The Company is subject to U.S. federal and various states' income taxes. The federal returns for tax years 2019 through 2022 remain open to examination and the state returns remain subject to examination for tax years 2018 through 2022. Carryforward attributes that were generated in years where the statute of limitations is closed may still be adjusted upon examination by the Internal Revenue Service or other respective tax authorities. All other state jurisdictions remain open to examination. There are no cumulative earnings in our foreign subsidiaries as of December 31, 2022 and 2021 that would be subject to U.S. income tax or foreign withholding tax. The Company plans to indefinitely reinvest any future earnings of its foreign subsidiaries.

Note 12 – Leases

The Company has operating and finance leases for facilities and certain equipment. Leases with an initial term of 12 months or less are not recorded on the consolidated balance sheets. Lease expense for operating leases is recognized on a straight-line basis over the lease term. The Company does not combine lease and non-lease components in the recognition of lease expense.

The Company's leases have remaining non-cancelable lease terms of up to 3 years, some of which include options to extend the leases for up to 15 years. The exercise of lease renewal options is at the Company's sole discretion. The Company recognizes rent expense for minimum lease payments on a straight-line basis over the expected lease term, including rent holidays, rent escalation clause and/or cancelable option periods where failure to exercise such options would result in an economic penalty.

As of December 31, 2022, the Company held four leases for office, manufacturing and warehouse facilities in Aliso Viejo, California. The four leases are for approximately 121,000 square feet in the aggregate and expire between March 31, 2023 and January 31, 2026. For one of the facilities operating leases, the lessor provided $900,000 in tenant allowances.

On April 4, 2022, the Company entered into a thirty-four-month sublease agreement for a portion of the 5 Columbia Building, in Aliso Viejo, CA. The sublease commencement date was June 13, 2022 and will expire on March 31, 2025. The base rent receivable is $11,410 per month. On January 4, 2023, the Company amended the base rent of sublease agreement to $5,319 per month beginning on March 1, 2023.

The following table presents the lease balances within the consolidated balance sheets (in thousands):

Leases	Classification	December 31, 2022	December 31, 2021
Assets			
Operating	Operating leases right-of-use assets	3,943	$ 4,284
Finance	Property and equipment, net	206	$ 33
Total lease assets		4,149	4,317
Liabilities			
Current			
Operating	Lease liabilities	1,818	1,509
Finance	Lease liabilities	152	20
Noncurrent			
Operating	Long-term lease liabilities	2,813	3,625
Finance	Long-term lease liabilities	43	17
Total lease liabilities		$ 4,826	$ 5,171

As the implicit rates in the Company's leases were not readily available, the incremental borrowing rate was determined based upon information available at the lease commencement date in determining the present value of future lease payments.

For the years ended December 31, 2022 and 2021, the components of operating and finance lease expenses were as follows (in thousands):

Lease Cost	Classification	Year Ended December 31, 2022	2021
Operating lease cost	Cost of sales	$ 14	$ 14
	Research and development	324	297
	Selling, general and administrative	1,688	1,608
Finance lease cost	Research and development	110	—
	Selling, general and administrative	28	25
Finance lease cost	Interest expense	18	5

Maturities of the Company's operating and finance lease liabilities as of December 31, 2022, were as follows (in thousands):

Year Ended December 31,	Operating Leases	Finance Leases
2023	$ 2,128	$ 164
2024	1,876	40
2025	1,024	6
2026	79	-
2027	—	—
Total lease payments	5,107	210
Less: imputed interest	(476)	(15)
Total lease liabilities	$ 4,631	$ 195

The weighted average remaining lease term and weighted average discount rate used to determine lease liabilities related to the Company's operating and finance leases as of December 31, 2022 and 2021 were:

Lease Term and Discount Rate	December 31, 2022	December 31, 2021
Weighted average remaining lease term (years)		
Operating leases	2.42	3.30
Finance leases	1.29	1.72
Weighted average discount rate		
Operating leases	10.3%	10.5%
Finance leases	9.5%	10.5%

Note 13 – Commitments and Contingencies

Letter of credit

The Company has a standby letter of credit, expiring September 30, 2024, issued by a financial institution as required security for one operating lease. The aggregate amount of the letter of credit was $260,000 and $310,000 as of December 31, 2022 and 2021, respectively.

Legal matters

From time-to-time, the Company may be involved in certain legal proceedings or regulatory matters arising in the ordinary course of business, including without limitation, actions with respect to intellectual property, employment, regulatory, product liability and contractual matters. In connection with these proceedings or matters, the Company regularly assesses the probability and amount (or range) of possible issues based on the developments in these proceedings or matters. A liability is recorded in the consolidated financial statements if it is determined that it is probable that a loss has been incurred, and that the amount (or range) of the loss can be reasonably estimated.

Because of the uncertainties related to any pending proceedings or matters, the Company is currently unable to predict their ultimate outcome and, with respect to any legal proceeding or regulatory matter where no liability has been accrued, to make a reasonable estimate of the possible loss (or range of loss) that could result from an adverse outcome. At December 31, 2022 and 2021, there were no legal proceedings, regulatory matters, or other disputes or claims for which a material loss was considered probable or for which the amount (or range) of loss was reasonably estimable. However, regardless of the outcome, legal proceedings, regulatory matters, and other disputes and claims can have an adverse impact on the Company because of legal costs, diversion of management time and resources, and other factors.

Note 14 – Employee benefit plan

401(k) retirement savings plan

The Company maintains a defined contribution 401(k) retirement savings plan for the benefit of its employees, including its named executive officers, who satisfy certain eligibility requirements. Under the 401(k) plan, eligible employees may elect to defer a portion of their compensation, within the limits prescribed by the Code, on a pre-tax or after-tax (Roth) basis, through contributions to the 401(k) plan. The 401(k) plan is intended to qualify under Sections 401(a) and 501(a) of the Code. As a tax-qualified retirement plan, pre-tax contributions to the 401(k) plan and earnings on those pre-tax contributions are not taxable to the employees until distributed from the 401(k) plan, and earnings on Roth contributions are not taxable when distributed from the 401(k) plan. In July 2021, the Company began making matching contributions of up to 2% of eligible compensation, as contributed by eligible participating employees. Employer matching contributions vest 25% per year over four years. The Company contributed $688,000 and $228,000, net of forfeitures, to the 401(k) plan for the year ended December 31, 2022 and 2021, respectively.

Note 15 – Subsequent events

Public Offering

On February 7, 2023, the Company entered into an underwriting agreement with BofA Securities, Inc., in which the Company agreed to issue and sell 4,000,000 shares of the Company's common stock in a Public Offering (“Public Offering”), pursuant to the Company's $200.0 million in aggregate value shelf registration statement, which was declared effective on August 12, 2022. The shares of common stock were sold at a price to the public of $12.50 per share. Under the terms of the underwriting agreement, the Company also granted the underwriters an option exercisable for 30 days from the date of the underwriting agreement to purchase up to an additional 600,000 shares of common stock on the same terms and conditions. The underwriters' option was exercised in full on February 10, 2023 and closed on February 14, 2023. The Company received net proceeds of approximately $53.7 million from the Public Offering, after deducting underwriters' discounts and commissions of $3.5 million and offering expenses of $0.3 million.

ATM Offering

As of the date of this Annual Report on Form 10-K, through the ATM offering, a total of 1,355,216 shares of the Company's common stock, for total net proceeds of $17.1 million, have been issued and sold, of which 879,341 shares of the Company's common stock, for net proceeds of $11.1 million, were sold subsequent to December 31, 2022.

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

As of December 31, 2022, 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). Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2022. 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.

Changes in internal control over financial reporting

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 quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the effectiveness of controls

Control systems, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

Management's annual report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance of achieving their control objectives. With the participation of our Chief Executive and Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") 2013 Framework in Internal Control – Integrated Framework. Based upon such evaluation, our management concluded that we did maintain effective internal control over financial reporting as of December 31, 2022, based on the COSO framework criteria.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to an exemption for non-accelerated filers from the internal control audit requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002.

Item 9B. Other Information.

On March 2, 2023, our Board of Directors (the "Board"), acting upon a recommendation from our Compensation Committee, approved increases in the base salaries for each of our named executive officers for the fiscal year 2023, effective March 1, 2023. The Board approved, effective March 1, 2023, (i) an increase in the base salary of each of Eric Weinberg, Ilya Goldshleger and Shelley Thunen from $425,000 to $460,000 and (ii) an increase in the base salary of our Chief Executive Officer, Ron Kurtz, from $575,000 to $645,000.

On March 2, 2023, our Board, acting upon a recommendation from our Compensation Committee, also approved annual target cash incentive payments ("2022 Cash Bonuses") for each of our named executive officers. The 2022 Cash Bonuses were awarded pursuant to our Executive Incentive Compensation Plan (the "Master Bonus Plan") which allows our Board or a committee appointed by our Board to provide awards to our "officers" as defined in Rule 16a-1(f) of the Exchange Act. Such Master Bonus Plan provides executive officers with the opportunity to earn cash bonuses based upon the achievement of pre-established performance metrics determined by the Board. The Board set the target award for each participating executive as a percentage of annual base salary, in accordance with each such executive's confirmatory offer letter or employment letter, as applicable. Following the end of 2022, the Board reviewed our attainment of the metrics and determined actual payouts, subject to upward or downward adjustment in its discretion. Pursuant to the Master Bonus Plan, the Board approved the following 2022 Cash Bonuses for the named executive officers: (i) Ron Kurtz received a 2022 Cash Bonus of $457,566, based on a bonus target of 85% of annual base salary and 95.7% achievement of target; (ii) Eric Weinberg received a 2022 Cash Bonus of $214,042, based on a bonus target of 55% of annual base salary and 93.4% achievement of target; (iii) Ilya Goldshleger received a 2022 Cash Bonus of $219,313, based on a bonus target of 55% of annual base salary and 95.7% achievement of target; and (iv) Shelley Thunen received a 2022 Cash Bonus of $223,667, based on a bonus target of 55% of annual base salary and 97.6% achievement of target. The Board also approved of Messrs. Weinberg and Goldshleger and Ms. Thunen also receiving an increase in the annual target cash incentive payment from 55% of their base salaries to 65% of their base salaries and an increase in the annual target cash incentive payment for Dr. Kurtz from 85% of his base salary to 90% of his base salary.

Our Master Bonus Plan allows our Board or Compensation Committee to grant incentive awards, generally payable in cash, to employees selected by our Board or Compensation Committee, including our executive officers, based upon performance goals established by our Board or Compensation Committee. Under our Master Bonus Plan, our Board or Compensation Committee determines the performance goals applicable to any award, which goals may include, without limitation, goals related to research and development, regulatory milestones or regulatory-related goals, gross margin, financial milestones, new product or business development, operating margin, product release timelines or other product specific milestones, publications, cash flow, procurement, savings, internal structure, leadership development, project, function or portfolio-specific milestones, license or research collaboration agreements, capital raising, initial public offering preparations, patentability and individual objectives such as peer reviews or other subjective or objective criteria. The performance goals may differ from participant to participant and from award to award. Our Board or Compensation Committee administers our Master Bonus Plan and may, in its sole discretion and at any time, increase, reduce or eliminate a participant's actual award, and/or increase, reduce or eliminate the amount allocated to the bonus pool for a particular performance period. The actual award may be below, at or above a participant's target award, in the discretion of the administrator. The administrator may determine the amount of any increase, reduction or elimination on the basis of such factors as it deems relevant, and it will not be required to establish any allocation or weighting with respect to the factors it considers. Actual awards generally will be paid in cash (or its equivalent) only after they are earned, and, unless otherwise determined by the administrator, to earn an actual award a participant must be employed by us through the date the actual award is paid. Our Board or Compensation Committee may reserve the right to settle an actual award with a grant of an equity award under our then-current equity compensation plan, which equity award may have such terms and conditions, including vesting, as our Board or Compensation Committee determines. Payment of awards will occur as soon as practicable after they are earned, but no later than the dates set forth in our Master Bonus Plan. Our Board and our Compensation Committee have the authority to amend, suspend or terminate our Master Bonus Plan, provided such action does not impair the existing rights of any participant with respect to any earned awards.

This disclosure is provided in this Part II, Item 9B in lieu of disclosure under Item 5.02(e) of Form 8-K.

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

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information called for by this item will be set forth in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022 (the "Proxy Statement") and is incorporated herein by reference.

Code of Business Conduct and Ethics

The information called for by this item will be set forth in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2022 (the "Proxy Statement") and is incorporated herein by reference.

Our Board of Directors has adopted a Code of Business Conduct and Ethics applicable to all employees, officers and directors of the Company. The full text of our Code of Business Conduct and Ethics is posted on our investor relations website at https://investors.rxsight.com/corporate-governance/governance-overview. We will post any amendments to our code of business conduct and ethics or waivers of its requirements, on its website.

Amended and Restated Bylaws

As disclosed under Item 5.03 of our Current Report on Form 8-K filed with the SEC on December 9, 2022, on December 9, 2022, our Board of Directors, upon recommendation of the Corporate Governance and Nominating Committee, amended and restated our amended and restated bylaws, effective immediately. The bylaws were amended and restated, among other things, to:

- revise the procedures and requirements for the nomination of directors and the submission of proposals for consideration at meetings of stockholders, including by adding a requirement that a stockholder seeking to nominate director(s) at a meeting of stockholders deliver to the Company reasonable evidence that it has complied with the requirements of Rule 14a-19 of the Exchange Act no later than five business days before the meeting;
- revise certain additional procedures related to stockholder meetings to conform to the provisions of the Delaware General Corporation Law, as recently amended (the "DGCL");
- revise the provision regarding Board action by unanimous written consent in lieu of a meeting to conform to the provisions of the DGCL;
- update various provisions regarding directors, Board committees and officers; and
- make various updates throughout to conform to current Delaware law (including the recent amendments to the DGCL) and to make ministerial changes, clarifications, and other conforming revisions.

The foregoing description is qualified in its entirety by reference to the Amended and Restated Bylaws, a copy of which was filed as Exhibit 3.1 to our Form 8-K filed on December 9, 2022 and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference from the applicable information set forth in "Board of Directors and Corporate Governance", and "Executive Compensation" which will be included in our Proxy Statement.

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

The information required by this item is incorporated by reference from the applicable information set forth in "Security Ownership of Certain Beneficial Owners and Management" which will be included in our Proxy Statement.

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

The information required by this item is incorporated by reference from the applicable information set forth in "Certain Relationships and Related Party Transactions" and "Board of Directors and Corporate Governance" which will be included in our Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference from the applicable information set forth in "Ratification of Independent Registered Public Accounting Firm" which will be included in our Proxy Statement.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

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

(1) Financial Statements: The financial statements included in Part II, Item 8 of this document are filed as part of this Annual Report on Form 10-K.

(2) Financial Statement Schedules: Schedule II – Valuation and Qualifying Accounts and Reserves.

All other schedules have been omitted because the information either has been shown in the financial statements or notes thereto, or is not applicable or required under this section.

(3) The exhibits listed in the following Exhibit Index are filed or incorporated by reference as part of this Annual Report on Form 10-K.

Exhibit Index

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	10-Q	001-40690	3.1	November 10, 2021
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-40690	3.1	December 12, 2022
4.1	Specimen stock certificate of the Registrant.	S-1/A	333-257790	4.2	July 26, 2021
4.2	Description of common stock.	10-K	001-40690	4.2	March 8, 2022
10.1+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-257790	10.1	July 9, 2021
10.2+	2015 Equity Incentive Plan of the registrant, as amended, and forms of agreement thereunder.	S-1/A	333-257790	10.2	July 26, 2021
10.3+	2021 Equity Incentive Plan of the registrant, as amended, and forms of agreement thereunder.	10-Q	001-40690	10.2	November 10, 2021
10.4+	2021 Employee Stock Purchase Plan of the registrant.	10-Q	001-40690	10.3	November 10, 2021
10.5	Loan and Security Agreement, by and among the Registrant, Oxford Finance LLC and the lenders listed on Schedule 1.1 thereto, dated as of October 29, 2020.	S-1	333-257790	10.5	July 9, 2021
10.6	Consent and First Amendment to Loan and Security Agreement, by and among the Registrant, Oxford Finance LLC and the lenders listed on Schedule 1.1 thereto, dated as of July 6, 2021.	S-1/A	333-257790	10.6	July 26, 2021
10.7#	Second Amendment to Loan and Security Agreement, by and among the Registrant, Oxford Finance LLC, as collateral agent, and	10-Q	001-40690	10.3	May 5, 2022

	the lenders party thereto, dated as of May 3, 2022.				
10.8#	License Agreement by and between the Registrant and the California Institute of Technology, dated as of July 28, 2015.	S-1	333-257790	10.6	July 9, 2021
10.9	License and Maintenance Agreement between QAD, Inc. and its subsidiaries and the Registrant, dated as of October 29, 2015.	S-1	333-257790	10.8	July 9, 2021
10.10	QAD Hosted On Premise Project Proposal between Strategic Information Group and the Registrant, dated as of October 29, 2015.	S-1	333-257790	10.9	July 9, 2021
10.11	Cloud Services Agreement between QAD, Inc. and its subsidiaries and the Registrant, dated as of May 28, 2021.	S-1	333-257790	10.10	July 9, 2021
10.12	Lease, dated as of October 27, 2015, by and between the Registrant and Accuride International Inc., as amended by that certain First Amendment to Lease, dated November 23, 2015, that certain Second Amendment to Lease, dated December 22, 2015, that certain Third Amendment to Lease, dated January 18, 2016, and that certain Fourth Amendment to Lease, dated November 12, 2016, for premises located at 100-150 Columbia, Suites 100 and 200, Aliso Viejo, California 92656.	S-1	333-257790	10.11	July 9, 2021
10.13	Lease, dated as of March 27, 2020, by and between Pacific Park Investments, Inc. and the Registrant, for premises located at 75 Columbia, Aliso Viejo, California 92656.	S-1	333-257790	10.12	July 9, 2021
10.14	Lease, dated as of January 10, 2018, by and between the Registrant and Clifford D. Downs, as amended by that certain Commencement Date Memorandum dated as of February 22, 2018, for premises located at 5 Columbia, Aliso Viejo, California 92656.	S-1	333-257790	10.13	July 9, 2021
10.15	Sublease, dated as of April 4, 2022, by and between the Registrant and Compass Bible Church for premises located at 5 Columbia, Aliso Viejo, California 92656.	10-Q	001-40690	10.1	May 5, 2022
10.16	Lease Addendum, dated as of April 5, 2022, by and between the Registrant and Clifford D. Downs for premises located at 5 Columbia, Aliso Viejo, California 92656.	10-Q	001-40690	10.2	May 5, 2022
10.17	Amendment #1 to Sublease, dated as of June 8, 2022, by and between the Registrant and Compass Bible Church for premises located at 5 Columbia, Aliso Viejo, California 92656.	10-Q	001-40690	10.1	August 8, 2022
10.18*	Amendment #2 to Sublease, dated as of January 16, 2023, by and between the				

	Registrant and Compass Bible Church for premises located at 5 Columbia, Aliso Viejo, California 92656.				
10.19+	Confirmatory Employment Letter, by and between the Registrant and Ron Kurtz, dated as of July 8, 2021.	S-1	333-257790	10.14	July 9, 2021
10.20+	Confirmatory Employment Letter, by and between the Registrant and Shelley Thunen, dated as of July 8, 2021.	S-1	333-257790	10.15	July 9, 20211
10.21+	Confirmatory Employment Letter, by and between the Registrant and Eric Weinberg, dated as of July 8, 2021.	S-1	333-257790	10.16	July 9, 2021
10.22+	Confirmatory Employment Letter, by and between the Registrant and Ilya Goldshleger, dated as of July 8, 2021.	S-1	333-257790	10.17	July 9, 2021
10.23+	Change in Control and Severance Agreement, by and between the Registrant and Ron Kurtz, dated as of July 8, 2021.	S-1	333-257790	10.18	July 9, 2021
10.24+	Change in Control and Severance Agreement, by and between the Registrant and Shelley Thunen, dated as of July 8, 2021.	S-1	333-257790	10.19	July 9, 2021
10.25+	Change in Control and Severance Agreement, by and between the Registrant and Eric Weinberg, dated as of July 8, 2021.	S-1	333-257790	10.20	July 9, 2021
10.26+	Change in Control and Severance Agreement, by and between the Registrant and Ilya Goldshleger, dated as of July 8, 2021.	S-1	333-257790	10.21	July 9, 2021
10.27	Consulting Agreement, by and between the Registrant and Yelroc Consulting, Inc., dated as of January 1, 2019, as amended by that certain Amendment No. 1 to Consulting Agreement, dated as of December 16, 2020.	S-1	333-257790	10.22	July 9, 2021
10.28	Termination Agreement, by and between the Registrant and Yelroc Consulting, Inc., dated as of August 3, 2021.	S-1/A	333-257790	10.24	July 26, 2021
10.29	Consulting Agreement, by and between the Registrant and Daniel Schwartz, M.D., dated as of January 1, 2019, as amended by that certain Amendment No. 1, dated as of December 16, 2020.	S-1	333-257790	10.23	July 9, 2021
10.30	Amended and Restated Secured Full Recourse Promissory Note, by and between the Registrant and Daniel Schwartz, dated as of April 18, 2019.	S-1	333-257790	10.24	July 9, 2021

10.31	Share Forfeiture and Release Agreement, by and between the Registrant and Daniel Schwartz, dated as of July 23, 2021.	S-1/A	333-257790	10.27	July 26, 2021
10.32	Lease, dated as of March 7, 2022, by and between BML Management, LLC, and the Registrant, for premises located at 125 Columbia, Aliso Viejo, California 92656.	10-K	001-40690	10.28	March 8, 2022
10.33	ATM Equity Offering℠ Sales Agreement, dated August 8, 2022, between the Company and BofA Securities, Inc.	S-3	333-266651	1.2	August 8, 2022
10.34	Underwriting Agreement, dated as of February 7, 2023 by and between the Company and BofA Securities, Inc.	8-K	001-40690	1.1	February 7, 2023
10.35*	Executive Incentive Compensation Plan				
21.1	Subsidiaries of the Registrant.	10-K	001-40690	21.1	March 8, 2022
23.1*	Consent of Independent Registered Public Accounting Firm.				
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				

104	Cover page Interactive Data File (embedded with the Inline XBRL document).

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*	Filed herewith.
†	Furnished herewith.
+	Indicates a management contract or compensatory plan or arrangement.
#	Portions of the exhibit were omitted pursuant to Item 601(b)(10) of Regulation S-K. The Company agrees to furnish to the Securities and Exchange Commission a copy of any omitted portions of the exhibit upon request.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

RxSight, Inc.

Date: March 6, 2023

By: /s/ Ron Kurtz, M.D.
Ron Kurtz, M.D.
Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Ron Kurtz, M.D. and Shelley Thunen as such individual's true and lawful attorney in fact and agent with full power of substitution, for such individual in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K (including post-effective amendments), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney in fact, proxy and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney in fact, proxy and agent, or the individual's substitute, may lawfully do or cause to be done by virtue hereof.

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	Title	Date
/s/ Ron Kurtz, M.D. Ron Kurtz, M.D.	President and Chief Executive Officer and Director (Principal Executive Officer)	March 6, 2023
/s/ Shelley Thunen Shelley Thunen	Chief Financial Officer (Principal Financial and Accounting Officer)	March 6, 2023
/s/ J. Andy Corley J. Andy Corley	Chairman of the Board	March 6, 2023
/s/ William Link, Ph.D. William Link, Ph.D.	Director	March 6, 2023
/s/ Juliet Tammenoms Bakker Juliet Tammenoms Bakker	Director	March 6, 2023
/s/ Julie Andrews Julie Andrews	Director	March 6, 2023
/s/ Robert Palmisano Robert Palmisano	Director	March 6, 2023
/s/ Robert Warner Robert Warner	Director	March 6, 2023
/s/ Shweta Singh Maniar Shweta Singh Maniar	Director	March 6, 2023
/s/ Tamara R. Fountain, M.D. Tamara R. Fountain, M.D.	Director	March 6, 2023

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