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, 2023

OR

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

Commission File Number 001-40988

Sonendo, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-5041718**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
26061 Merit Circle, Suite 102 **Laguna Hills, CA**	**92653**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(949) 766-3636**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	SONX	OTC Markets

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. YES ☐ NO ☒

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 ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2023 was approximately $56.5 million, based on the closing price of the shares of common stock on New York Stock Exchange on such date.

The number of shares of Registrant's Common Stock outstanding as of March 1, 2024 was 66,778,504 .

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2024 Annual Meeting of Stockholders are incorporated herein by reference into Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2023.

Table of Contents

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which involve risks and uncertainties, including statements based on our current expectations, assumptions, estimates and projections about future events, our business, financial condition, results of operations and prospects, our industry and the regulatory environment in which we operate. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, or other comparable terms intended to identify statements about the future. The forward-looking statements included herein are subject to risks and uncertainties that could cause actual results to differ materially from those expressed in the forward-looking statements. These risks and uncertainties, all of which are difficult or impossible to predict accurately and many of which are beyond our control, include, but are not limited to those described below under "Summary of Risk Factors" and in Item 1A. Risk Factors in this Annual Report.

You should carefully consider these risks, as well as the additional risks described in other documents we file with the Securities and Exchange Commission (the "SEC"). We also operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for our management 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, or implied by, any forward-looking statements.

The forward-looking statements included herein are based on current expectations of our management based on available information and are believed to be reasonable. In light of the significant risks and uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by us or any other person that such results will be achieved, and readers are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date hereof. Except as required by law, we undertake no obligation to revise the forward-looking statements contained herein to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. You should read this Annual Report and the documents we file with the SEC, with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by the cautionary statements referenced above.

Summary of Risk Factors

We are subject to a number of risks, including risks that may prevent us from achieving our business objectives or that may adversely affect our business, financial condition and results of operations. You should carefully consider the risks discussed in this Annual Report under the section titled "Risk Factors." These risks include, among others, the following:

- We are an early-stage company with a history of significant net losses, we expect to continue to incur operating losses for the foreseeable future and we may not be able to achieve or sustain profitability.
- Our common stock has been suspended from trading on the NYSE and may be delisted from the NYSE, which may negatively impact our stockholders and the trading price and liquidity of our common stock.
- Our revenue is primarily generated from sales of our GentleWave Console and the accompanying single-use procedure instruments ("PIs") and, until recently, the TDO software segment and we are therefore highly dependent on the success of our remaining offerings.
- Our future operating results may be difficult to predict and could fall below expectations or any guidance we may provide.
- The terms of our credit agreement contain operating and financial covenants and place restrictions on our operating and financial flexibility.
- We need additional funding to finance our planned operations, and may not be able to raise capital when needed.

- The commercial success of our GentleWave System and the GentleWave Procedure will depend upon the degree of market acceptance of our products by dental practitioners, our ability to maintain strong working relationships with our existing clinicians and dental customers and our ability to increase penetration in existing markets and expand into adjacent markets.
- We may provide inadequate training, fail to increase our sales and marketing capabilities or fail to develop and maintain broad brand awareness in a cost-effective manner.
- We may not be able to obtain or maintain adequate levels of third party coverage and reimbursement.
- We may not be able to achieve or maintain satisfactory pricing and margins for our products.
- We may not be able to compete successfully.
- We may be unable to develop or commercialize new products on a timely basis and our products may become obsolete.
- We have limited experience manufacturing our products in large-scale commercial quantities and we face a number of manufacturing risks that may adversely affect our manufacturing abilities, which could delay, prevent or impair our growth.
- We depend upon third-party suppliers, including contract manufacturers and single source suppliers, making us vulnerable to supply shortages and price fluctuations that could negatively affect our business, financial condition and results of operations.
- Any changes in our shipping arrangements or damages or losses sustained from shipping could adversely affect our business, financial condition, results of operations and prospects.
- Our operating expenses may substantially increase and our business and financial results will be adversely affected if we receive a significant number of warranty claims or our GentleWave Systems require significant amounts of service after sale.
- We may encounter difficulties in managing our growth, forecasting demand and managing inventory.
- Our internal computer systems or those used by our contractors or consultants, may fail or suffer security breaches, and such failure could negatively affect our business, financial condition and results of operations.
- Natural or man-made disasters and other similar events may significantly disrupt our business, including by causing delays in production or an increase in costs, and negatively impact our business, financial condition and results of operations.
- The sizes of the addressable markets for our GentleWave System have not been established with precision and our potential market opportunity may be smaller than we estimate and may decline.
- We may incur substantial liabilities and other negative impacts on our business as a result of product liability lawsuits and we may not be able to obtain or maintain insurance to cover these and other risks.
- Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.
- Our products and operations are subject to extensive government regulation and oversight in the United States.
- Our ability to utilize our net operating loss carryforwards and research and development credit carryforwards may be limited.
- We are highly dependent on our senior management team.
- Our success depends on our ability to obtain and maintain our intellectual property.
- The market price of our common stock may be volatile and an active trading market may not develop.

- Anti-takeover provisions in our certificate of incorporation, bylaws and Delaware law could prevent or delay a change in control.
- We are subject to additional risks and costs as a result of being a public company.
- We maintain cash deposits in excess of federally insured limits. Adverse developments affecting financial institutions, including bank failures, could adversely affect our liquidity and financial performance.

PART I

Item 1. Business.

Overview

We are a commercial-stage medical technology company focused on saving teeth from tooth decay, the most prevalent chronic disease globally. We have developed and manufacture the GentleWave® System, an innovative technology platform designed to treat tooth decay by cleaning and disinfecting the microscopic spaces within teeth without the need to remove tooth structure.

The GentleWave System is a Class II device and has received 510(k) clearance from the United States Food and Drug Administration (the "FDA") for preparing, cleaning, and irrigating teeth indicated for root canal therapy ("RCT"). Our initial focus is on leveraging the GentleWave System to transform RCT by addressing the limitations of conventional methods. The key components of our GentleWave System are a sophisticated and mobile console and pre-packaged, sterilized, single-use procedure instruments ("PIs"). The GentleWave System utilizes a proprietary mechanism of action that is designed to combine procedure fluid optimization, broad-spectrum acoustic energy and advanced fluid dynamics to efficiently and effectively reach microscopic spaces within teeth and dissolve and remove tissue and bacteria with minimal or no removal of tooth structure. We have invested significant resources in establishing a broad intellectual property portfolio directed to the GentleWave Procedure and its unique mechanism of action, as well as future capabilities under development. As of December 31, 2023, we held 162 issued patents and there were 64 pending patent applications that include device, design, system and method claims.

We believe our GentleWave System transforms both patient and dental practitioner experience and addresses many of the limitations of conventional RCT by providing the following key benefits:

Clinical Outcome Benefits

- *Superior cleaning and disinfection.*
- *Less invasive procedure.*
- *High and rapid rates of healing.*
- *Minimal to no post-operative pain.*

Practice and Dental Practitioner Benefits

- *More procedures completed in a single patient visit.*
- *Standardized protocol enabling procedure efficiency and predictable outcomes.*
- *Simple to use technology.*
- *Low risk of cross-contamination.*
- *Practice differentiating technology*

Our business is operated through two segments, Product and Software. Our Product segment includes the sales of the GentleWave System console and related accessories and instruments. Our Software segment, which was divested in March 2024, included the sales of our traditional software licenses for practice management software to enable an integrated digital office for endodontists.

As of December 31, 2023, we had an installed base of approximately 1,134 GentleWave Systems that had performed a milestone of more than one million GentleWave patient procedures since commercialization. We generated revenue of $43.9 million and incurred a net loss of $60.9 million for the year ended December 31, 2023 compared to revenue of $41.7 million and a net loss of $57.1 million for the year ended December 31, 2022. As of December 31, 2023, our accumulated deficit was $430.0 million.

Milestones Achieved in 2023

Since the commercialization of our current technology in 2017, we have been focusing on establishing the GentleWave Procedure as the standard of care for RCT. We achieved the following major milestones in 2023:

- We launched the second generation of our CleanFlow PI ("CleanFlow G2"), which includes an optimized design and enhanced matrix system, for heightened efficacy and ease of use when performing the GentleWave Procedure, further simplifying the root canal treatment process for clinicians and

improving the overall patient experience. CleanFlow G2 allows doctors to use one procedure instrument for all teeth. As of December 31, 2023, the CleanFlow PI has substantially replaced existing PIs, creating a more efficient platform.

- With the launch of GentleWave G4 in late 2022, we have now discontinued the sale of the legacy GentleWave Gen3 system. We assemble the G4 console in-house, which has improved our gross margin and operating leverage. We will continue to support service and warranty of both G4 and Gen 3 systems with our in-house teams.
- As of December 31, 2023, with thanks to our dedicated community of GentleWave doctors, over 1.3 million patients have now been treated with the GentleWave Procedure since commercialization.

Recent Development

On March 1, 2024, we divested our software segment by selling substantially all the assets and liabilities of TDO Software, Inc, our wholly owned subsidiary, to Valsoft Corporation Inc., a Quebec corporation, and Aspire USA LLC, a Delaware limited liability company and affiliate of Valsoft (collectively "Valsoft") for approximately $16.0 million, with $15.0 million received upon closing and the balance due in approximately 12 months.

In connection with this transaction, on March 1, 2024, we amended our term loan with Perceptive Credit Holdings III, LP, pursuant to which, we made a one-time $15.0 million principal repayment on March 1, 2024, and agreed to make an amortization payment of $1.8 million on the outstanding principal on March 31, 2024 and make monthly amortization payments on the outstanding principal amount each in the amount of $0.9 million on each payment date commencing on April 30, 2024. Certain covenants included in the term loan were also amended. See the section of this Annual Report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Indebtedness." and the section Financial Statements and Supplementary Data —*Note 9* and *Note 13* for more discussion.

Market Overview

Tooth decay is the most prevalent chronic disease globally. In the United States, 92% of adults between the ages of 20 and 64 have had dental cavities in their permanent teeth. The incidence of tooth decay has grown significantly over the past several decades, primarily driven by an aging population and unhealthy diets that are high in sugar and other carbohydrates. The United States spends approximately $148 billion annually on professional dental services, of which we estimate that approximately 55%, or $81 billion, of spending is directly associated with treating tooth decay. If left untreated, tooth decay may progress and also result in a number of uncomfortable symptoms, including tooth discoloration, severe toothache or tooth sensitivity, and may eventually lead to tooth loss. Additionally, studies have shown that poor oral health may impact overall health and is associated with diseases such as cardiovascular disease, pneumonia, and pregnancy and birth complications.

We are initially focused on utilizing our GentleWave System to transform RCT. Our commercial efforts are primarily focused on driving awareness and adoption of our system in our initial target markets of the United States and Canada, where we estimate that approximately 17 million root canal procedures are performed annually, accounting for approximately $17 billion in healthcare-related expenditures. We estimate that there are approximately 5,000 endodontists and 176,000 general dentists in this market. Within the general dentist population, we estimate that a subset of approximately 50,000 general dentists perform approximately 90% of their root canal procedures instead of referring to a specialist. Collectively, we estimate that endodontists and this subset of non-referring general dentists perform more than 75% of all root canal procedures in the United States and Canada. Given the average selling price of our products and our estimates on replacement cycle, and the number of root canals performed annually, we estimate that our total annual addressable market in the United States and Canada is approximately $1.9 billion. We also believe there is a significant opportunity for our GentleWave System in RCT outside the United States and Canada, with more than 50 million root canal procedures performed annually on a global basis including the United States and Canada.

In addition, we are exploring opportunities to leverage our technology platform beyond RCT to treat cavities in earlier-stage tooth decay, for which we estimate there are approximately 175 million procedures performed in the United States each year. We believe that by utilizing our GentleWave System to treat cavities, the number of general dentists that we target could be expanded to include all 176,000 general dentists in the United States and Canada. We believe treatment for cavities would require separate regulatory approval.

Our direct sales force markets and sells the GentleWave System to dental practitioners in the United States and Canada, primarily endodontists and general dentists, performing a high volume of root canals as part of their practice. Our commercial strategy and sales model involves a focus on driving adoption of our GentleWave System by increasing our installed base of consoles and maximizing recurring PI revenue through increased utilization.

Our Success Factors

We believe the continued growth of our company will be driven by the following success factors:

- ***Paradigm-shifting platform technology for tooth decay, with an initial focus on transforming root canal therapy.*** We have developed the GentleWave System, an innovative technology platform designed to treat tooth decay and save teeth by cleaning and disinfecting the microscopic spaces within teeth without the need to remove tooth structure. Our initial focus is on transforming RCT by addressing the limitations of conventional methods. Conventional methods of RCT depend primarily on instruments to manually scrape at and remove tooth structure and open the canals inside of the tooth in order to remove and irrigate infected tissue. These methods, however, are limited in their ability to clean the entire root canal system, which increases the risk of treatment failure, and are commonly associated with post-operative pain, which has contributed to patient fear of the procedure. Utilizing our proprietary mechanism of action, which combines fluid optimization, broad-spectrum acoustic energy and advanced fluid dynamics, the GentleWave System debrides and disinfects deep regions of the complex root canal system in a less invasive procedure that preserves tooth structure. The GentleWave Procedure has been shown to produce favorable clinical outcomes, which we believe provides us an opportunity to transform the patient experience and encourage more patients to choose the GentleWave Procedure. Our goal is to leverage our disruptive technology to establish the GentleWave Procedure as the standard of care for RCT.

- ***Large market opportunity with significant need for innovation.*** As noted above, we estimate that our total annual addressable market in the United States and Canada is approximately $1.9 billion. We are exploring opportunities to leverage our technology platform beyond RCT to treat cavities in earlier-stage tooth decay, for which we estimate there are approximately 175 million procedures performed in the United States each year.
- ***Compelling and growing body of clinical and real-world evidence.*** The clinical benefits delivered by our GentleWave System have been demonstrated across two prospective, multi-center clinical studies, over 30 peer-reviewed journal publications and in real-world, clinical practice, with over 1.3 million patients treated using the GentleWave System as of December 31, 2023. Our robust base of peer-reviewed research and clinical data shows that the GentleWave System has delivered strong clinical outcomes, including high and rapid healing rates with minimal to no post-operative pain, and provided superior cleaning of the entire root canal system in a less invasive procedure. For example, we observed a treatment success rate of 97% for patients treated using the GentleWave System in our PURE study, the results of which were published in the peer-reviewed *Journal of Clinical and Experimental Dentistry* and *Journal of Endodontics.* The GentleWave System has also been shown to drive procedure efficiency, enabling a greater proportion of root canal procedures to be completed in a single patient visit and reducing the need for endodontic files. Results from a survey of GentleWave users that we performed in 2020 indicated that the number of root canal procedures performed in a single patient visit increased from 57% to 90% following adoption of the GentleWave System. These survey results are supported by data from our peer-reviewed, prospective clinical studies as well as commercial experience. We believe our compelling and growing body of clinical data and real-world evidence will continue to serve as a catalyst for driving adoption of our GentleWave System.
- ***Attractive value proposition for dental practitioners and their patients.*** We believe the GentleWave System offers a myriad of benefits for dental practitioners and their patients that will facilitate adoption and incorporation into their clinical practice. The clinical benefits of the GentleWave System include superior cleaning and disinfection of the root canal system that is independent of complexity and anatomy, high and rapid rates of healing, minimal to no post-operative pain, a less invasive procedure that enables the preservation of tooth structure and a closed-loop system with a sterilized PI. In addition to the clinical benefits, the GentleWave System offers dental practitioners several other benefits to improve the workflow and economics of their practice. For example, the GentleWave System provides a standardized protocol that promotes procedure efficiency and predictable, consistent outcomes. The GentleWave System also empowers dental practitioners to complete their root canal procedures in a single patient visit, increasing practice efficiency by reducing non-billable patient visits and is also more convenient for patients. In addition, we designed the GentleWave System to be simple to use with an intuitive touchscreen interface, generally requiring only a few days of training before dental practitioners are able to independently perform procedures. We believe these benefits will allow endodontists to establish stronger referral relationships with general dentists and result in improved practice economics for all dental practitioners.
- ***Transformative research and development capabilities and a robust intellectual property portfolio.*** We have invested significant resources in establishing strong research and development capabilities that are focused on developing simple-to-use solutions. We also have invested significant resources in establishing a broad intellectual property portfolio directed to the GentleWave Procedure and its unique mechanism of action, as well as future capabilities under development. As of December 31, 2023, we had 162 issued patents and 64 pending patent applications that include device, design, system and method claims.
- ***Recurring revenue business model.*** We generate revenue primarily from sales of our GentleWave Console and related PIs and accessories. Our PIs are sterilized devices with embedded features that do not allow for reuse. Our business model of selling capital equipment that generates corresponding recurring utilization is designed to provide a stream of predictable, recurring revenue.

Our Growth Strategies

Our mission statement is "Saving Teeth, Improving Lives." Our goal is to establish the GentleWave Procedure as the standard of care for tooth decay, with an initial focus on transforming RCT. The key elements of our growth strategy are:

- ***Execute Our Commercial Strategy in the United States and Canada.***
  - ***Grow GentleWave install base by increasing awareness and education among dental practitioners and increasing our team of capital sales representatives.*** We have focused on driving adoption of the GentleWave Procedure among endodontists. To drive further adoption of our system, we will continue to utilize our team of capital sales representatives, who are focused on system placement by directly engaging with dental practitioners and educating them about the compelling value proposition of the GentleWave Procedure. To facilitate the efforts of our capital sales team, we will strive to increase awareness of the GentleWave Procedure among dental practitioners and their patients by communicating the benefits of our system through various marketing and educational initiatives, including publications and podium presentations at various industry conferences and scientific forums, organizing peer-to-peer dialogue and educational events and leveraging our strong network of supportive key opinion leaders.
  - ***Increase utilization of our GentleWave System by partnering with clinicians and increasing awareness among dental practitioners and patients.*** We strive to increase awareness of the GentleWave Procedure among dental practitioners and, in select markets where we establish a large installed base, directly with patients through various targeted direct-to-patient marketing initiatives, showcasing the benefits and points of difference of the GentleWave Procedure from conventional RCT. We believe that once patients become aware of the GentleWave Procedure, they will seek the GentleWave Procedure over conventional RCT. We believe these initiatives will drive a greater volume of root canal procedures to dental practitioners who offer the GentleWave Procedure, thereby increasing utilization of our system.
- ***Reduce product costs and improve production efficiency.*** We expect to realize operating leverage through increased scale efficiencies as our commercial operations expand. We are continuously driving gross margin improvement initiatives, such as improving product design, implementing lean manufacturing methods and collaborating with suppliers to curtail material costs.
- ***Continue to invest in research and development to drive future innovations and expand our addressable market.*** We are currently developing new features and next generation products to further improve the usability of the GentleWave System and enhance the efficiency and predictability of the GentleWave Procedure. In the future, we intend to pursue marketing authorization to expand the application of our GentleWave System beyond RCT for use in treating cavities in earlier-stage tooth decay. By introducing our next-generation innovations, we believe we have an opportunity to leverage and expand our position in the market and add incremental revenue to our business.
- ***Grow our footprint into international markets.*** While our current commercial focus is on the United States and Canada, we believe the GentleWave System can offer compelling benefits to the large population of patients suffering from tooth decay in other international markets. We plan to pursue marketing authorizations and related certifications, and engage in other market access initiatives over time in attractive international regions in which we see significant potential opportunity.

Our Solution

We have developed a proprietary technology platform with an innovative approach to the treatment of tooth decay. Our GentleWave System is a Class II device and is FDA-cleared for preparing, cleaning and irrigating teeth indicated for RCT and is the first and only FDA-cleared system for RCT that employs a sterilized, single-use PI to automate the cleaning and disinfection of microscopic spaces within root canals without the need to remove tooth structure.

In addition to our GentleWave Console and single-use PIs, we also offer ancillary products, such as SoundSeal and our Sonendo-branded liquid solution of ethylenediaminetetraacetic acid ("EDTA"). SoundSeal is a material used during the GentleWave Procedure to build and create a sealing platform on the top of the crown, which facilitates an airtight seal between the PI and the tooth. Our company-branded EDTA is used during the GentleWave Procedure to

help debride and disinfect the root canal system, and is introduced and circulated throughout the root canal system via the GentleWave System.

Benefits of our solution in comparison to conventional RCT

We believe our GentleWave System transforms the patient and clinician experience and addresses many of the limitations of conventional RCT. The following table summarizes the limitations of conventional RCT as compared to the benefits of our GentleWave solution in terms of clinical outcomes and clinical workflow.

Conventional RCT	Our Solution
Clinical Outcomes:	
Ineffective cleaning. We believe that conventional methods of RCT do not adequately clean and disinfect the entire root canal system, primarily due to the complexity and uniqueness of each root canal and the inability of current endodontic technologies to reach the microscopic spaces within the tooth. For example, studies have shown that instrumentation alone does not successfully remove all bacteria and infected tissue, with endodontic files generally only able to reach between 35% and 65% of the surfaces within the root canal. In addition, studies have demonstrated that approximately 74% of all root canal procedures show signs of residual tissue and bacteria post-procedure, most often occurring in regions of the root canal with complex anatomic features.	***Superior cleaning and disinfection.*** Utilizing our proprietary mechanism of action that combines fluid optimization, broad-spectrum acoustic energy and advanced fluid dynamics, the GentleWave System debrides and disinfects deep regions of the complex root canal system in a less invasive procedure that preserves tooth structure. Our innovative mechanism of action enables more consistent and complete cleaning and disinfection of the root canal system in a manner that is independent of its complexity and anatomy. In multiple published studies, the GentleWave System was observed to clean significantly more debris as well as more complex anatomies compared to conventional methods of RCT.
Extensive use of instrumentation. Conventional methods of performing RCT rely on extensive use of instrumentation to remove infected tissue and enlarge root canals in preparation for irrigation, which may weaken the tooth and impact its long-term survival. Use of instrumentation within the root canal system during conventional RCT is also frequently associated with several risk factors and may increase the likelihood of procedural errors that can result in fracture and therefore loss of the tooth. For example, endodontic files may cause bacteria and debris to extrude into the periapical region around the apex of the root, causing post-operative pain and preventing the tooth from properly healing. Endodontic files may also perforate the wall of the root canal, at which point tooth extraction is required. Pieces of endodontic files can break off into the canal, which may cause additional inflammation and post-operative pain, and generally requires retreatment to remove the instrument fragments from the root canal.	***Less invasive procedure.*** Our technology is designed to clean and disinfect multiple root canals within the root canal system simultaneously, without requiring insertion of our PI into each root canal, thereby reducing the need for instrumentation and removal of healthy tooth structure. We believe this helps clinicians avoid common risk factors associated with the excessive use of files, such as extrusion, perforation or thinning of the root canal walls which may result in fracture and therefore loss of the tooth. For example, once the tooth is accessed using traditional access methods, the clinician will generally rely on the GentleWave System's mechanism of action to debride and disinfect the root canal system. Based on our commercial experience, we have observed that clinicians using the GentleWave System require fewer and smaller files, and in some cases no files, instead of using many files to manually scrape and remove tooth structure and enlarge canals. In addition, in a published study, the GentleWave System was observed to completely clean the root canal system of debris and tissue without any instrumentation while leaving the original tooth structure intact.
Poor clinical outcomes. The limitations of conventional methods of RCT may lead to poor clinical outcomes, such as treatment failure and post-operative pain. Published studies have shown that 28% to 74% of endodontic lesions can remain unhealed at 12 months after treatment with conventional methods of RCT. These methods are also commonly associated with	***High and rapid rates of healing.*** In our PURE study, 97% of patients treated using the GentleWave Procedure were healed or healing at the six-month follow-up, which was sustained through the 12-month follow-up. We believe our high and rapid healing rate is the result of the GentleWave System's novel mechanism of action that enables cleaning and disinfection of microscopic spaces within root canals.

more frequent and more severe post-operative pain as compared to other dental procedures. According to published studies, between 29% and 70% of patients undergoing conventional RCT report post-operative pain and the estimated weighted average success rate of conventional methods of RCT at 12+ months after treatment ranges between 68% and 85%.

Minimal to no post-operative pain. In our PURE study, patients treated using the GentleWave Procedure experienced minimal to no post-operative pain. We believe this is due to the ability of our technology to remove and clean diseased tissue and bacteria from within even the smallest spaces in the root canal system. In addition, the risk of extrusion of debris, tissue and bacteria beyond the apex of the root is minimized by dramatically reduced or no use of files as well as the negative pressure of the GentleWave System. These results are supported by our commercial experience and clinician feedback, where patients are reporting less post-operative pain and are requiring fewer prescriptions for pain-relieving medications such as opioids.

Clinical Workflow:

Lack of standardized procedure protocols. Given the uniqueness and complexity of the root canal system, there is generally a lack of standardized protocols for critical steps of conventional RCT. For example, the chemical concentrations, techniques and devices utilized during irrigation can vary widely between clinicians. The concentration of the most important chemical used during irrigation – sodium hypochlorite – also varies between 3% and 8%, depending on the brand, season and method of storage. Clinicians typically select, manually mix and inject this and other chemicals during the procedure, which requires time and caution in administration and can result in inconsistent concentrations across procedures. Additionally, the amount of instrumentation, including the depth to which the root canal is instrumented, is determined on a case-by-case basis by each individual dental practitioner, and can vary significantly based on the complexity of the procedure. We believe this lack of standardization contributes to unpredictable procedure times and outcomes.

Standardized protocol that enables procedure efficiency and predictable outcomes. The GentleWave System is designed to provide a consistent, automated and standardized cleaning and disinfection protocol, regardless of anatomy or complexity. Key parameters, such as the sequence and duration of delivery of each solution are controlled by the software. For example, the system measures and adjusts procedure fluids, including distilled water, sodium hypochlorite and EDTA, for clinicians, thereby standardizing the concentration and mixing of procedure fluids across every procedure and delivering these fluids through the PI to a sealed root canal system. We believe the standardization of this procedure enables clinicians to have a more predictable procedure time and outcome and reduces the number of personnel required for the procedure, freeing up time and improving efficiency.

Complex procedure. RCT using conventional methods can be difficult to perform due to the complexity and uniqueness of each root canal system, which can lead to outcomes that are dependent on the experience of the clinician and drive large disparities in patient outcomes. For example, one of the challenges in conventional RCT is to locate all root canals within the tooth. This process is considered to be a crucial part of the procedure and is entirely technique-dependent. Peer-reviewed literature indicates that approximately 12% of root canal procedures miss at least one root canal, which has been shown to increase the likelihood of treatment failure by over six times. General dentists also may elect not to perform some or all root canal procedures due to their complexity, instead referring those patients to endodontists for treatment. In addition, conventional methods of RCT utilize techniques and

Simple-to-use technology. We designed our technology to enable ease of use due to its standardized treatment protocol and intuitive touch screen interface. In our commercial experience, clinicians are generally able to independently perform procedures following a few days of training.

Low risk of cross-contamination. The console and PI together form a closed-loop fluid management system, whereby fluids are delivered via the PI and then collected and evacuated into the waste canister inside the console. The procedure is designed to generate virtually no aerosols, which is not only convenient, but may appeal to clinicians and patients concerned with the potential cross-contamination associated with aerosols, which became a particularly sensitive issue during the COVID-19 pandemic. In addition, our PIs are pre-packaged, sterilized

devices that create aerosols during the procedure, which became a concern for some clinicians and patients during the COVID-19 pandemic due to the with the potential cross-contamination associated with aerosols.

Need for multiple visits. In many cases, conventional methods of performing RCT require multiple visits, depending on a variety of factors such as the clinician's experience and preference, severity of the disease and anatomy of the root canal system being treated. Peer-reviewed data shows that approximately half of root canal procedures are completed in a single patient visit, with more complex cases typically requiring multiple visits. The need for multiple visits may be inconvenient for patients and may result in more non-billable visits for the practice, as payment is typically the same regardless of the number of visits.

and single-use, which further reduces the risk of cross contamination.

More procedures completed in a single patient visit. Our GentleWave System empowers clinicians to perform even the most challenging RCT procedures in a single patient visit. This was demonstrated by our PURE study, where 92% of GentleWave Procedures were completed in a single-visit procedure. These results were further supported by our survey of GentleWave users, which showed the number of RCT procedures completed in a single patient visit increased from 57% to 90% following the clinician's adoption of the GentleWave System. We believe the GentleWave System enhances practice efficiency for clinicians by reducing non-billable patient visits and is also more convenient for patients.

Practice differentiating technology with the ability to establish stronger referral relationships with general dentists and attract patients. Based on our commercial experience, we believe clinicians who use and promote our GentleWave System benefit from stronger referral relationships with other general dentists resulting in more profitable practices and differentiation relative to peers who do not use our system.

The table below summarizes description of our products:

Product	Image	Description
GentleWave G4		Our current generation console designed for optimized performance, refined for a simplified workflow and enhanced for an elevated experience.
CleanFlow Procedure Instrument		Designed to work with all GentleWave system. Enables a simpler workflow as compared to earlier PIs and helps create a better patient experience.

Components of the GentleWave System and Mechanism of Action

The key components of our GentleWave System are a sophisticated and mobile console and a sterilized single-use PI. We also offer ancillary products such as SoundSeal and our company-branded EDTA. The console is a one-time capital equipment purchase, while the PIs and ancillary products are recurring consumable purchases based on the number of procedures performed and clinician need.

GentleWave Consoles

Our GentleWave G4 consoles are designed to prepare and deliver procedure fluids into the PI via a high-pressure hose. The consoles include fluid containers, electronics, software, corrosion-resistant tubes, a high-pressure pump, sensors, valves and a waste canister. The consoles are controlled by advanced software and operated via an intuitive touchscreen interface that simplifies procedure setup and treatment delivery. The consoles also collect the waste fluids delivered from the PI via a low-pressure evacuation tube. The consoles feature an integrated RFID reader, which reads the RFID tag inside the PI and verifies that the correct PI is being used while also preventing re-use. The consoles are enabled with wireless connectivity capabilities that allow for automatic software updates, remote monitoring of the system to ensure reliability and real-time tracking of system utilization.

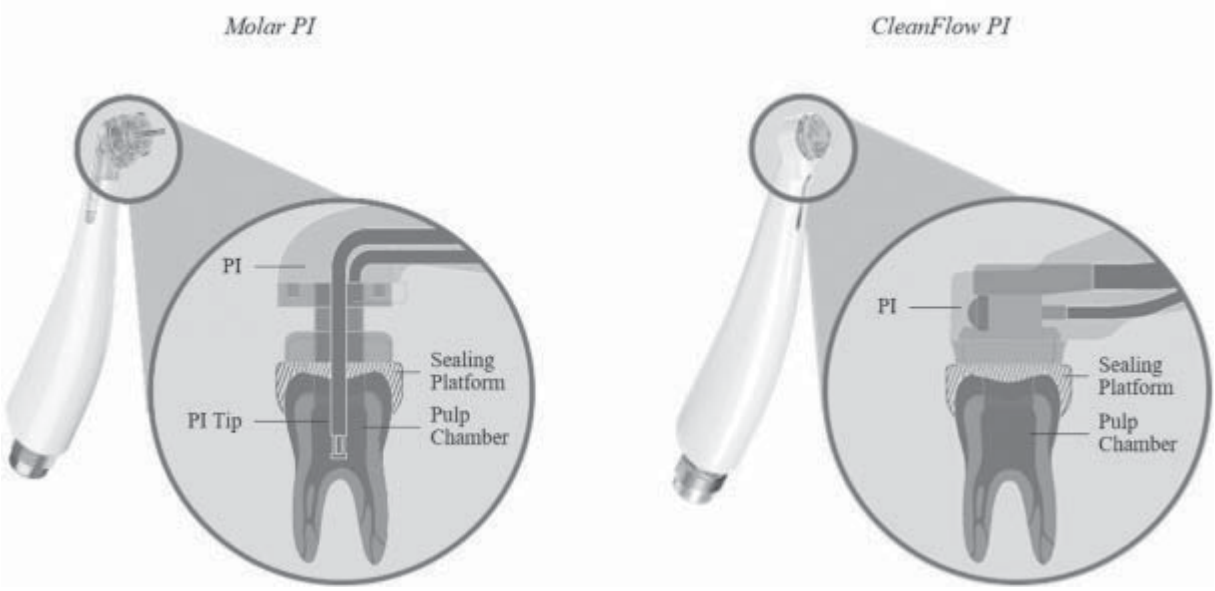
We have phased out our legacy GentleWave Consoles in 2023, but will continue support and service our installed base.

GentleWave Procedure Instruments

The PI is a pre-packaged, sterilized, single-use instrument connected to the console via a high-pressure hose that delivers optimized fluids from the console to the end of the PI.

We launched the CleanFlow PI in April 2022. In August 2023, we received CleanFlow's FDA clearance to include anterior teeth. CleanFlow PI is now our leading PI and we have phased out the legacy PI designed for molar teeth (a "Molar PI"), anteriors and premolars (an "APM PI") in early 2024. The CleanFlow PI utilizes the same mechanism of action as our legacy PIs, but has been improved so that no components of the PI enter the tooth, regardless of tooth type. We believe the CleanFlow PI will transform the way root canal procedures are performed by cleaning the inside of the tooth from outside the tooth through the endodontic access opening, and will further simplify the GentleWave Procedure, expand our indications for use, improve user experience and enable clinicians to preserve even more tooth structure.

The image below depicts our Molar PI and CleanFlow PI and their respective mechanisms of action:



GentleWave System Mechanism of Action

The GentleWave System mechanism of action is designed to clean and disinfect the entire root canal system simultaneously and remotely, or without requiring insertion of our PI into each root canal. The key components of the GentleWave System utilize a proprietary mechanism of action that combines procedure fluid optimization, broad-spectrum acoustic energy and advanced fluid dynamics to efficiently dissolve tissue and bacteria using minimal or no instrumentation.

The console enables a multi-stage process of optimizing procedure fluids, which include distilled water, sodium hypochlorite and EDTA, before they are delivered to the PI. Initially, the console extracts fluids from built-in containers and passes them through degassers, or components designed to reduce the fluid's dissolved air content. In the absence of the console's proprietary degassing process, air bubbles in the procedure fluids may act as barriers that inhibit the delivery of fluids and broad-spectrum acoustic energy throughout the root canal system. After degassing, the concentration of each procedure fluid is measured and adjusted precisely in preparation for delivery to the root canal system, thereby standardizing the concentration of procedure fluids, including sodium hypochlorite, across every procedure. The console detects and notifies the user if an incorrect or chemically degraded solution is being used, and also continuously refreshes procedure fluids during treatment.

The PI enables a process by which broad-spectrum acoustic energy and advanced fluid dynamics are created within the root canal system. Once optimized and pressurized, procedure fluids are delivered from the console to the PI via a high-pressure hose. In the distal end of the PI, a proprietary orifice converts the procedure fluids into a high-speed fluid jet. This fluid jet interacts with surrounding fluids within the procedure instrument and creates a strong shear force, which causes continuous hydrodynamic cavitation in the form of a cavitation cloud containing thousands of cavitation bubbles. The continuous formation and implosion of cavitation bubbles generates shock waves and broad-spectrum acoustic energy that propagate throughout the root canal system. The hydrodynamic cavitation that is created generates a broad range of frequencies that enables the optimal delivery of acoustic energy into structures of various dimensions inside the root canal system. The PI is also designed to generate a flow over the orifices of the root canal, which induces a vortical flow and negative pressure inside the root canals. The vortical flow is optimized to rapidly dissolve and remove tissue, bacteria and debris from the root canal system, while the negative pressure minimizes the possibility of extrusion of the procedure fluids beyond the apex of the root.

The GentleWave Procedure

We designed the GentleWave Procedure to be simple to learn, requiring only general dental skills to perform, and easy to integrate into a practice's existing workflow. Certain steps of the GentleWave Procedure, including access and obturation and tooth restoration, are generally the same as conventional RCT. However, the GentleWave

Procedure transforms cleaning and disinfection, the most important aspect of RCT, by replacing the cumbersome, ineffective and invasive step of shaping and irrigation with the following simpler, more effective and less-invasive steps:

- Ensuring an unobstructed path within the root canal: Once the tooth is accessed using traditional access methods, the clinician may use endodontic files to ensure there is an open fluid path to the apex and to facilitate obturation later in the procedure. Based on our commercial experience, we are seeing clinicians move towards using only one file, and in some cases no files, for this step of the procedure, instead of using many files to scrape and remove tooth structure and enlarge canals.
- Standardizing and automating cleaning and disinfection: Once a fluid pathway is established, a material, such as our SoundSeal product, is used to create a platform on top of the crown, which facilitates an airtight seal between the PI and the tooth. Once the PI is positioned on the tooth and a sealed environment is confirmed, the clinician uses the intuitive touchscreen interface on the GentleWave Console to select from a predefined set of treatment protocols. The foot pedal attached to the GentleWave Console is depressed to activate the GentleWave System, creating a closed loop fluid management system that seamlessly transitions between stages of the procedure, requiring minimal intervention from the clinician during treatment.

Peer-Reviewed Research and Clinical Studies

We are committed to continuing to generate evidence to support the clinical benefits of the GentleWave System. These benefits have been observed in-vivo and in-vitro across two prospective, multi-center clinical studies, over 30 peer-reviewed journal publications and by real-world, clinical practice, with over one million patients treated using the GentleWave System as of December 31, 2023. Our robust base of research and clinical data supports our belief that the GentleWave System has delivered strong clinical outcomes, including high and rapid healing rates with minimal to no post-operative pain, and provided superior cleaning of the entire root canal system in a less invasive procedure. In addition, the GentleWave System has been observed to drive procedure efficiency, enabling a greater proportion of root canal procedures to be completed in a single patient visit and reducing the need for endodontic files. Other than the SUPREME study referred to below, we do not believe any studies were powered for statistical significance, which we believe is common in the field of endodontic and dental research.

Strong Clinical Outcomes

We have conducted two prospective, multi-center clinical studies to date, in which we have observed strong clinical outcomes and benefits for patients treated with the GentleWave System. For these studies, the primary effectiveness endpoint was treatment success, defined as teeth that were considered to be healed or healing. Healing was assessed using a composite endpoint that included both clinical and radiographic components. Post-operative pain was also assessed as a secondary endpoint using a visual analog scale, where each patient ranked their level of pain from zero to ten, with ten being the highest level of pain.

Healing Rates after Endodontic Treatment Using the GentleWave System

In 2013, we conducted a prospective, multi-center, non-significant risk clinical study to assess the long-term performance of the GentleWave System (the "PURE study"), which evaluated healing rates for molars 12 months after root canal treatment. The study also included data evaluating healing rates at six months after treatment. Six-month results were published in the *Journal of Clinical and Experimental Dentistry* in 2016 and 12-month results were published in the *Journal of Endodontics* in 2016.

The study cohort was composed of 89 patients in need of endodontic therapy who were consented and received treatment via a GentleWave System from one of six private endodontic clinics in Southern California. The six endodontists that participated as investigators were trained to use the GentleWave System and performed a standardized treatment procedure at each respective clinical site. Additionally, 92.1% of the enrolled patients were treated in a single patient visit. Pre-operative, intra-operative and post-operative data were collected from the patients and assessed by two trained, blinded and independent evaluators. Seventy-seven patients, or 86.5%, returned for the six-month follow-up and 75 patients, or 84.2%, returned for the 12-month follow-up.

At the six-month follow-up, the cumulative success rate was 97.4%, with 77.9% classified as healed and 19.5% as healing. At the 12-month follow-up, the cumulative success rate was 97.3%, with 92.0% classified as healed and 5.3% as healing. The observed high, rapid and sustained healing rates in this study imply efficient cleaning of tissue debris, bacteria and biofilm from the root canal system in a single-visit procedure using the GentleWave System.

In addition to the high rate of healing, patients reported minimal to no post-operative pain. At two days after treatment, zero patients experienced severe post-operative pain and 3.8% experienced moderate post-operative pain. Zero patients reported any incidence of pain after 14 days following treatment.

Healing Rates of Periapical Lesions after Endodontic Treatment Using the GentleWave System

A study was published in the *Journal of Endodontics* in 2018 that included data from the PURE study and another prospective, multi-center study conducted in 2015 comparing healing after treatment with the GentleWave System as compared to a traditional root canal therapy literature control (the "SUPREME study"). The published study evaluated healing rates for molars with significant periapical lesions 12 months after root canal treatment using the GentleWave System.

The study cohort was composed of 45 patients from the PURE and SUPREME studies with periapical lesions in need of endodontic therapy who were consented and received treatment via a GentleWave System from one of four private endodontic clinics in Southern California. The four endodontists that participated as investigators were trained to use the GentleWave System and performed a standardized treatment procedure at each respective clinical site. Additionally, 88.9% of the enrolled patients were treated in a single-visit procedure. Data were collected from the patients and assessed by two trained, blinded and independent evaluators. Forty-four patients, or 97.8%, returned for the 12-month follow-up.

At the 12-month follow-up, the cumulative success rate was 97.7%, with 81.8% classified as healed and 15.9% as healing. Further, all teeth that were treated successfully were considered completely functional and had resolution for measured indices of mobility, soft tissue lesions, sinus tract and furcation involvement. The exhibited healing rate in this study implies that the GentleWave System treats root canal infections, causing inflammation in or around the root canal system to abate, ultimately allowing periapical lesions to heal.

In addition to the high rates of healing, patients reported minimal to no post-operative pain. At two days after treatment, zero patients experienced moderate or severe post-operative pain, and 15.6% reported mild pain. No patients reported post-operative pain at the six- and 12-month follow-up visits.

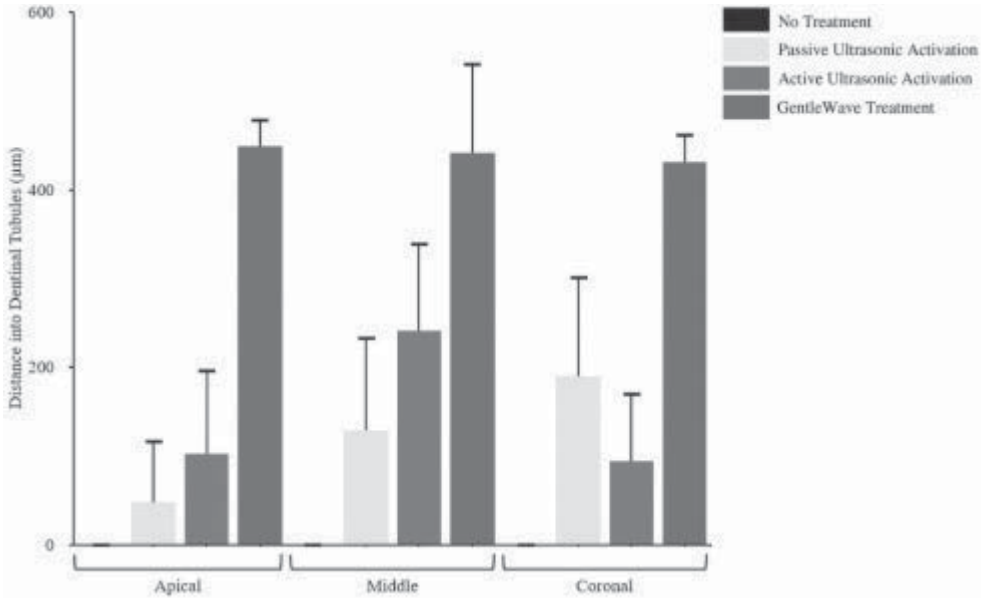
Superior Cleaning in a Less Invasive Procedure

Numerous in-vitro studies have been conducted that validate the novel mechanism of action of our GentleWave System. In these studies the GentleWave System successfully cleaned the root canal system, including complex anatomies, in a procedure that is less invasive than conventional methods.

Cleaning of Complex and Small Root Canal Anatomies Superior to Conventional Methods

A study supported by us and published in the *Dentistry Journal* in 2016 compared the penetration depth of treatment fluids using the GentleWave System with devices commonly used in conventional methods. Specifically, the conventional methods in the study used passive ultrasonic activation with a PiezonMaster 700 (EMS) with an ESI-tip and active ultrasonic activation using a PiezonMaster 700 with an ESI-tip with maximum irrigation rate. The in-vitro study included 40 extracted human molars. The GentleWave System achieved statistical significance in

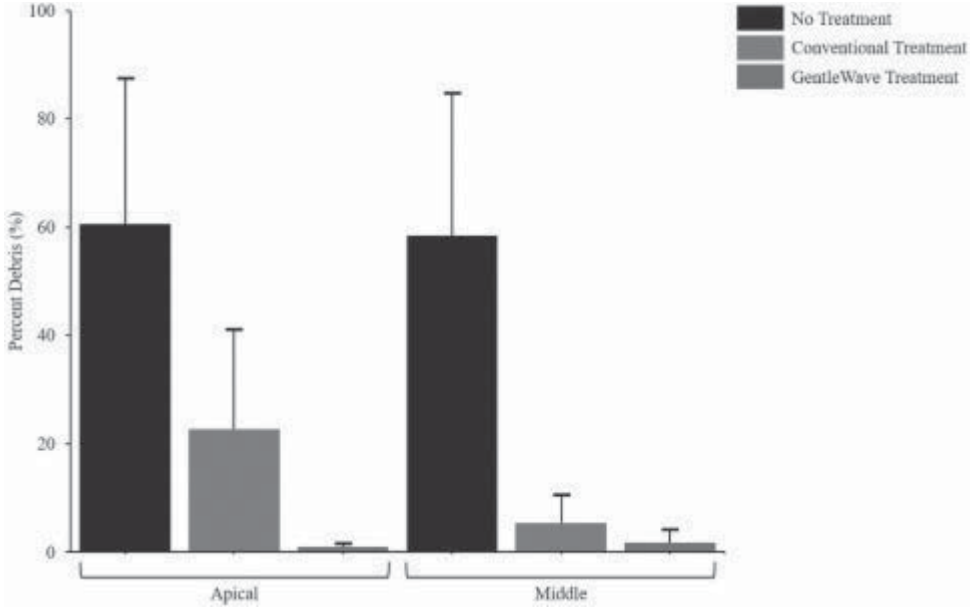
cleaning deeper into the dentinal tubules in the apical, middle and coronal regions, with treatment fluids cleaning dentinal tubules in the apical region between 4 and 8.5 times deeper than the other devices.



Debridement of GentleWave Compared to Conventional Methods

A study published in the *Journal of Endodontics* in 2015 compared the debridement efficacy of the GentleWave System with a conventional method for cleaning root canals. This study was funded by us and our employees were involved in the design of the study. Study data was acquired and analyzed independently of us. The conventional method in the study used a 30G Max-i-Probe side-vented irrigation needle and NiTi rotary instruments (endodontic files). The in-vitro study included 45 freshly extracted molars. The GentleWave System showed a statistically significant greater cleaning capacity and reduction in residual debris compared to teeth that were cleaned conventionally. Conventional instrumentation and irrigation cleaned debris from 67.8% and 87.3% of the apical and middle regions of the root canal, respectively. The GentleWave System cleaned substantially more debris, removing 97.2% and 98.1% of the debris from the apical and middle regions, respectively. The GentleWave System also

demonstrated more complete cleaning in complex anatomies. In teeth with isthmi, 98.3% of isthmi areas were free of tissue debris after the GentleWave Procedure, compared to 64.3% of isthmi areas after conventional methods.



Removal of Biofilm and Bacteria Superior to Conventional Methods

A study funded by us and published in *Materials* in 2019 compared disinfection and biofilm removal efficacy using the GentleWave System with minimal instrumentation with a device commonly used in conventional methods with conventional instrumentation. The device used in conventional methods used passive ultrasonic activation with a PiezonMaster 700 with an ESI-tip together with conventional rotary instrumentation (endodontic files). The in-vitro study included 47 freshly extracted human molars. The GentleWave System showed an ability to remove biofilm and bacteria in complex anatomies, demonstrated by statistically significant greater biofilm removal in the apical and isthmus regions of the root canal compared with conventional methods. Independent evaluators assessed and scored treated teeth on a scale from zero to three, with zero representing no bacteria and three representing large colonies of bacteria with greater than 50% of the wall covered in biofilm. In the middle and isthmus regions of the root canal, teeth treated with the GentleWave System all received scores of zero while teeth treated conventionally received scores of two and three. In the apical region of the root canal, teeth treated with the GentleWave System received scores ranging from zero to one while teeth treated conventionally received scores ranging from two to three.

Ability to Preserve More of the Original Tooth Structure without Instrumentation

A study funded by us and published in the *Journal of Endodontics* in 2018 examined root canal wall anatomy in uninstrumented premolar teeth cleaned using the GentleWave System. The in vitro study included 24 freshly extracted human premolars. The GentleWave System fully cleaned the root canal system of organic material without any instrumentation while leaving the original tooth structure intact. No organic tissue remnants or dentin debris were detected following treatment.

Enhanced Procedure Efficiency

The GentleWave System has been shown to improve procedure efficiency by enabling clinicians to perform RCT in a single patient visit while reducing the need for instrumentation. In 2020, we conducted a survey of 35 clinicians that focused on quantifying the practice benefits provided by our GentleWave System. The survey compared the percentage of single-visit RCT procedures and endodontic file costs before and after adoption of the GentleWave System. The results of the survey showed an increase in the number of single-visit RCT procedures from 57% to 90% of total RCT procedures following GentleWave System adoption. This increase in the proportion of single-visit RCT procedures enabled by the GentleWave System was observed across cases of varying complexity. These survey results are supported by data from our peer-reviewed, prospective clinical studies as well as commercial

experience. Our survey also demonstrated a reduction in the need for instrumentation, with users reporting an average reduction in endodontic file costs of 41% after adopting the GentleWave System. The results of this survey may not be representative of the entire dental population and are based on informal feedback we received in performing the survey.

Sales and Marketing

Our commercial strategy and sales model focuses on facilitating adoption of our GentleWave System by increasing our installed base of consoles and maximizing procedural instrument revenue through increased utilization of our GentleWave Systems. As of December 31, 2023, our sales and marketing team consisted of approximately 61 employees working collaboratively across a range of clinician facing roles to support an installed base of approximately 1,134 GentleWave Systems. We have structured our sales and clinician support team with specialized roles, including 22 capital sales representatives, 17 consumable sales representatives, 13 field service engineers and nine marketing team members.

Sales

Our capital sales representatives are responsible for generating demand for consoles both from new clinicians and broadening adoption among clinicians that already use our products. Our sales and marketing teams identify key opportunities that enable capital sales representatives to drive expansion of console placements across markets. Following the sale of a console, capital sales representatives participate in the onboarding process with the clinical training specialist and consumable sales representatives.

Our clinical training specialists are dedicated to clinician training and continuing education, often within larger group practices, and universities. Our clinical training specialists train and onboard new accounts and provide continuing education and practice support for existing accounts. They play an important role in supporting our sales organization to enable increased confidence and utilization.

Our field service engineers, augmented by a third-party service partner, work closely with our sales team to ensure high uptime for the GentleWave Systems and a positive user experience by performing preventive maintenance and responding to on-site device needs. Field service engineers operate efficiently to ensure our console installed base remains well-maintained and capable of high utilization levels. The GentleWave System has continuous monitoring capabilities that we can use to remotely diagnose and proactively identify needed maintenance to maximize the efficiency of our targeted site visits.

The GentleWave System is currently authorized for sale within the United States and Canada. We plan to pursue regulatory clearances, certifications and other market access initiatives over time in attractive international regions in which we see significant potential opportunity. For these select international regions, we intend to explore the commercial opportunity either through distributors or direct sales.

Marketing

Our marketing team is focused on expanding awareness of the GentleWave System and its benefits among prospective patients and the broader dental practitioner community. Our professional marketing and educational initiatives include publications and podium presentations at industry conferences and scientific forums, organizing peer-to-peer dialogue and events to educate clinicians on the benefits of the GentleWave System and leveraging our strong network of supportive key opinion leaders. Moving forward, we will work to draw more attention to the GentleWave Procedure in select markets where we have established a large installed base by communicating the benefits of our system through targeted direct-to-patient marketing activities including social, digital and search optimization.

We partner with clinicians through various practice support programs, which focus on increasing awareness and strengthening referral relationships with general dentists. For example, through our GentleWave Practice Success (“GPS”) Program, we provide guidance to our partner practices on comprehensive staff training, expansive Sonendo-sponsored marketing initiatives and engaging self-marketing strategies. We also provide content for digital marketing and social media postings to educate patients on the GentleWave Procedure and increase new business for practices. We believe our marketing programs help differentiate the GentleWave System and are valuable in helping clinicians further grow their practices.

Research and Development

We are committed to developing innovations that transform dentistry, with a focus on saving teeth. We have strong research and development capabilities in the treatment of tooth decay using fluid optimization, broad-spectrum acoustic energy and advanced fluid dynamics as well as integrating hardware and software to create an exceptional user and patient experience. A core part of our research and development strategy is engagement with our network of clinicians, which enables us to leverage real-world feedback to deliver meaningful innovation to clinicians. We believe our strategy will allow us to continue to develop new functionalities and upgrades to our GentleWave System, enable us to innovate, enhance our competitive position and expand our addressable market.

As we continue to transform RCT, our research and development efforts are focused on innovating our technologies to improve the usability of the GentleWave System and enhancing the efficiency and predictability of the GentleWave Procedure. We are also exploring development of next-generation technologies that expand the application of our GentleWave System beyond RCT for use in treating cavities in earlier-stage tooth decay.

Manufacturing and Supply Chain

We currently manufacture, assemble, test and ship our GentleWave System, which includes our console and single-use PI, at our approximately 55,000 square foot facility in Laguna Hills, California. This facility provides approximately 10,000 square feet of space for our production operations, including receiving, manufacturing, quality control, inventory and shipping.

We use a combination of internally manufactured and externally-sourced components to produce our GentleWave System. Externally-sourced components include off-the-shelf materials, sub-assemblies and custom parts that are provided by approved suppliers. Our GentleWave Console includes a number of components, including high pressure lines, high pressure pumps, fluid temperature control systems, degassing components and user interface control systems, most of which we source externally from third party suppliers. For certain of these components, there are relatively few alternative sources of supply. We seek to manage single-source supplier risk by regularly assessing the quality and capacity of our suppliers and actively managing lead times and inventory levels of sourced components. In addition, particularly as we expand our business and sales, we are continuously reviewing sources and approving alternative suppliers to dual or multi-source certain of our 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. Finished single-use PIs are sterilized at one of two qualified suppliers. The manufacture of our ancillary products, including our branded EDTA solution and SoundSeal Material, is outsourced to a contract manufacturer. For a discussion of associated risks, see Part I, Item 1A, Risk Factors – "*We depend upon third-party suppliers, including contract manufacturers and single and sole source suppliers, making us vulnerable to supply shortages and price fluctuations that could negatively affect our business, financial condition and results of operations*."

We are undertaking continuous margin improvement programs, including implementing lean manufacturing methods and collaborating with our suppliers to reduce material costs, and have executed several product design improvements to reduce product cost. We are also currently working to optimize several parts of our manufacturing process as well as consolidate the manufacture of several of the components for our console and single-use PI to fewer third-party suppliers.

Competition

Our proprietary technology platform represents an innovative approach to the treatment of tooth decay. As a result, our treatment method competes directly against conventional methods of treating root canals. We compete with manufacturers and suppliers of devices, instruments and other supplies used in connection with such conventional treatments. The market for these devices and instruments is highly fragmented with primary supply chains concentrated across a few larger manufacturers and distributors, such as Dentsply Sirona, Envista and Henry Schein. Many of our competitors have longer, more established operating histories, and significantly greater name recognition and financial, technical, marketing, sales, distribution and other resources.

We believe the primary competitive factors for companies that market new or alternative treatments and solutions in dental applications include acceptance by leading clinicians, patient outcomes and adverse event rates, patient experience and treatment time, ease-of-use and reliability, patient recovery time and level of discomfort, economic

benefits and cost savings, intellectual property protection and the development of successful sales and marketing channels. One of the major hurdles to widespread adoption of our solutions will be overcoming established treatment patterns, which will require education of patients, clinicians and their referral sources.

In addition, we may compete with additional competitors and products outside the United States and Canada when we pursue plans to market our products internationally. Among other competitive advantages, such companies may have more established sales and marketing programs and networks, established relationships with clinicians and greater name recognition in such markets.

We believe our ability to compete effectively will depend on our ability to build the commercial infrastructure necessary to demonstrate the value of the GentleWave Procedure, maintain and improve product quality and feature functionality, build the infrastructure to support the operating needs of the business and achieve cost reductions.

Intellectual Property

We actively seek to protect the intellectual property and proprietary technology that we believe is important to our business. We rely on a combination of trademark, copyright, patent, trade secret and other intellectual property laws, employment, confidentiality and invention assignment agreements, and protective contractual provisions with our employees, contractors, consultants, suppliers, partners and other third parties, to protect our intellectual property rights.

We have more than 200 active patents and patent applications worldwide and have many patent applications in process. We continually seek additional U.S. and international patents directed to our technology. Our pending patent and trademark applications may not result in issued patents or registered trademarks, and we cannot assure you that any current or subsequently issued patents or registered trademarks will protect our intellectual property rights, provide us with any competitive advantage or withstand or retain its original scope after a validity or enforceability challenge from a third party.

As of December 31, 2023, we had 36 U.S. patents, which are expected to expire between February 9, 2027 and July 17, 2041, and there were 25 pending U.S. patent applications. As of December 31, 2023, we had 126 total issued foreign patents, which include issued foreign utility patents with anticipated expiration dates ranging from 2027 to 2035, and 39 total pending foreign patent applications.

As of December 31, 2023, our patent portfolio included 17 U.S. patents, 11 pending U.S. patent applications, 79 foreign patents, 22 pending foreign patent applications that relate to our GentleWave Console and PIs. These patents and patent applications belong to patent families relating to the following technology areas:

- Three utility-type patent families directed to procedure instruments with pressure wave generators and to the use of such instruments for dental procedures, the patents and patent applications (if issued) in these three patent families have anticipated expiration dates ranging from 2027 to 2031;
- Five utility-type patent families directed to pressure waves and irrigational flow for dental procedures, the patents in these five patent families have anticipated expiration dates ranging from 2033 to 2035, and the patent applications in these four patent families—if issued—would have anticipated expiration dates ranging from 2033 to 2041;
- Four design-type patent families directed to designs for a procedure instrument and console, the patents and patent applications (if issued) in these four patent families have anticipated expiration dates ranging from 2029 to at least 2039; and
- One utility-type patent family directed to other aspects of our GentleWave products, including console features such as security, authentication, and fluid management, the patents and patent applications (if issued) in this patent family have anticipated expiration dates in 2034.

The term of any individual patent depends on the relevant laws and regulations in the country in which it is granted. In most countries, including the United States, the patent term for a nonprovisional patent is generally 20 years from the filing date of the earliest filed nonprovisional patent application to which priority is claimed.

As of December 31, 2023, we owned 130 registered trademarks and 34 pending trademark applications worldwide, including trademark registrations for “Sonendo” and “GentleWave” in the United States and other countries.

Our pending patent and trademark applications may not result in issued patents or registered trademarks, and we cannot assure you that any current or subsequently issued patents or registered trademarks will protect our intellectual property rights, provide us with any competitive advantage or withstand or retain its original scope after a validity or enforceability challenge from a third party. Notwithstanding the scope of the patent protection available to us, a competitor could develop competitive products that are not covered by our intellectual property, and we may be unable to stop such competitor from commercializing such products. Because patent applications can take many years to issue, there may be applications unknown to us, which applications may later result in issued patents that our existing or future products or technologies may be alleged to infringe. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. We may, from time to time, be forced to engage in litigation to enforce patents issued or licensed to us, protect our trade secrets or know-how, defend against claims of infringement of the rights of others or determine the scope and validity of the proprietary rights of others. Litigation could be costly and could divert our attention from other functions and responsibilities. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties and pay significant royalties to such third parties and could prevent us from manufacturing, selling or using our product or techniques, any of which could severely harm our business.

We are committed to protecting our intellectual property and any future application of our intellectual property and investments in innovation. For example, in January 2023, our wholly-owned subsidiary, PIPStek LLC, filed a patent infringement lawsuit against BIOLASE, Inc. in the U.S. District Court for the District of Delaware. In the lawsuit, PIPStek asserts infringement of three of its U.S. patents by BIOLASE's Waterlase laser. Trial is currently scheduled for May 2025.

Our knowledge and experience, creative product development, marketing staff and trade secret information, with respect to manufacturing processes and product design, are important in maintaining our proprietary product lines. As a condition of employment, we require employees and key contractors to execute an agreement obligating them to maintain the confidentiality of our proprietary information and assign to us inventions and other intellectual property created during their employment or engagement. See "Risk Factors—Risks Related to Our Intellectual Property" for additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us.

Government Regulation

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

United States Regulation

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

FDA Premarket Clearance and Approval Requirements

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

the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries, and FDA guidance documents.

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

Our currently marketed GentleWave System, which includes our GentleWave Console and PIs, is a Class II device and has received 510(k) clearance from the FDA.

510(k) Clearance Marketing Pathway

Our current products are subject to requirements for pre-market notification and clearance under section 510(k) of the FDCA. To obtain 510(k) clearance, we must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device. A predicate device is a legally marketed device that is not subject to premarket approval (*i.e.*, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that has been reclassified from Class III to Class II or I, a device that was found substantially equivalent through the 510(k) process, or a 501(k)-exempt device). The FDA's 510(k) clearance process usually takes from three to twelve months, but may take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "*de novo*" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until such marketing authorization has been granted. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

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

In September 2019, the FDA issued revised final guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety

and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list device types appropriate for the "safety and performance based" pathway and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

In September 2023, FDA issued a draft guidance document – *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. FDA outlined recommended practices when selecting predicate devices, including selecting a predicate device that was cleared using well-established methods (e.g., voluntary consensus standard, FDA guidance document, and others), considering the predicate device's history relating to reported adverse events, malfunctions, or deaths, ensuring that the predicate device does not have unmitigated use- or design-related safety issues, and selecting a predicate device that has not been subject to a design-related recall, among others.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include but are not limited to:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a new or different intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal, and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA's authority to hold, detail, or refuse imported shipments of FDA-regulated products, including medical devices and their components;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Manufacturing processes for medical devices and accessories are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation, and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled and unscheduled inspections by the FDA. Failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations, adverse inspection or audit reports such as Form 483 Notices of Inspectional Observations, warning letters, untitled letters, recall, market withdrawal, or seizure of marketed products, or other enforcement actions by the FDA or other regulatory agencies. The discovery of previously unknown problems with any marketed products, including unanticipated adverse events or adverse events of

increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or approval, or by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls. On January 31, 2024, the FDA issued a final rule that is intended to amend the QSR requirements to align more closely with the ISO 13485:2016 standard. The new set of regulations will become effective on February 2, 2026. While the ISO 13485:2016 and the FDA's previous QSR requirements are similar, there are certain differences that remain, and we will need to review our quality systems to ensure compliance with the new regulations. The FDA may also make additional changes to the requirements in the future.

The FDA has broad regulatory compliance and enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers and manufacturers. If the FDA determines that a manufacturer or supplier has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following, among others:

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

Regulation of Medical Devices in the European Union

In the European Union, ("EU"), until May 25, 2021, medical devices were regulated by the Council Directive 93/42/EEC, or the EU Medical Devices Directive, which has been repealed and replaced by Regulation (EU) No 2017/745 (the "EU Medical Devices Regulation"). Unlike directives, regulations are directly applicable in all EU member states without the need for member states to implement into national law.

All medical devices placed on the EU market must meet general safety and performance requirements of the EU Medical Devices Regulation, including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

Compliance with the general safety and performance requirements is a prerequisite for European Conformity Marking ("CE-Mark"), without which medical devices cannot be marketed or sold in the EU. To demonstrate compliance with the general safety and performance requirements medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Except for low-risk medical devices (Class I), where the manufacturer can self-assess the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossiers and the manufacturer's quality system. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a CE marking certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE Mark to the device, which allows the device to be placed on the market throughout the EU.

Throughout the term of the CE Mark, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant CE marking certificate(s) or in case of substantial changes to the device or quality system.

All manufacturers placing medical devices into the market in the EU must comply with the EU medical device vigilance system. Under this system, serious incidents and Field Safety Corrective Actions (the "FSCAs") must be reported to the relevant authorities of the EU member states. Manufacturers are required to take FSCAs defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device.

The aforementioned EU rules are generally applicable in the European Economic Area ("EEA"), which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Regulation of Medical Devices in Canada

Canada regulates the import and sale of medical devices through Health Canada ("HC"). HC classifies medical devices into four classifications, with Class I being the lowest risk and Class IV being the highest. Class I and II devices are often cleared for sale after they are CE marked or listed on the company's ISO certification and filed via fax-back applications for a Medical Device License. Higher classification risk devices (Class III and IV) require filing dossiers that resemble U.S. 510(k) applications. These applications can range in cost and typically take longer for approval. Our Canadian medical device license (#101958) was issued in 2018 and, as a holder of such a license, we are subject to inspection by HC and must maintain a valid Medical Device Single Audit Program ("MDSAP") certificate. We were issued a MDSAP certificate by DQS Medizinprodukte GmbH in June 2020 and it remains valid through June 2023. We plan to renew the certificate before it expires.

U.S. Healthcare Fraud and Abuse Laws

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

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The federal Anti-Kickback Statute includes statutory exceptions and regulatory safe harbors that protect certain arrangements. Failure to meet the requirements of the safe harbor, however, does not render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances, including the parties' intent and the arrangement's potential for abuse, and may be subject to greater scrutiny by enforcement agencies.

The Federal False Claims Act (the "FCA") prohibits a person from knowingly presenting, or caused to be presented, a false or fraudulent request for payment from the federal government, or from making a false statement or using a false record to have a claim approved. The federal FCA further provides that a lawsuit thereunder may be initiated in the name of the United States by an individual, a "whistleblower," who is an original source of the allegations. Moreover, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Penalties for a violation of the FCA include fines for each false claim, plus up to three times the amount of damages caused by each false claim.

Further, the Civil Monetary Penalties Statute authorizes the imposition of civil monetary penalties, assessments and exclusion against an individual or entity based on a variety of prohibited conduct, including, but not limited to offering remuneration to a federal health care program beneficiary that the individual or entity knows or should know is likely to influence the beneficiary to order or receive health care items or services from a particular provider, practitioner, or supplier.

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder (collectively "HIPAA") also established federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals, and teaching hospitals. Applicable manufacturers and applicable group purchasing organizations must also report annually to CMS ownership and investment interests held by physicians and their immediate family members.

Several states in which we operate have also adopted similar fraud and abuse laws as described above. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Some state fraud and abuse laws apply to items or services reimbursed by any payor, including patients and commercial insurers, not just those reimbursed by a federally funded healthcare program.

Violation of any of these laws or any other governmental regulations that apply may result in significant penalties, including, without limitation, administrative civil and criminal penalties, damages, disgorgement, fines, additional reporting requirements and compliance oversight obligations, contractual damages, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and/ or imprisonment.

U.S. Coverage and Reimbursement

Our customers are typically reimbursed, in part, for the cost of our products by third party payors or are otherwise paid directly by patients in connection with procedures performed. In the United States, approximately 50% of adults aged 18 to 64 with private health insurance have dental care coverage. Dental practitioners bill for the procedures using the applicable Code on Dental Procedures and Nomenclature ("CDT") established by the American Dental Association. Reimbursement rates vary by payor, however, based on the procedure performed and are unrelated to the costs actually incurred by the dental practitioner in that procedure. We believe that the reimbursement rates for RCT have remained stable and generally cover dental practitioners for the cost of the GentleWave Procedure under existing billing codes. Where patients are uninsured and are not otherwise covered by a third party payor, these patients are expected to pay their respective dental practitioner out-of-pocket for their RCT.

Further, in the United States, government healthcare programs, including Medicare and Medicaid, generally provide limited to no coverage and reimbursement for dental procedures in which our products are used. Where third-party payor coverage is not available, patients are responsible for all of the costs associated with treatment using our products. As a result, our success depends in part on the ability and willingness of patients to pay out-of-pocket for treatment using our products. Certain commercial payors, Medicare Advantage plans and plans purchased through the ACA marketplace do, however, provide coverage and reimbursement for the procedures in which our products are used. No uniform policy of coverage and reimbursement among payors in the United States exists and coverage and reimbursement for procedures can differ significantly from payor to payor. As a result, the coverage determination process can be a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. To contain costs of new technologies, third-party payors are increasingly scrutinizing new and existing treatments by requiring extensive evidence of favorable clinical outcomes. Dentists may not purchase our products if they do not receive sufficient reimbursement from payors for the cost of the product or procedures using our product. If third-party payors do not provide coverage or adequate reimbursement levels for procedures using our products, the demand for our products will not increase and/or there may be significant pricing pressure, either of which could adversely impact our business and financial condition.

U.S. Healthcare Reform

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, many of which are intended to contain or reduce healthcare costs. By way of example, the Affordable Care Act ("ACA") substantially changed the way healthcare is financed by both governmental and private insurers. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. President Biden has issued executive orders instructing certain governmental agencies to review their existing policies or practices to identify ways to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage. It is unclear how these and other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact post-market regulation, the ACA or our business.

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

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and federal and state consumer protection laws and regulations (*e.g.*, Section 5 of the Federal Trade Commission Act) that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners.

For example, HIPAA imposes privacy, security and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, 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. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties.

Even when HIPAA does not apply, according to the Federal Trade Commission ("FTC"), violating consumers' privacy rights or 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. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

In addition, certain state and non-U.S. laws, such as the California Consumer Privacy Act ("CCPA"), the California Privacy Rights Act ("CPRA"), and the EU General Data Protection Regulation ("GDPR"), govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to make compliance efforts more challenging, and can result in investigations, proceedings, or actions that lead to significant penalties and restrictions on data processing.

Human Capital Resources and Employees

We employ a growing and highly-skilled employee base, including our sales force, and promote a culture of innovation to continuously iterate and enhance our products, systems and commercial footprint. Our human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and future employees.

As of December 31, 2023, we had 216 employees (including 200 full-time employees). Employee turnover has not had a material impact on our operations. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Our employees are our greatest asset and we seek to attract purpose-driven individuals who are devoted to our mission of saving teeth while improving lives. We have the following core values around three key focuses of Patients, Accountability and Positivity:

- *Diversity and inclusion. Our* team is comprised of a diverse group of different backgrounds, orientations, beliefs, perspectives and capabilities. We are committed to a culture where diversity, respect, belonging and authenticity are valued. In our recruitment practice we have diversity outreach to various employment boards.
- *Attraction and recruitment efforts.* We are committed to hiring the best talent. Our recruiting strategy involves utilization of social media, employee referral programs, as well as internal and external recruiters.
- *Training and development.* We are committed to developing our employees through on-boarding and continuous training sessions which are routinely re-administered, updated and refreshed. Employees are encouraged to participate in a variety of Company-provided learning resources and external training programs.
- *Workplace safety.* The safety, health, and well-being of our employees is our first priority by maintaining high safety and health standards. In addition to complying with all Federal, State and Local ordinances, we sponsor a safety committee to routinely review our polices, practices and programs to seek opportunities to further improve our safety and health standards.
- *Financial benefits and rewards.* We have designed and implemented our cash and stock compensation programs to attract, motivate, and retain our employees. We regularly review our compensation structure to ensure that we remain competitive, reward top performance, and ensure internal equity, while maintaining proper fiscal governance. Our compensation packages are designed based on market benchmarks. We offer robust benefits package including health (medical, dental & vision) insurance, paid time off, paid parental leave, a retirement plan and life and disability coverage.
- *Employee engagement.* We believe having employees be the best version of themselves is critical to our success, which is achieved by keeping our employees engaged through frequent and transparent communication across management levels. “Let the Best Idea Win” is our core value underlying the communication.

Corporate Information

We were incorporated in the State of Delaware in June 2006. Our principal executive offices are located at 26061 Merit Circle, Suite 102, Laguna Hills, California, and our telephone number is (949) 766-3636. Our website address is www.sonendo.com. We do not incorporate the information on or accessible through our website into this Annual Report, and you should not consider any information on, or that can be accessed through, our website a part of this Annual Report or any other filing we make with the SEC. We are an emerging growth company under the Jumpstart Our Business Startups Act of 2012 and also a smaller reporting company, and therefore we are subject to reduced public company reporting requirements.

Available Information

We make available, free of charge, on our website at www.sonendo.com our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to such reports, as soon as reasonably

practicable after such reports are electronically filed with, or furnished to, the SEC. All such reports are also available free of charge via EDGAR through the SEC website at www.sec.gov. We do not incorporate the information on or accessible through these websites into this Annual Report, and you should not consider any information on, or that can be accessed through, these websites a part of this Annual Report or any other filing we make with the SEC.

Item 1A. Risk Factors.

We operate in a rapidly changing environment that involves numerous uncertainties and risks. 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 contained in this Annual Report, including our consolidated financial statements and related notes as disclosed. 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 also contains forward-looking statements that involve risks and uncertainties. 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.

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

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

We have incurred significant net losses in each reporting period since our inception and expect to continue to incur net losses for the foreseeable future. For the years ended December 31, 2023 and 2022, we had net losses of $60.9 million and $57.1 million, respectively. Prior to our initial public offering (the "IPO"), we financed our operations primarily through net proceeds from the sale of our redeemable convertible preferred stock in private placements, indebtedness, including our credit agreement and, to a lesser extent, product and software revenue from sales of our GentleWave System and TDO software business. The losses and accumulated deficit have primarily been due to the substantial investments we have made to develop our products and software, costs related to our sales and marketing efforts, including costs related to clinical and regulatory initiatives to obtain marketing clearance or approval, and infrastructure improvements.

We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early-stage medical technology companies in rapidly evolving fields. In addition, as a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. Accordingly, we expect to continue to incur significant operating losses for the foreseeable future and we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult to finance our capital requirements needed to operate our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline.

Our common stock has been suspended from trading on the NYSE and may be delisted from the NYSE, which may negatively impact our stockholders and the trading price and liquidity of our common stock.

On November 15, 2023, we received notice from the NYSE that we were not in compliance with the continued listing standard set forth in Section 802.01B of the NYSE's Listed Company Manual ("Section 802.01B") because the Company's average global market capitalization over a consecutive 30 trading-day period was less than $50 million and, at the same time, its stockholders' equity was less than $50 million.On November 21, 2023, we received a notice from the NYSE that we were not in compliance with the continued listing standard set forth in Section 802.01B because we failed to maintain an average global market capitalization over a consecutive 30-day trading period of at least $15,000,000 under Section 802.01B. Accordingly, the NYSE commenced proceedings to delist the Common Stock. Trading of our common stock suspended on the NYSE effective at the opening of business Eastern Standard Time on November 22, 2023. While the Company has appealed this decision in

accordance with NYSE rules, and the appeal is still in process, there can be no assurance that an appeal will be successful. In the meantime, the Company's common stock is currently trading on the OTCQX, operated by the OTC Markets Group, Inc., under the symbols "SONX". The over-the-counter markets are a more limited market than the NYSE, and it is likely that there will be significantly less liquidity in the trading of our common stock.The suspension of trading and potential delisting of our common stock could have material adverse effects on our business, financial condition and results of operations due to, among other things:

- reduced trading liquidity and market prices for our common and preferred stock ;
- decreased number of institutional and other investors willing to hold or acquire our stock, coverage by securities analysts, market making activity and information available concerning trading prices and volume, as well as fewer broker-dealers willing to execute trades in our stock, thereby further restricting our ability to obtain equity financing;
- resulting event of default or noncompliance under certain of our debt facilities and other agreements; and
- reduced ability to retain, attract and motivate our directors, officers and employees by means of equity compensation.

If we are unsuccessful in our appeal, the NYSE will apply to the SEC to delist our common stock upon completion of all applicable procedures. Delisting our common stock from the NYSE may adversely impact its liquidity, impair our stockholders' ability to buy and sell our common stock, impair our ability to raise capital, and the market price of our common stock could decrease. Delisting our common stock could also adversely impact the perception of our financial condition and have additional negative ramifications, including further loss of confidence by our employees, the loss of institutional investor interest and fewer business opportunities.

Our revenue is primarily generated from sales of our GentleWave Console and the accompanying single-use PIs and, until recently, the TDO software segment, and our business, financial condition and results of operations are therefore highly dependent on the success of our remaining offerings.

To date, substantially all of our revenue has been derived from sales of our GentleWave Console and the accompanying single-use PIs, as well as our TDO software. On March 1, 2024, we divested our software segment by selling substantially all assets and liabilities of TDO Software, Inc. Our GentleWave Console and the accompanying single-use PIs are used to deliver the GentleWave Procedure. We began scaled commercialization of our current suite of products in the United States in 2017 and dental practitioner awareness of, and experience with, our products has been and is currently limited. As a result, our products currently have limited product and brand recognition within the dental industry as an alternative to the conventional methods of performing RCT. We do not have a long history operating as a commercial company, and the novelty of our products, together with our limited commercialization experience, makes it difficult to evaluate our current business and predict our future prospects with precision. These factors also make it difficult for us to forecast our financial performance and future growth, and such forecasts are subject to a number of uncertainties, including those outside of our control.

In addition, because we devote substantially all of our resources to our products and software and rely on these offerings as our primary source of revenue, any factors that negatively impact our offerings or result in a decrease in sales could have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline.

Our quarterly and annual operating results may fluctuate significantly and may not fully reflect the underlying performance of our business. This makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

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 operating results may fluctuate significantly 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. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the level of adoption of and demand for our offerings and the GentleWave Procedure;
- positive or negative coverage in the media or clinical publications, or changes in public, patient and/or dental practitioner perception, of our products or competing products and treatments, including our brand reputation;
- the degree of competition in our industry and any change in the competitive landscape, including consolidation among competitors or future partners;
- any safety, reliability or effectiveness concerns that arise regarding our products or other procedures to treat tooth decay;
- unanticipated pricing pressures in connection with the sale of our products and downward pressure on healthcare costs in general;
- the effectiveness of our sales and marketing efforts, including our ability to deploy a sufficient number of qualified sales representatives to sell and market our products;
- the timing of product orders or procedures using our products and the number of available selling days in any quarterly period, which can be impacted by holidays, the mix of products sold and the geographic mix of where products are sold;
- changes in reimbursement rates by government or commercial payors;
- unanticipated delays in product development or product launches;
- the cost of manufacturing our products, which may vary depending on the quantity of production, cost of labor and components and the terms of our arrangements with third-party suppliers;
- our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of our products;
- disruptions to our business and operations or to the business and operations of our suppliers and other third parties with whom we conduct business;
- our ability to achieve and maintain compliance with all regulatory requirements applicable to our products and services;
- our ability to obtain, maintain and enforce our intellectual property rights;
- our ability and our third-party suppliers' ability to supply the components of our products in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements; and
- introduction of new products, technologies or alternative treatments for tooth decay that compete with our products.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results and may decrease the value of our common stock. 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 deviate materially from our expectations and our business could suffer.

This variability and unpredictability could also result in our failure to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it will negatively affect our business, financial condition and results of operations and cause the market price of our common stock to decline.

As a result of the divestiture of our TDO software segment, we lost a substantial source of our revenues.

Our TDO software segment represented 21% and 20% of total revenues for fiscal years ended December 31, 2023 and 2022, respectively. By divesting our TDO software segment, we will no longer have the assets that generated these revenues and, unless we are able to increase our revenues through organic growth or acquisitions, our revenues following the disposition will be lower than they have been for these historical periods.

The divestiture of our TDO software segment may cause potential customers to be less likely to commit to purchases of GentleWave Console.

Our TDO practice management software is designed to improve practice workflow and seamlessly integrate with the GentleWave System. As a result of the divestiture of our TDO software segment and that the TDO software will be operated by a third party, potential customers may be less likely to commit to purchases of our GentleWave System.

The recent divestiture of our TDO software segment may disrupt our business or result in costs that could have a material adverse effect on our financial condition and results of operations.

The recent divestiture of our TDO software segment may disrupt our other business segments and divert management's attention away from our continuing operations. We have incurred expenses in connection with our divestiture of this business segment, which could materially adversely affect our financial condition or results of operations.

The terms of our credit agreement require us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility.

As of December 31, 2023, there was $40.0 million of outstanding principal under our amended and restated credit agreement with Perceptive Credit Holdings III, LP. Our indebtedness under this agreement is secured by substantially all of our assets. See the section of this Annual Report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Indebtedness."

The amended and restated credit agreement contains customary representations and warranties and affirmative covenants and also contains certain restrictive covenants, related to, among others, limitations on the incurrence of additional debt, liens and other encumbrances on property, fundamental changes and acquisitions, including mergers, consolidations and liquidations, changes to our type of business, use of cash and investment activities, dividends and other payments in respect of our capital stock, payments and prepayments of certain debt, changes in our fiscal year, sales of assets transactions with affiliates, licensing arrangements, modifications to material agreements and foundational documents, sale and leaseback arrangements and handling of hazardous materials. The amended and restated credit agreement also includes financial covenants that require us to (i) maintain, at all times, a minimum aggregate balance of $3.0 million in cash in one or more controlled accounts, and (ii) satisfy certain minimum revenue thresholds, measured for the 12 consecutive month period on each calendar quarter-end until June 30, 2026. See Note 9 to the consolidated financial statements for details.

Failure to satisfy these financial covenants would constitute an event of default under the agreement. These covenants may restrict our current and future operations, particularly our ability to respond to certain changes in our business or industry, or take future actions.

The amended and restated credit agreement also contains customary events of default. If we fail to comply with our affirmative and restrictive covenants, including the financial covenants, payments or other terms of the agreement, our lender could declare an event of default, which would give it the right to terminate its commitments and declare all amounts outstanding under the agreement immediately due and payable, together with accrued interest and all fees and other obligations. The amount of such repayment will include payment of any prepayment premium applicable due to the time of such payment. In addition, upon the occurrence and during the continuance of any event of default, the applicable margin will increase by 3.00% per annum to 12.25%. In addition, our lender would have the right to proceed against the assets we provided as collateral. If the debt under the amended and restated credit agreement were accelerated, we may not have sufficient cash or be able to sell sufficient assets to repay this debt, which would harm our business and financial condition. There is a material uncertainty that raise substantial doubt about our ability to continue as a going concern and, therefore, that we may be unable to realize our assets and discharge our liabilities in the normal course of business.

On March 1, 2024, we entered to Amendment No. 3 to the amended and restated credit agreement. Pursuant to this amendment, we made a one-time $15.0 million principal repayment on March 1, 2024, and agreed to make an amortization payment of $1.8 million on the outstanding principal on March 31, 2024 and make monthly amortization payments on the outstanding principal amount each in the amount of $0.9 million on each payment date commencing on April 30, 2024. The Third Amendment also modified certain covenants included in the Amended Perceptive Loan Agreement and released all liens granted to the TDO software assets. We may need to refinance or secure separate financing in order to repay amounts outstanding when due, however, no assurance can

be given that an extension will be granted, that we will be able to renegotiate the terms of the agreement with the lender or that we will be able to secure separate debt or equity financing on favorable terms, if at all.

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

We may need additional funding beyond the capital resources currently available to us to finance our planned operations, and may not be able to raise capital when needed, which could force us to delay, reduce or eliminate one or more of our product development programs and future commercialization efforts.

As of December 31, 2023, we had cash and cash equivalents and short-term investments of $46.8 million, an accumulated deficit of $430.0 million and a $40 million outstanding principle under our term loan facility, of which $24.9 million will be repaid by the end of 2024. There is a material uncertainty that raise substantial doubt about our ability to continue as a going concern and, therefore, that we may be unable to realize our assets and discharge our liabilities in the normal course of business.

We require additional capital in the future for our planned operations. To the extent additional capital is necessary, there are no assurances that we will be able to raise additional capital on favorable terms or at all, and therefore we may not be able to execute our business plan. Our future funding requirements will depend on many factors, including:

- the degree and rate of market acceptance of our current and future products and the GentleWave Procedure;
- the scope and timing of investment in our sales force;
- the cost of our research and development activities;
- the cost and timing of additional regulatory clearances or approvals;
- the costs associated with any product recall that may occur;
- the costs associated with the manufacturing of our products at increased production levels;
- the costs of attaining, defending and enforcing our intellectual property rights;
- whether we acquire third-party companies, products or technologies;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the scope, rate of progress and cost of our current or future clinical studies and registries;
- the emergence of competing new products, technologies or alternative treatments or other adverse market developments;
- the rate at which we expand internationally;
- our ability to raise additional funds to finance our operations;
- debt service requirements; and
- the cost associated with being a public company.

We may seek to raise additional capital through equity offerings or debt financings and such additional financing may not be available to us on acceptable terms, or at all. In addition, any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. For example, if we raise funds by issuing equity or equity-linked securities, the issuance of such securities could result in dilution to our stockholders. Any

equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline, and the price per share at which we sell additional shares of our common stock, or securities convertible into or exercisable or exchangeable for shares of our common stock, in future transactions may be higher or lower than the price per share paid by investors to purchase our common stock.

In addition, the terms of debt securities issued or borrowings could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to pay dividends, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. For example, our current credit agreement prohibits us from incurring certain additional indebtedness without the consent of our lender.

In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, such as relinquishment or licensing of certain technologies or products that we otherwise would seek to develop or commercialize ourselves, or reserve for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us.

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

We maintain cash deposits in excess of federally insured limits. Adverse developments affecting financial institutions, including bank failures, could adversely affect our liquidity and financial performance.

We regularly maintain domestic cash deposits in Federal Deposit Insurance Corporation ("FDIC") insured banks, which exceed the FDIC insurance limits. Bank failures, events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about such events, may lead to widespread demands for customer withdrawals and liquidity constraints that may result in market-wide liquidity problems. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the U.S. government in the future or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a future failure or liquidity crisis.

Risks Related to Our Business and Industry

The commercial success of our GentleWave System and the GentleWave Procedure will depend upon the degree of market acceptance of our products by dental practitioners, and failure to achieve or maintain market acceptance and/or market share could materially and adversely affect our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations.

Our success will depend, in large part, on the acceptance of our GentleWave System as effective, reliable, easy to use and cost-effective. We believe the GentleWave Procedure represents a new approach for treating tooth decay by effectively debriding and disinfecting deep regions of the complex root canal system in a less invasive procedure that preserves tooth structure. We believe that market acceptance will be driven primarily by dental practitioners, and if they do not adopt the concept of a less invasive, fluid-based technology and perceive such technology as having significant advantages over other surgical alternatives, patients will be less likely to accept or be offered the GentleWave Procedure and we will fail to meet our business objectives. Dental practitioners' perceptions of our technology having significant advantages are likely to be based on a determination that, among other factors, our products are safe, effective, cost-effective and represent acceptable methods of treatment. Even if we can prove the

effectiveness of the GentleWave Procedure through in vitro and clinical trials, there may not be broad adoption and use of our products and dental practitioners may elect not to use our products for any number of other reasons, including:

- lack of experience with our products and concerns that we are relatively new to market;
- perceived liability risk generally associated with the use of new products and treatment options, and with respect to converting from existing software and systems to our software offering;
- lack or perceived lack of (i) sufficient clinical evidence regarding our claims of superior cleaning and disinfection in a less invasive procedure, high and fast rates of healing, minimal to no post-operative pain and (ii) long-term data, supporting clinical benefits or the cost-effectiveness of our products over existing treatment alternatives;
- the failure of key opinion leaders to provide recommendations regarding our products, or to assure dental practitioners and healthcare payors of the benefits of our products as an attractive alternative to other treatment options;
- perception that our products are unproven in practice and our failure to maintain practice and dental practitioner benefits;
- perception that our GentleWave Procedure is appropriate for only a limited percentage of patients;
- long-standing relationships with companies and distributors that sell other products or treatment options for treating tooth decay;
- concerns over the capital investment required to purchase our GentleWave System and perform the GentleWave Procedure;
- concerns relating to adverse events that are reported with the use of the GentleWave System;
- lack of availability of adequate third-party payor coverage or reimbursement;
- pricing pressure, including from Dental Service Organizations;
- competitive response and negative selling efforts from providers of alternative treatments; and
- limitations or warnings contained in the labeling cleared or approved by the FDA, or approved or certified by other authorities or bodies.

We believe that educating notable industry key opinion leaders and dental practitioners about the merits and benefits of our GentleWave System, such as safety, performance, ease of use and efficiency, is one of the key elements of increasing the adoption of our products. If they do not adopt our products for any reason, our ability to execute our growth strategy will be impaired, and it will negatively affect our business, financial condition, prospects and results of operations.

Even if our GentleWave System achieves widespread market acceptance, it may not maintain such level of market acceptance over the long-term if competing products or technologies, which are more cost-effective or received more favorably, are introduced. In addition, our limited commercialization experience makes it difficult to evaluate our current business and predict our future prospects. We cannot predict how quickly, if at all, dental practitioners and patients will accept our GentleWave System or, if accepted, how frequently it will be used. Failure to achieve or maintain market acceptance and/or market share could materially and adversely affect our ability to generate revenue and would have a material adverse effect on our business, financial condition and results of operations.

The continuing acceptance of our products depends upon maintaining strong working relationships with our existing clinician and dental customers, and if we cannot maintain strong working relationships with these professionals, the development and marketing of our products could suffer, which could harm our business, financial condition and results of operations.

The development, marketing, and sale of our products depends upon our ability to maintain strong working relationships with dental practitioners and other key opinion leaders. We rely on these professionals' knowledge and experience for the development and sale of our products. Among other things, dental practitioners assist us in

product development matters and provide public presentations at trade conferences regarding our products. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could harm our business, financial condition and results of operations.

Our future success is dependent upon our ability to increase penetration in our existing markets and expand into adjacent markets.

Currently, we are focused on leveraging our GentleWave System to transform conventional methods of performing RCT, which we believe are antiquated. Our success will depend upon our ability to increase our market penetration. We cannot guarantee that we will be able to further penetrate our existing markets or that these markets will be able to sustain our current and future product and service offerings. Any failure to increase penetration in our existing markets would adversely affect our ability to improve our operating results.

The extent of our success will also depend on our ability to further expand into adjacent markets, such as the treatment of cavities and earlier-stage tooth decay. We plan to generate supporting publications and data for such alternative treatments, as well as pursue any required regulatory clearances and approvals. We may be unsuccessful in receiving such regulatory clearances and approvals or generating supporting data and our efforts to expand the application of our GentleWave System may fail. Our failure to further expand in new markets and attract new customers could adversely affect our ability to improve our operating results.

We may provide inadequate training, fail to increase our sales and marketing capabilities or fail to develop and maintain broad brand awareness in a cost-effective manner.

We rely on our direct sales force to sell our products in targeted geographic regions and territories, and any failure to maintain and grow our direct sales force could harm our business. The members of our direct sales force are specifically trained to market and sell our products and the GentleWave Procedure and they possess technical expertise, which we believe is critical in driving the awareness and adoption of our products. The members of our 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 comparable expertise and qualifications, or if we are unable to successfully instill such expertise in replacement personnel, our product sales, revenues and results of operations could be materially harmed.

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

Our ability to increase our base of clinicians and achieve broader market acceptance of our products will depend, to a significant extent, on our ability to expand our sales and marketing and educational efforts. We plan to dedicate significant resources to our sales and marketing and educational programs. Our business may be harmed if these efforts and expenditures do not generate a corresponding increase in revenue.

In addition, we believe that developing and maintaining broad awareness of the GentleWave Procedure in a cost-effective manner is critical to achieving broad acceptance of our products and reaching new dental practitioners and patients. Promotion and educational activities may not generate dental practitioner awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur. If we fail to successfully promote the GentleWave Procedure in a cost-effective manner, we may fail to attract or retain the

market acceptance necessary to realize a sufficient return on our promotional and educational efforts, or to achieve broad adoption of our products.

We may not be able to obtain or maintain adequate levels of third-party coverage and reimbursement, and third parties may rescind or modify their coverage or delay payments related to our products.

We derive the majority of our revenue from sales of our GentleWave Console and single-use PIs to dental practitioners. Sales of our products will depend, in part, on the extent to which the procedures using our products are covered and reimbursed by third-party payors, including private insurers and government healthcare programs such as Medicare Advantage plans and plans purchased through the ACA marketplace. Where third-party payor coverage is not available, patients are responsible for all of the costs associated with treatment using our products. Even if a third-party payor covers a particular treatment that uses our products, the resulting reimbursement rate may not be adequate to cover a provider's cost to purchase our products or ensure such purchase is profitable for the provider.

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

- a covered benefit;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- supported by guidelines established by the relevant professional societies;
- cost-effective; and
- neither experimental nor investigational.

Our clinician and dental customers typically bill third-party payors for the costs and fees associated with the procedures in which our products are used. Because there is often no separate reimbursement for supplies used in a root canal procedure or for the purchase of the capital equipment needed to perform a procedure, the additional cost associated with the use of our products can affect the profit margin of the dental practitioner. Some of our target customers may be unwilling to adopt our products in light of potential additional associated cost. In addition, clinicians that perform the procedure may be subject to reimbursement claim denials upon submission of the claim. Clinicians may also be subject to recovery of overpayments if a payor makes payment for the claim and subsequently determines that the payor's coding, billing or coverage policies were not followed. These events, or any other decline in the amount payors are willing to reimburse our clinician and dental customers, could make it difficult for existing customers to continue using or to adopt our products and could create additional pricing pressure for us. If we are forced to lower the prices we charge for our products, our gross margins will decrease, which could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business.

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

Payors continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing products and procedures. There can be no assurance that third-party payor policies will provide coverage for procedures in which our products are used. Many third-party payors do not

currently cover our products and the related procedures because they have determined that our products and the related procedures are experimental or investigational. When our products and the related procedures are reimbursed, they are reimbursed primarily on a per-patient prior authorization basis for patients covered by commercial insurers.

Further, future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the United States, Canada and in relevant international markets in which we plan to operate. Third-party coverage and reimbursement for procedures using our products or any of our products in development for which we may receive regulatory clearance, approval or certification may not be available or adequate in either the United States, Canada or international markets. Further, other RCT procedures may be more widely covered or subject to different co-pay policies and requirements, which could impact demand for our products. If dental practitioner and/or patient demand for our products is adversely affected by changes in third-party reimbursement policies and decisions, it could have a material adverse effect on our business, financial condition 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 current or any new products or maintain prices at the levels we have historically achieved. For example, any decline in the amount that third-party payors reimburse clinicians for our products could make it difficult for them to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, including during any international expansion, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. Additionally, some parts of the dental market continue to be impacted by price competition which are driven in part by the consolidation of dental practices, innovation and product advancements, and the price sensitivity of consumers and patients. We will continue to be subject to significant pricing pressure, which could negatively affect our business, financial condition and results of operations.

We face competition from many sources, including larger companies, and we may be unable to compete successfully.

We operate in a highly competitive industry that is significantly affected by the introduction of new products and technologies and other activities of industry participants. Our products and the GentleWave Procedure represent an innovative approach to the treatment of tooth decay and, as a result, our treatment method competes directly against conventional methods of treating root canals, including sonic, ultrasonic and laser- assisted irrigation devices. We compete with manufacturers and suppliers of devices, instruments and other supplies used in connection with such conventional treatments. The market for these devices and instruments is highly fragmented with primary supply chains concentrated across a few larger manufacturers and distributors, such as Dentsply Sirona, Envista and Henry Schein.

Many of our competitors have longer, more established operating histories, and significantly greater name recognition and financial, technical, marketing, sales, distribution and other resources, which may prevent us from achieving significant market penetration or improved operating results. These companies may enjoy several other competitive advantages, including established relationships with dental practitioners who are familiar with other alternatives for performing root canals, additional lines of products, and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage and established sales, marketing and worldwide distribution networks.

We believe the primary competitive factors for companies that market new or alternative treatments and solutions in dental applications include acceptance by leading clinicians, patient outcomes and adverse event rates, patient experience and treatment time, ease-of-use and reliability, patient recovery time and level of discomfort, economic benefits and cost savings, intellectual property protection and the development of successful sales and marketing channels. One of the major hurdles to widespread adoption of our solutions will be overcoming established treatment patterns, which will require education of patients, clinicians and their referral sources.

In addition, we may compete with additional competitors and products outside the United States and Canada when we pursue plans to market our products internationally. Among other competitive advantages, such companies may have more established sales and marketing programs and networks, established relationships with clinicians and greater name recognition in such markets.

If we are unable to continue to innovate and improve our GentleWave System, we could lose market share.

The medical device industry is characterized by rapid and significant change. Our success will depend on our ability to keep ahead of innovative developments in the treatment of tooth decay and performance of root canal treatments. It is critical to our competitiveness that we continue to innovate and make improvements to our GentleWave System's functionality and efficiency. If we fail to make improvements to our GentleWave System's functionality over time, our competitors may develop products that offer features and functionality similar or superior to those of our GentleWave System or that are more cost- effective than our GentleWave System. Our failure to make continuous improvements to our GentleWave System to keep ahead of the products of our competitors could result in the loss of market share that would adversely affect our business, results of operations, and financial condition.

New product development takes time and requires considerable resources and we may be unable to develop or commercialize products on a timely basis, or at all.

Products from our research and development programs will take time and considerable resources to develop, and may include improvements or changes to our current products, and we may not be able to complete development and commercialization of new or enhanced products on a timely basis, or at all. There can be no assurance that our research and development efforts will produce commercially viable products and technologies. Commercializing new products requires expending significant funds to, for example:

- conduct substantial research and development;
- obtain necessary regulatory clearance or approval;
- further develop and scale our engineering, manufacturing and packaging processes to accommodate different products;
- source and enter into agreements with new suppliers; and
- further develop and scale our infrastructure.

Our product development processes involve a high degree of risk, and these efforts may be delayed or fail for many reasons, including failure of the product to perform as expected, failure to receive the necessary regulatory clearance or approval, and failure to reliably demonstrate the advantages of the product.

Even if we are successful in developing new products, it will require us to make significant additional investments in marketing and selling resources to commercialize any such products. As a result, we may be unsuccessful in commercializing new products that we develop, which could adversely affect our business, financial condition, results of operations and prospects.

We have limited experience manufacturing our products in large-scale commercial quantities and we face a number of manufacturing risks that may adversely affect our manufacturing abilities, which could delay, prevent or impair our growth.

Our growth strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet demand, while adhering to product quality standards, complying with regulatory quality system requirements, such as the FDA's quality system regulations, and managing manufacturing costs in our current manufacturing facility or any future manufacturing facilities. We have a sole manufacturing facility located in Laguna Hills, California, where we manufacture, assemble, test, package and ship our products. We currently assemble all of our GentleWave Console and single-use PIs at this one facility, and we do not have

additional facilities. If this facility, or any of our future manufacturing facilities, suffers damage, or a force majeure event, such damage or event could materially impact our ability to operate, which could materially and adversely affect our business, financial condition and results of operations.

We are also subject to numerous other risks relating to our manufacturing capabilities, including:

- quality and reliability of components, sub-assemblies and materials that we source from third-party suppliers, who are required to meet our quality specifications, some of whom are single or sole source suppliers for the items and materials that they supply;
- our inability to secure components, sub-assemblies and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our inability to maintain compliance with quality system requirements or pass regulatory quality inspections;
- our failure to increase production capacity or volumes to meet demand;
- potential risks associated with disruptions in our supply chain, such as on account of the COVID-19 pandemic or another pandemic, epidemic or infectious disease outbreak or due to political, economic or other social instability;
- longer than expected lead times associated with securing key components;
- our inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements; and
- difficulty identifying and qualifying, and obtaining new regulatory clearances or approvals, for alternative suppliers for components in a timely manner.

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

As we continue to scale the commercial production of our products and increase our manufacturing capacity, we may encounter quality issues that could result in product defects, errors or recalls. Manufacturing delays related to quality control, including such delays that are caused by our suppliers, could negatively impact our ability to bring our products to market, harm our reputation and decrease our revenue. Further, in the past, we have voluntarily replaced and recalled certain of our products, including based on design iterations and customer feedback, and no assurance can be given that such events or actual product recalls will not occur in the future. Any defects, errors, recalls or other replacement of products could be expensive and generate negative publicity, which could impair our ability to market or sell our products, and adversely affect our results of operations.

Furthermore, we may be unable to renew our lease 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 investors that such a move would not delay or otherwise adversely affect our manufacturing activities or operating results. If our manufacturing capabilities were impaired by our move, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business, financial condition and results of operations.

We depend upon third-party suppliers, including contract manufacturers and single and sole source suppliers, making us vulnerable to supply shortages and price fluctuations that could negatively affect our business, financial condition and results of operations.

We rely on third-party suppliers, including in some instances single or sole source suppliers, to provide us with certain components, sub-assemblies and finished products for our products. These components, sub-assemblies and finished products are critical and, for a small number of items, there are relatively few alternative sources of supply. For example, our GentleWave Console includes a number of components, including high pressure lines, high pressure pumps, fluid temperature control systems, degassing systems and user interface control systems, most of which we source externally from third party suppliers. We do not currently have long-term supply contracts with certain of the sole and single source suppliers of these key components, and there are no minimum purchase or payment requirements. Additionally, we believe we are not a major customer to many of our suppliers. Our suppliers may therefore give other customers' needs higher priority than ours, and we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms. These single or sole source suppliers may be unwilling or unable to supply the necessary materials and components or manufacture and assemble our products in a reliable manner and at the levels we anticipate or at levels adequate to satisfy demand for our products. While our suppliers have generally met our demand for their products and services on a timely basis in the past, we cannot guarantee that they will in the future be able to meet our demand for such products, either because of acts of nature, regulatory enforcement actions, the nature of our agreements with those suppliers or our relative importance to them as a customer, and our suppliers may decide in the future to discontinue or reduce the level of business they conduct with us.

We have not been qualified or obtained necessary regulatory clearances for additional suppliers for most of these components, sub-assemblies and materials. While we currently believe that alternative sources of supply or sterilization may be available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers or providers would be able to provide the quantity and quality of components, materials and sterilization that we would need to manufacture and ship our products if our existing suppliers and providers were unable to satisfy our requirements. To utilize other sources, we would need to identify and qualify new providers to our quality standards and obtain any additional regulatory clearances or approvals required to change providers, which could result in manufacturing delays and increase our expenses.

Although we believe that we have stable relationships with our existing suppliers, we cannot assure you that we will be able to secure a stable supply of components or materials going forward. In the event that any adverse developments occur with our suppliers, in particular for those components that are single or sole sourced, or if any of our suppliers modifies any of the components they supply to us, our ability to supply our products may be temporarily or permanently interrupted. Obtaining substitute components could be difficult, time and resource-consuming and costly. Also, there can be no assurance that we will be able to secure a supply of alternative components at reasonable prices without experiencing interruptions in our business operations. In addition, quarantines, shelter-in-place and similar government orders related to infectious disease outbreaks, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, could impact the suppliers upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our products.

Our dependence on third-parties subjects us to a number of additional risks that could impact our ability to manufacture our products and harm our business, including:

- interruption of supply or sterilization resulting from modifications to, or discontinuation of, a third party's operations;

- delays in product shipments resulting from uncorrected defects or errors, reliability issues or a third party's failure to produce components or complete sterilizations that consistently meet our quality specifications;
- price fluctuations due to a lack of long-term supply arrangements with our third parties for key components or sterilization requirements;
- inability to obtain adequate supply or services in a timely manner or on commercially reasonable terms;
- difficulty identifying and qualifying alternative third parties for the supply of components or for sterilization of our products in a timely manner;
- interruptions or delays in logistics and transportation of the required components;
- inability of third parties to comply with applicable provisions of the FDA's QSR, or other applicable laws or regulations enforced by the FDA, state and global regulatory authorities;
- inability to ensure the quality of products manufactured or sterilization conducted by third parties;
- production delays related to the evaluation and testing of products and services from alternative third parties and corresponding regulatory qualifications;
- trends towards consolidation within the medical device manufacturing supplier industry; and
- delays in delivery by our suppliers and service providers.

Although we require our third-party suppliers and providers to supply us with components and services that meet our specifications and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that these third parties will not always act consistent with our best interests, and may not always supply components or provide services that meet our requirements or in a timely manner. In addition, we cannot assure you that our suppliers have obtained and will be able to obtain or maintain all licenses, permits, clearances and approvals necessary for their operations or comply with all applicable laws and regulations, and failure to do so by them may lead to interruption in their business operations, which in turn may result in shortages of components supplied to us.

Shipping is a critical part of our business and any changes in our shipping arrangements or damages or losses sustained during shipping could adversely affect our business, financial condition, results of operations and prospects.

We currently rely on third-party vendors for our shipping. If we are not able to negotiate acceptable pricing and other terms with these entities or they experience performance problems or other difficulties, it could negatively impact our operating results and the experience of our clinical and dental customers. Additionally, our manufacturing operations and growing business may require global shipping services which are subject to certain factors outside of our control, such as delays passing through customs and disruptions to global shipping routes. Moreover, there is no guarantee that our systems will not become damaged or lost in transit, and we have experienced, and expect to continue to experience, delivery difficulties. If a system is damaged in transit, it may result in a substantial delay in the fulfillment of the order, and depending on the type and extent of the damage and whether the incident is covered by insurance, it may result in clinician dissatisfaction and a substantial financial loss for us. If our products are not delivered in a timely fashion or are lost during the delivery process, clinicians could also become dissatisfied and cease using our products or services, which would adversely affect our business, financial condition, results of operations and prospects.

If we receive a significant number of warranty claims or our GentleWave Systems require significant amounts of service after sale, our operating expenses may substantially increase and our business and financial results will be adversely affected.

We currently warrant each GentleWave System against defects in materials and workmanship primarily for a period of 12 months from receipt of our product by a customer. We also expect to provide technical and other services beyond the warranty period pursuant to a supplemental service plan that we sell for our GentleWave System. We have a limited history of commercial placements from which to judge our rate of warranty claims, and we expect that the number of warranty claims we receive may increase as we scale our operations and as our existing commercial placements age. If product returns or warranty claims are significant or exceed our expectations, we could incur unanticipated reductions in sales or additional operating expenditures for parts and service. In addition, our reputation could be damaged and our products may not achieve the level of market acceptance that we are targeting in order to achieve and maintain profitability. Unforeseen warranty exposure could negatively impact our business and financial results.

We need to ensure strong product performance and reliability to maintain and grow our business, otherwise our business, financial condition and results of operations will suffer.

We need to maintain and continuously improve the performance and reliability of our GentleWave System to achieve our profitability objectives. Poor product performance and reliability could lead to clinician dissatisfaction, adversely affect our reputation and revenues, and increase our service and distribution costs and working capital requirements. In addition, software and hardware incorporated into our GentleWave System may contain errors or defects, especially when first introduced and while we have made efforts to test this software and hardware extensively, we cannot assure that the software and hardware, or software and hardware developed in the future, will not experience errors or performance problems.

We believe that our clinicians and consumers are sensitive to product defects and errors. Our reputation and the public image of our products, services and technologies may be impaired if our products or services fail to perform as expected. If our products do not perform, or are perceived to not have performed, as expected or favorably in comparison to competitive products, our operating results, reputation, and business will suffer, including due to the costs associated with replacing products and decreased demand for our product offering. Any of the foregoing could have an adverse effect on our business, financial condition and results of operations.

Although our products are tested prior to shipment, defects or errors could nonetheless occur. Our operating results depend on our ability to execute and, when necessary, improve our quality management strategy and systems and our ability to effectively train and maintain our employee base with respect to quality management. A failure of our quality control systems or those of our third party suppliers could result in problems with facility operations or preparation or provision of products. In each case, such problems could arise for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with off- the-shelf materials, sub-assemblies, parts and other components or environmental factors and damage to, or loss of, manufacturing operations.

We may encounter difficulties in managing our growth, which could disrupt our operations.

We have experienced substantial growth in our operations, and we expect to experience continued substantial growth in our business. Over the next several years, we expect to increase significantly the scope of our operations, particularly in the areas of manufacturing, sales and support, research and development, product development, regulatory affairs, marketing and other functional areas, including finance, accounting, quality control, and legal, especially as we transition to operating as a public company. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational quality and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to manage the expansion of our operations or recruit and train additional qualified personnel in an effective manner. In addition, the physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our results of operations will be materially harmed if we are unable to accurately forecast demand for, and utilization of, our GentleWave System and manage our inventory.

To ensure adequate inventory supply, we must forecast inventory needs and manufacture our GentleWave System console and the single-use PIs based on our estimates of future demand for, and utilization of, our GentleWave System. Our ability to accurately forecast demand and utilization could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in demand for our products or for products of our competitors, our failure to accurately forecast 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 demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate demand and utilization, our supply chain, manufacturing partners and/or internal manufacturing team may not be able to deliver components and products to meet our requirements, and this could result in damage to our reputation and relationships with clinicians and dental practitioners. In addition, if we experience a significant increase in demand or utilization, additional supplies of off-the-shelf materials, sub-assemblies, parts and other components or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, which will adversely affect our business, financial condition and results of operations.

Our internal computer systems or those used by our contractors or consultants, may fail or suffer security breaches, and such failure could negatively affect our business, financial condition and results of operations.

The continued development, maintenance and operation of our software are important factors impacting the success of our offerings and level of market acceptance and adoption of products. These efforts are expensive and complex and may involve unforeseen difficulties, including material performance problems and undetected defects or other technical or human errors. We may encounter technical obstacles, and it is possible that we may discover additional problems that prevent our software and technologies from operating properly. If our software or technologies, individually or collectively, do not function reliably or fail to meet clinician, payor or patient expectations of performance or outcomes, then clinicians may stop using or offering our solutions, payors could attempt to cancel their contracts with us and patients may generate negative publicity about their experience or our products.

Proprietary software development is time-consuming, expensive and complex, and may involve unforeseen difficulties. Our software sold may contain errors or vulnerabilities. Any real or perceived errors, failures, bugs or other vulnerabilities discovered in our existing or new software could result in negative publicity and damage to our reputation, loss of customers, loss of or delay in market acceptance of our products, loss of competitive position, loss of revenue or liability for damages, overpayments and/or underpayments, any of which could harm our business and results of operation.

In the ordinary course of our business, we collect, use, disclose, transfer, process and store sensitive data, including legally protected individually identifiable health information in the United States, credit card, and other financial information, insurance information, and other potentially personally identifiable information. We also process and store, and use additional third parties to process and store, sensitive intellectual property and other proprietary business information, including that of our customers.

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing, inventory management and other related functions. We do not have redundant information technology in all aspects of our systems at this time. Despite the implementation of security and back-up measures, our internal computer, server, and other information technology systems as well as those of our third-party consultants, contractors, suppliers, and service providers, may be vulnerable to damage from physical, electronic or technical break-ins, accidental or intentional exposure of our data by employees or others with authorized access to our networks, computer viruses, malware, ransomware, supply chain attacks, natural disasters, terrorism, war, telecommunication and electrical failure, denial of service, “phishing attacks” and other cyberattacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive, and/or proprietary data, including personal information, including health-related information, and could subject us to

significant liabilities and regulatory and enforcement actions, and reputational damage. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Such theft could also lead to loss of intellectual property rights through disclosure of our proprietary business information, and such loss may not be capable of remedying. We have also outsourced elements of our information technology infrastructure, and as a result a number of third- party vendors may or could have access to our confidential information. If we or our third-party consultants, contractors, vendors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal or health information, we may have to notify consumers, partners, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Likewise, we rely on third parties to conduct clinical trials, and similar events relating to their computer systems and networks could also have a material adverse effect on our business. The COVID-19 pandemic has generally increased the risk of cybersecurity intrusions. Our reliance on internet technology and the number of our employees who are working remotely may create additional opportunities for cybercriminals to exploit vulnerabilities. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from "hackers" hoping to use the recent COVID-19 pandemic to their advantage. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. If our systems are damaged or cease to function properly due to any number of causes, ranging from catastrophic events to power outages to security breaches, and our business continuity plans do not effectively compensate timely, we may suffer interruptions in our ability to manage operations, and would also be exposed to a risk of loss, including financial assets or litigation and potential liability. We must have a designated employee to oversee cybersecurity operations and maintain a data security/information security program with specific measures, employee training, comprehensive risk assessments, vendor contract requirements, and timely data disposal. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems or data or systems of our commercial partners, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, or other sensitive, personal, or health information, we could incur liability and suffer reputational harm. Failure to maintain or protect our information technology systems effectively could negatively affect our business, financial condition and results of operations.

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

Natural or man-made disasters and other similar events may significantly disrupt our business, including by causing delays in production or an increase in costs, and negatively impact our business, financial condition and results of operations.

A significant portion of our employee base, and our research and development, manufacturing and administrative facility and infrastructure are centralized in Southern California. We do not currently have additional operational facilities. Should our facility be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, wildfires, floods, nuclear disasters, riots, acts of terrorism or other criminal activities, public health emergencies such as infectious disease outbreaks, power outages and other infrastructure failures, it could take months to relocate or rebuild, during which time our employees may seek other positions, our research, development and manufacturing capabilities would cease or be delayed and our products may be unavailable. To the extent any additional facilities are available and operational at the time of such events, transitioning manufacturing capacity to offset the loss of our manufacturing facility in Laguna Hills may not be possible or may not be cost effective. Moreover, the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems may require regulatory review and approval of the new facility prior to commencing full-scale production

and commercialization. Because of the time required to register and/or authorize manufacturing in a new facility under FDA, 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 in the event that we lose our manufacturing capacity. Any disruptions in our operations could adversely affect our business and results of operations and harm our reputation. Moreover, although we have disaster recovery plans, they may prove inadequate. We may not carry sufficient business insurance to compensate for losses that may occur. The inability to perform our research and development and manufacturing activities, combined with our limited inventory of materials and components and manufactured products, may cause dental practitioners to discontinue using our products or harm our reputation, and we may be unable to reestablish relationships with such dental practitioners in the future. Consequently, a catastrophic event at our facility could have a material adverse effect on our business, financial condition and results of operations. In addition, the facilities of our suppliers may be harmed or rendered inoperable by such natural or man-made disasters, which may cause disruptions, difficulties or otherwise materially and adversely affect our business, financial condition and results of operations.

The sizes of the addressable markets for our GentleWave System have not been established with precision and our potential market opportunity may be smaller than we estimate and may decline.

Our estimates of the potential annual total addressable market for our GentleWave System are based on a number of internal and third-party estimates, including, without limitation, the assumed prices at which we can sell our GentleWave Console and the single-use PIs. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our GentleWave System may prove to be incorrect. If the actual number of dental practitioners in our target markets, the number of RCT procedures performed each year, the price at which we can sell our GentleWave System, or the total addressable market for our GentleWave System is smaller than we have estimated, it may impair our sales growth and materially and adversely affect our business, financial condition and results of operations.

In addition, our growth strategy involves launching new products or features and expanding sales of existing products into new markets and geographies in which we have limited experience. Sales of new or existing products into new market opportunities may take several years to develop and mature, and we cannot be certain that these market opportunities will develop as we expect. As a result, the sizes of the annual total addressable market for new markets and new products are even more difficult to predict.

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 GentleWave System, the single-use consumable or any of their component parts causes, or is perceived to cause, injury or is found to be otherwise unsuitable during manufacturing, marketing or sale. We may also be subject to product liability claims if our products or services are deemed to be non-compliant with applicable laws or regulations. 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 conditions of the patient. 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, or manufacturers who produce our GentleWave Console and the single-use PIs.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt the marketing and sale 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;
- harm to our reputation;

- initiation of investigations by regulators, which could result in enforcement action against us or our contract manufacturers;
- 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; and
- exhaustion of any available insurance and our capital resources.

The risk of a product liability lawsuit may increase if our products were deemed to be non-compliant with applicable laws and regulation. In the event we face a product liability lawsuit, 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 our products. 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.

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

We do not carry insurance for all categories of risk that our business may encounter. Although we have general and product liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. Similarly, we have limited insurance coverage regarding hazardous waste and cybersecurity events. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could negatively affect our business, financial condition and results of operations.

Additionally, the substantial increase in the cost of directors' and officers' liability insurance may cause us to opt for reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, on our board committees or as executive officers. We do not know if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition and results of operations.

We may seek strategic alliances, joint ventures or collaborations, or enter into licensing or partnership arrangements in the future and may not be successful in doing so, and even if we are, we may not realize the benefits or costs of such relationships.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into licensing or partnership arrangements with third parties that we believe will complement or augment our sales and marketing efforts with respect to our GentleWave System. We may not be successful in our efforts to establish such collaborations. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for our products. We cannot be certain that, following a strategic alliance or similar arrangement, we will achieve the revenue or specific net income that justifies such transaction. In addition, any potential future collaborations may be terminable by our collaborators, and we may not be able to adequately protect our rights under these agreements. Any termination of collaborations we enter into in the future, or delays in entering into new strategic partnership agreements could delay tour sales and marketing efforts, which would harm our business prospects, financial condition and results of operations.

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

As international expansion of our business occurs in future years, it will expose us to market, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our long-term strategy is to increase our international presence, including securing regulatory clearances or approvals in targeted countries outside the United States. This strategy may include establishing and maintaining dental practitioner outreach and education capabilities outside of the United States and expanding our relationships with international payors. Doing business internationally involves a number of risks, including:

- difficulties in staffing and managing our international operations;
- multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental clearances, approvals, permits and licenses;
- reduced or varied protection for intellectual property rights in some countries;
- obtaining regulatory clearance, approval or certification where required for our products in various countries;
- requirements to maintain data and the processing of that data on servers located within such countries;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits on our ability to penetrate international markets if we are required to manufacture our products locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, foreign tax laws and complexities of foreign value-added tax systems, the effect of local and regional financial pressures on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;

- restrictions on the site-of-service for use of our products and the economics related thereto for dental practitioners, providers and payors;

- natural disasters, political and economic instability, including wars, terrorism, political unrest, outbreak of disease, boycotts, curtailment of trade and other market restrictions; and

- regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the United States Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), U.K. Bribery Act of 2010 (the "U.K. Bribery Act") and comparable laws and regulations in other countries.

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

We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.

We are highly dependent on our senior management, including our chief executive officer, Bjarne Bergheim, and other key personnel. The chief operating officer and the chief commercial officer departed in 2023, and the chief financial officer resigned in March 2024.Their positions were replaced by new roles to continue to focus on operational improvement, innovation and commercial strategy. In addition, a director of our board resigned in March 2024. Our success will depend on our ability to retain senior management and to attract, recruit, retain, manage and motivate qualified personnel in the future, including sales and marketing professionals, scientists, clinical specialists, engineers and other highly skilled personnel and to integrate current and additional personnel in all departments. The loss of members of our senior management, sales and marketing professionals, scientists, clinical and regulatory specialists and engineers could result in delays in product development and harm our business. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition and results of operations.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuable employees to remain at our company, we have issued and may continue to issue equity awards that vest over time, in addition to salary and cash incentives. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Other than with respect to our chief executive officer, we generally do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We could be adversely affected by violations of the FCPA and similar worldwide anti-bribery laws, as well as violations of export or import controls or economic sanctions laws and regulations. Any investigation, and the outcome of any investigation, by government agencies of possible violations by us of such laws and regulations could have a material adverse effect on our business.

We are subject to anti-corruption laws and regulations, including the FCPA, the U.S. domestic bribery statute in 18 U.S.C. 201, the International Travel Act of 1961, as amended, the U.K. Bribery Act, and similar anti-bribery laws in jurisdictions in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, and intermediaries from corruptly authorizing, promising, providing, or offering, directly or indirectly, improper payments or anything else of value to government officials and persons in the private sector for the purpose of obtaining or retaining business. In addition, an organization that fails to prevent bribery by anyone associated with the organization can be charged under the U.K. Bribery Act, unless the organization can establish the defense of having implemented adequate procedures to prevent bribery.

We are also subject to export control and import laws and regulations, including the U.S. Export Administration regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Compliance with applicable regulatory requirements regarding the export of our products and services may require us to obtain licenses and authorizations prior to export, create delays in the introduction of our products and services in certain international markets or, in some cases, prevent the export of our products and services 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.

In the future, we may operate in parts of the world that pose a heightened corruption risk, and we will review policies to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, the U.K. Bribery Act, OFAC laws and regulations, and other export control, anti- corruption, anti-money-laundering and anti-terrorism laws and regulations as needed. Moreover, because of the significant role government entities play in the regulation of many foreign healthcare markets, we may be exposed to heightened FCPA and similar risks arising from our efforts to seek regulatory approval of and pricing and reimbursement for our products in such countries. We cannot assure you that our internal control policies and procedures will protect us from improper acts committed by our employees or agents, nor can we assure you that our business partners have not engaged and will not engage in improper conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of anti-corruption laws, economic sanctions laws, and export control and import laws. In addition, violations of these laws, or allegations of such violations, would significantly disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

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

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

Our ability to utilize our net operating loss carryforwards and research and development credit carryforwards may be limited.

As of December 31, 2023, we had U.S. federal and state net operating loss ("NOL") carryforwards of approximately $361.2 million and $205.1 million, respectively, and U.S. federal and state research and development credit carryforwards of $4.1 million and $4.6 million, respectively. Certain federal NOLs incurred in taxable years beginning before December 31, 2018, and certain state NOLs will begin to expire in the calendar year 2026, unless previously utilized. In addition, certain federal research and development credit carryforwards will begin to expire in the calendar year 2032. NOL carryforwards and research and development credit carryforwards subject to expiration could expire unused and be unavailable to offset future taxable income or income tax liabilities, as applicable. Federal NOLs incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the utilization of such federal NOLs to offset taxable income in taxable years beginning after December 31, 2020 is limited to 80% of current year taxable income. For state income tax purposes, the extent to which states will conform to federal laws is uncertain and there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California State NOLs and tax credits in tax years beginning after 2019 and before 2022.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point cumulative change by value in its equity ownership by certain stockholders (or groups of stockholders) over a rolling three-year period, is subject to limitations on its ability to utilize its pre-change NOL carryforwards and its

pre-change research and development credit carryforwards (and certain other tax attributes) to offset post- change taxable income or income tax liabilities, as applicable. Similar rules may apply under state tax laws. Although we have not completed a formal analysis as to whether past ownership changes have resulted in limitations on our use of our NOL carryforwards and research and development credit carryforwards under Sections 382 and 383 of the Code, we expect our IPO in November 2021 and private placement in September 2022 to trigger an ownership change and result in such limitations going forward. In addition, future changes in our stock ownership, some of which might be beyond our control, could also result in ownership changes under Sections 382 and 383 of the Code. For the foregoing reasons, we may not be able to utilize a material portion of our NOL carryforwards or research and development credit carryforwards, even if we attain profitability.

The tax benefit of NOL carryforwards and research and development credit carryforwards are required to be recorded as an asset to the extent that we assess that realization is more likely than not. We believe that recognition of the deferred tax assets arising from these future tax benefits is not likely to be realized and, accordingly, have provided a full valuation allowance against our net deferred tax asset.

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

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

To date, the growth of our operations has been largely organic, and we have limited experience in acquiring other businesses or technologies. We may not be able to successfully integrate any acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business fails to meet our expectations, our business, financial condition and results of operations may be negatively affected.

Risks Related to Governmental Regulation

Healthcare reform measures could hinder or prevent the commercial success of our GentleWave System.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that may harm our future revenues and profitability and the demand for our GentleWave System. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative and regulatory 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 GentleWave System. 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 GentleWave System.

By way of example, in the United States, the ACA was enacted in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry.

The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which have impacted existing government healthcare programs and will result in the development of new programs. Since its enactment, there have been numerous amendments to the ACA and revisions to implementing regulations, along with judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the Supreme Court ruled that states and individuals lacked standing to challenge the constitutionality of the ACA's individual mandate, post-repeal of its associated tax penalty. Additionally, President Biden has issued executive orders instructing certain governmental agencies to review their existing policies and practices to identify ways to expand the availability of affordable health coverage, to improve the quality of coverage, to strengthen benefits, and to help more Americans enroll in quality health coverage. Additional legislative changes, regulatory changes and judicial challenges related to the ACA remain possible. We cannot predict what effect these and further changes related to the ACA, including under the Biden administration, will have on our business.

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 GentleWave System;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

The current presidential administration and Congress may continue to pursue significant changes to the current healthcare laws. We cannot predict what other laws and regulations will ultimately be enacted and implemented at the federal or state level or the effect of any future legislation or regulation in the United States on our business, financial condition, and results of operations. Future changes in healthcare policy could increase our costs and subject us to additional requirements that may interrupt commercialization of our current and future solutions, decrease our revenue and impact sales of and pricing for our current and future products.

We must comply with anti-kickback, fraud and abuse, false claims, transparency, and other healthcare laws and regulations.

Our current and future operations are subject to various federal and state healthcare laws and regulations. These laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, dental practitioners or other potential purchasers or users, including patients, of medical devices and services. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales, placement and rental offerings, including discount practices, clinician support, education and training programs and dental practitioner consulting and other service arrangements. The laws that affect our practices and arrangements include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of, or a specific intent to violate, the law. The Anti-Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; however, those exceptions and safe harbors are drawn narrowly, and there is no exception or safe harbor for many common business activities. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute, but the legality of the arrangement will be evaluated on a case-by-case basis based on the

totality of the facts and circumstances. Practices that involve remuneration to those who prescribe, purchase, or recommend medical device products, including discounts, or engaging individuals as speakers, consultants, or advisors, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability;

- the U.S. federal civil False Claims Act, which prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds; knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government. In addition, any claims submitted as a result of a violation of the federal Anti-Kickback Statute constitute false claims and are subject to enforcement under the False Claims Act. Actions under the False Claims Act may be brought by the government or as a qui tam action by a private individual in the name of the government and to share in any monetary recovery. Qui tam actions are filed under seal and impose a mandatory duty on the U.S. Department of Justice to investigate such allegations. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties (adjusted annually for inflation) per false claim or statement for violations. Because of the potential for large monetary exposure, healthcare companies often resolve allegations without admissions of liability for significant and sometimes large settlement amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings. Many device manufacturers have resolved investigations of alleged improper activities, including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non reimbursable uses, and other interactions with prescribers and others including those that may have affected their billing or coding practices and submission to the federal government. Moreover, to avoid the risk of exclusion from federal healthcare programs as a result of a False Claims Act settlement, companies may enter into corporate integrity agreements with the government, which may impose substantial costs on companies to ensure compliance. There are also criminal penalties, including imprisonment and criminal fines, for making or presenting a false or fictitious or fraudulent claim or statement to the federal government;

- criminal healthcare statutes that were added by HIPAA and its implementing regulations, which impose criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate them in order to have committed a violation;

- the Physician Payments Sunshine Act, or Sunshine Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments made in the preceding calendar year and other transfers of value to certain healthcare professionals (including dental practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians (including dental practitioners) and their immediate family members; and

- foreign and state laws and regulations, including state payment reporting, anti-kickback and false claims laws, that may apply to items or services reimbursed by any third-party payor, including private insurers; foreign and state laws that require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated with respect to interactions with healthcare providers and other potential referral sources; and foreign and state laws and regulations that require device manufacturers to report information related to payments and other transfers of value to dental practitioners and other healthcare providers or marketing

expenditures, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The scope and enforcement of these laws is substantial and subject to rapid change. The shifting compliance environment and the need to build and maintain robust compliance programs, systems, and processes to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that we may run afoul of one or more of the requirements or that federal or state regulatory authorities might challenge our current or future activities under these laws. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive. We have a variety of arrangements with clinicians that could implicate these laws, including, among others, our practice of loaning instrument sets at no additional cost and certain sales and marketing programs such as our GPS Program. We have also entered into consulting agreements with dental practitioners, including some who have ownership interests in us and/or influence the ordering of or use our products in procedures they perform. Compensation under some of these arrangements includes the provision of stock or stock options. We could be adversely affected if regulatory agencies determine our financial relationships with such dental practitioners to be in violation of applicable laws. 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 could be subject to challenge under one or more of such laws. Any government investigation, even if we are able to successfully defend against it, will require the expenditure of significant resources, is likely to generate negative publicity, harm our reputation and potentially our financial condition and divert the attention of our management. Moreover, any investigation into our practices could cause adverse publicity and require a costly and time-consuming response. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment of individuals, exclusion from government funded healthcare programs, such as Medicare and Medicaid, imposition of compliance obligations and monitoring, and the curtailment or restructuring of our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

If we fail to obtain and maintain necessary clearances, approvals or certifications from the FDA, other applicable foreign regulatory authorities and notified bodies, if clearances, approvals or certifications for future products, product modifications or enhancements, and indications are delayed or not issued, or if there are state, federal or international level regulatory changes, our commercial operations could be harmed.

Our products are medical devices subject to extensive regulation in the United States by the FDA and by corresponding state regulatory agencies and authorities. Likewise, our products are subject to extensive medical device regulations in other countries, such as Canada, by applicable regulatory agencies. To the extent we intend to market and sell our products in the EU, our products will also be subject to extensive regulation by EU institutions as well as EU member states' regulatory authorities and notified bodies. These regulations pertain to the design, development, evaluation, manufacturing, testing, labeling, marketing, sale, advertising, promotion, distribution, post-market surveillance, shipping and servicing of our products. These entities regulate and oversee record-keeping procedures, safety alerts, recalls, market withdrawals, product import and export, removals and field corrective actions, and post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to reoccur, could lead to death or serious injury.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. Such regulations, and interpretations thereof, may limit our ability to market our products. Further, the FDA, foreign regulatory agencies and U.S. state agencies have broad enforcement powers, and our failure to comply with state, federal and international regulations could lead to the clearance or approvals, product recalls, safety alerts, termination of distribution, product seizures, consent decrees, civil penalties, import detention, import refusal, or placement on FDA’s Import Alerts. In the most extreme cases, criminal sanctions or closure of our manufacturing facilities are possible.

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive in most cases either clearance under Section 510(k) of the FDCA, or approval of a pre-market approval application (“PMA”) from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is “substantially equivalent” to a legally-marketed “predicate” device, which includes a device that has been previously

cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that has been reclassified from Class III to Class II or I, or a device that was granted marketing authorization through the De Novo classification process that is not exempt from the premarket notification requirement. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining a PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. To date, our products have received marketing authorization pursuant to the 510(k) clearance process.

Modifications to products that are approved through a PMA application generally require FDA approval, unless the modification does not affect the product's safety or effectiveness and the modification is reported to FDA. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from 12 to 18 months, but can last longer.

The process of obtaining and maintaining regulatory clearances, approvals or certifications to market a medical device in the United States and other countries can be costly and time-consuming, and we may not be able to obtain or maintain these clearances, approvals or certifications on a timely basis, if at all. In addition, regulations regarding the development, manufacturing and sale of our products are subject to change. For example, in December 2022, the FDA received a new authority under the Consolidated Appropriations Act, which allows FDA to require certain applicants that submit applications for 510(k), PMA, De Novo classification, or Humanitarian Device Exemption (HDE), among others, to provide the FDA with information that demonstrates the subject device's compliance with the FDCA's requirements relating to cybersecurity. The FDA may refuse to accept an application if such information is not submitted to the agency. In addition, the same law requires sponsors for drugs and devices to submit diversity action plans to increase the enrollment of subjects from underrepresented ethnic and racial groups. The diversity action plans must explain the sponsor's goals for enrollment, the rationale for the enrollment goals, and how the sponsor intends to achieve them.

We cannot predict the impact, if any, that such changes might have on our business, financial condition and results of operations. Changes in existing laws or requirements or adoption of new laws or requirements could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that we will not incur significant costs to comply with applicable laws and requirements in the future or that applicable laws and requirements will not have a material adverse effect upon our business, financial condition and results of operations.

The FDA, applicable foreign regulatory entity or notified body can delay, limit or deny clearance, approval or certification 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 and effective, or substantially equivalent, in the case of a 510(k) clearance;

- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials (including, for purposes of the EU, clinical investigations) or the interpretation of data from pre-clinical studies or clinical trials, as applicable and to the extent required to support marketing authorization or certification;

- our failure to follow and comply with the applicable current Good Clinical Practice ("GCP") requirements, including but not limited to obtaining informed consents, Investigational Device Exemption approvals, and receiving an IRB's approval for the clinical trial;

- our inability to comply with the new legal and regulatory requirements, including but not limited to requirements relating to cybersecurity and clinical trial diversity action plans;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements, including but not limited to the FDA's requirements under QSR; and
- the potential for policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data, as applicable, and/or regulatory filings insufficient for clearance, approval or certification.

Pursuant to the FDA's regulations, the scope of marketing claims we can make about a Class II device that is subject to the 510(k) clearance requirement is limited to the indications that were previously 510(k)-cleared. Other countries have similar laws and regulations restricting marketing to cleared indications. If a regulatory agency determines that any of our marketing claims exceed the cleared indications in a particular country, we may be subject to enforcement action and/or we may be required to cease making the challenged marketing claims, recall or with the products from the market, issue corrective communications, pay fines, stop selling products, or be subject to other enforcement actions.

In addition, if any regulatory agency determines that our marketing claims are false or misleading, or that they suggest a clinical benefit that is not supported in the studies applicable to such products, we may be required to cease making the challenged marketing claims, issue corrective communications, pay fines or stop selling products until the objectionable claims have been corrected, which could harm our business, financial condition and results of operations. Any regulatory action or penalty could lead to private party actions, or private parties could seek to challenge our claims even in the absence of formal regulatory actions, which could also harm our business, financial condition and results of operations.

To the extent we intend to sell our products in member states of the EU, our products must comply with the general safety and performance requirements of the EU Medical Devices Regulation (Regulation (EU) No 2017/745). Compliance with these requirements is a prerequisite to be able to affix the European Conformity ("CE") mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

To demonstrate compliance with the general safety and performance requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its risk classification. Except for low risk medical devices (Class I), where the manufacturer can self-assess of the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. See "Business—Government Regulation—Regulation of Medical Devices in the European Union."

Sales of our products outside the United States are subject to foreign regulatory requirements that vary widely from country to country, and such regulatory requirements have been changing and increasing in some countries. Complying with international regulatory requirements can be an expensive and time-consuming process and obtaining regulatory clearance, approvals or certifications is not certain. We may be unable to maintain regulatory qualifications, clearances, approvals or certifications in these countries or to obtain clearances, approvals or certifications in other countries. We may incur significant costs in attempting to obtain, renew, or modify foreign regulatory clearances or approvals, qualifications or certifications. If we experience difficulties in receiving, maintaining, renewing or modifying necessary qualifications, clearances, approvals or certifications to market our products outside the United States, or if we fail to receive, renew, modify or maintain those qualifications,

clearances, approvals or certifications, we may be unable to market our products or enhancements in certain international markets effectively, or at all.

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

Our future success depends on our ability to develop, receive regulatory clearance or approval for, and introduce new products that will be accepted by the market in a timely manner. There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our future products on a timely basis, if at all, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

It is important to our business that we build a pipeline of product offerings. As such, our success will depend in part on our ability to develop and introduce new products. However, we may not be able to successfully develop and obtain regulatory clearance or approval for product enhancements, or new products for any number of reasons, including due to the cost associated with certain regulatory approval requirements, these products may not be accepted by dental practitioners or users, or the FDA may not agree that the products are safe and effective.

The success of any new product offering or enhancement to an existing product will depend on a number of factors, including our ability to, among others:

- identify and anticipate dental practitioner and patient needs properly;
- develop and introduce new products or product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new products with data from clinical studies;
- obtain the necessary regulatory clearances or approvals for new products or product enhancements;
- comply fully with the FDA and foreign regulations on marketing of new products or modified products; and
- provide adequate training to potential users of our GentleWave System.

If we do not develop new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, or if our competitors introduce new products with functionalities that are superior to ours, our results of operations will suffer.

Some of our future products will require 510(k) clearance. Other products may require a PMA approval. Some of our future products may require clinical trials to support regulatory approval or clearance, and we may not successfully complete these clinical trials or the results may not show that our products are safe and effective for their intended uses. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or PMA of new products. Failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

New legislation and regulations and legislative and regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our new and modified products, or to manufacture, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in the legislative bodies of the countries in which we sell or intend to sell our products to revise the process for regulatory approval, clearance, authorization, certification, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA, EU and other applicable foreign regulations and guidance are often revised or reinterpreted by the applicable competent authority in ways that may significantly affect our business and our products. For example, over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. In September 2023, FDA issued a draft guidance document – *Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission*. FDA outlined recommended practices when selecting predicate devices, including selecting a predicate device that was cleared using well-established methods (e.g., voluntary consensus standard, FDA guidance document, and others), considering the predicate device's history relating to reported adverse events, malfunctions, or deaths, ensuring that the predicate device does not have unmitigated use- or design-related safety issues, and selecting a predicate device that has not been subject to a design-related recall, among others. The FDA may continue to issue new policies, or Congress may enact new legislations that make it more difficult for devices to be cleared through the 510(k) pathway. This may prevent our products from receiving the 510(k) clearance, subject the products to more difficult regulatory routes, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

In September 2019, the FDA finalized guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list of device types that are appropriate for the "safety and performance based" pathway and announced that it intends to continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

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

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

In addition, the EU landscape concerning medical devices in the EU has evolved. On May 25, 2017, the EU Medical Devices Regulation entered into force, which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation.

The EU Medical Devices Regulation entered into application on May 26, 2021. The new regulation among other things:

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

These modifications may have an effect on the way we intend to develop our business in the EU and EEA. For example, as a result of the transition towards the new regime, notified body review times have lengthened, and product introductions could be delayed or canceled, which could adversely affect our ability to grow our business.

Following the end of the Brexit transitional period on January 1, 2021, the rules for placing medical devices on the UK market differ from those in the EU. To the extent we intend to sell our products on the UK market, our products must comply with the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) that sought to give effect to the pre-existing EU Medical Devices Directive. Compliance with the UK Medical Devices Regulations 2002 is a prerequisite to be able to affix the UK Conformity Assessed ("UKCA") mark to our products, without which they cannot be sold or marketed in the UK, although manufacturers can continue to place CE-marked medical devices on the UK market during a transitional period. The UK government and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) are currently seeking to amend the UK Medical Devices Regulations 2002, in particular to create a new access pathways to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform in vitro diagnostic medical devices regulation, and foster sustainability through the reuse and remanufacture of medical devices. The new UK medical devices regime is expected to come into force in July 2025.

We sell our products to licensed practitioners, including dentists and endodontists. Current laws and regulations could change at any time, disallowing sales of our products to dentists or endodontists and other non-physician providers, imposing additional educational or regulatory requirements on dentists and endodontists and other non-physician providers and limiting the ability of a dentist, endodontist, and non-physicians to operate our products, which could adversely affect our business, financial condition and results of operations.

Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products or limit our ability to sell to clinicians. It is impossible to predict whether legislative changes will be enacted or if regulations, guidance or interpretations will change and what the impact of such changes, if any, may be.

Modifications to our products may require new clearances, premarket approvals or new or amended certifications, and may require us to cease marketing or recall the modified products until clearances, approvals or the relevant certifications are obtained.

In the United States, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510(k) clearance or, possibly, a PMA. The FDA requires every manufacturer to make this determination when a modification is made, but the FDA may review such determinations and may not agree with our position regarding whether new clearances or approvals are necessary. We have modified some of our 510(k)-cleared products and have determined based on our review of the applicable FDA regulations and guidance documents that in certain instances new 510(k) clearances or PMAs are not required. If the FDA disagrees with our determination and requires us to submit new 510(k)s or PMAs for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified products until we obtain clearance or approval, and we may be subject to significant regulatory fines, penalties, warning letters, untitled letters, or other enforcement actions. Similar requirements may apply in foreign jurisdictions.

Consistent with regulatory requirements for additional indications for use, we often seek marketing authorizations such as clearance from the FDA, or other marketing authorizations from Health Canada, and certifications by our notified body. Clinical trials in support of such clearances, approvals and certifications by our notified body may be costly and time-consuming. In the event that we do not obtain additional clearances or approvals from the FDA or foreign regulatory authorities or certifications from our notified body, our ability to market products in the United States, Canada, and the EU, EEA and UK and revenue derived therefrom may be adversely affected. Medical devices subject to premarket review may be marketed only for the indications for which they are approved, cleared, or assessed, and if we are found to be marketing our products for off-label uses or indications for use that have not received the requisite clearances, approvals, certifications or assessments, we might be subject to FDA and other competent authorities' enforcement action or have other resulting liability. In addition, if the FDA or the competent authorities in Canada and the EU member states and EEA countries determine that our promotional materials or training constitute promotion of a use which is unapproved, not cleared or not covered by the CE mark or in compliance with other regulatory authorities' requirements, they could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, an injunction, product seizures, consent decrees, civil fines, criminal penalties or import detention.

Clinical trials may be necessary to support a 510(k) clearance, comparable marketing authorization, or certification. Such trials may require the enrollment of large numbers of patients and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials may prevent us from commercializing modified or new products and may adversely affect our business, financial condition and results of operations.

Initiating and completing the clinical trials necessary to support our current and future products will be time consuming and expensive and the outcome of any such clinical trials is uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials. Regulatory authorities or bodies may disagree with our interpretation of data and results from our clinical trials, and data are often susceptible to various interpretations and analyses. 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, or regulatory authorities or bodies disagreed with such companies' conclusions. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

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

- we may be required for future products to submit an IDE application to the FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials; similar requirements may apply in foreign jurisdictions;

- regulators may disagree as to the design or implementation of our clinical trials;

- difficulties in achieving the goals for diversity in clinical trial enrollment;
- regulators and/or IRBs, ethics committees or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials may be larger than we anticipate, and enrollment in these clinical trials may be insufficient or slower than we anticipate. The number of clinical trials being conducted at any given time may be high and result in fewer available subjects for any given clinical trial, or subjects may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks or risks of serious adverse events;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB or ethics committee and/or regulatory authorities for re-examination;
- regulators, IRBs, ethics committees, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals, unanticipated adverse device effects, or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- supply chain shortages brought on by public health crises may disrupt or stop the supply of the products that we require for clinical trials;
- policies or regulations of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for marketing authorization or certification; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

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

Moreover, conducting successful clinical studies will require the enrollment of large numbers of patients and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the availability of diverse clinical trial population, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators and support staff, the proximity of patients to clinical trial sites, the availability of patients meeting the eligibility and exclusion criteria for participation in the clinical trial and patient compliance with the trial protocol. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the performance of our products, or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to the products being tested.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA and/or other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs or ethics committees at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under current good manufacturing practice ("cGMP") requirements and other regulations. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with GCP requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product claims or that the FDA, other foreign regulatory authorities, or our notified body will agree with our conclusions regarding the results of such trials. The clinical trial process may fail to demonstrate that our products are safe and effective for the proposed indications for use, or patients enrolled in the clinical trials may experience unanticipated adverse side effects, either of which could cause us to abandon or delay further development of a proposed product and may delay the development of other products. Furthermore, any delay or termination of our clinical trials will delay the filing of our product submissions to the relevant regulatory authorities or to our notified body and, ultimately, our ability to commercialize such product and generate revenues. In addition, despite considerable time and expense invested in our clinical trials, the FDA, foreign regulatory authorities, or our notified body may not consider our data adequate to support regulatory clearance, approval, certification of our products, or other required regulatory authorizations, as applicable. Such increased costs and delays or failures to complete our clinical trials or obtain the results we expect, delays in our ability to commercialize our products or the abandonment of proposed product lines in response to clinical trial results could adversely affect our business, financial condition and results of operations.

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

The products that we market in the United States are regulated as medical devices by the FDA and have received premarket clearance under Section 510(k) of the FDCA. In the 510(k) clearance process, before a device may be marketed the FDA must determine that a proposed device is "substantially equivalent" to a legally- marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (preamendments device), a device that has been reclassified from Class III to Class II or I, or a device that was granted marketing authorization through the De Novo classification process that is not exempt from the premarket notification requirement. This process is typically shorter and

generally requires the submission of less supporting documentation than the FDA's PMA process and oftentimes does not require long-term clinical studies.

Given that our product was cleared through the 510(k) process without clinical trials, we lack the breadth of published long- term clinical data supporting the safety and efficacy of our products and the benefits they offer that might have been generated in connection with other marketing authorization pathways. For these reasons, clinicians may be slow to adopt our products, we may not have comparative data that our competitors have or are generating, and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would slow the adoption of our products, would significantly reduce our ability to achieve expected sales and could prevent us from achieving and maintaining profitability.

If future patient uses or clinical testing do not support our belief that our products offer a more advantageous treatment for their cleared and authorized indications for use, market acceptance of our products could fail to increase or could decrease and our business could be harmed. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory or voluntary product recalls, suspension or withdrawal of FDA or other governmental clearance or approval, significant legal liability or harm to our business reputation.

Our facilities and those of our suppliers and contract manufacturers are subject to regulation under the FDCA and FDA implementing regulations as well as potential inspections by foreign regulatory authorities and audits.

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

Our operations could be harmed if regulatory authorities make determinations that we, or our suppliers or vendors, are not in compliance with these regulations. If the FDA finds a violation of the QSR requirement, it may enjoin our manufacturing operations, seize product, restrict importation of goods, and impose administrative, civil or criminal penalties or take other enforcement actions, such as requesting or requiring recalls, issuing warning letters or untitled letters, among others. Similar requirements may apply in foreign jurisdictions. If we or our contract manufacturers or suppliers fail to comply with applicable regulatory requirements, we or they could be required to take costly corrective actions, including suspending manufacturing operations, changing product designs, suspending sales, or initiating product recalls or market withdrawals, among others. In addition, compliance with these regulations has increased and may further increase the cost of manufacturing for certain of our products to ensure and maintain compliance. Any of these outcomes could have a material adverse effect on our business, financial condition and results of operations.

On January 31, 2024, the FDA issued a final rule that is intended to amend the QSR requirements to align more closely with the ISO 13485:2016 standard. The new set of regulations will become effective on February 2, 2026. While the ISO 13485:2016 and the FDA's previous QSR requirements are similar, there are certain differences that remain, and compliance with ISO 13485:2016 does not necessarily ensure compliance with FDA's amended requirements. We will need to review our quality systems and procedures to ensure compliance with the new regulations. The FDA may also make additional changes to the requirements in the future, which may make compliance more difficult or costly.

Even after clearance, approval or certification for our products is obtained, we and our contract manufacturers are subject to extensive post-market regulation by the FDA and foreign regulatory authorities and the notified body. Our failure to meet strict regulatory requirements could result in our being required to stop sales of our products, conduct voluntary or mandatory product recalls, pay fines, incur other costs or even close our facilities.

Even after a device is cleared, approved, certified or authorized, there are significant post-market regulations with which we must comply. For example, we are required to comply with the FDA's medical device reporting ("MDR") requirements, which are a set of mandatory requirements that are applicable to manufacturers, importers, and device user facilities. The FDA's MDR regulations and similar foreign regulations require us to report to the FDA and other foreign governmental authorities when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have experienced a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, or any other requirements of the FDA or other regulatory requirements, the FDA and other foreign governmental authorities or bodies could take action, including by issuing warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of a device clearance, approval or certification or failure to grant new clearances, approvals or certifications, seizure of our products or delay in clearance, approval or certification of future products, recalls, requirements for customer notifications or repairs, operating restrictions or partial suspension or total shutdown of production.

In the EU, if we were authorized to market, we would also be required to demonstrate compliance with similar quality system requirements which are laid down in the relevant Annexes to the EU Medical Devices Regulation. Such compliance can be supported by, among other things, a certificate of compliance with ISO 13485:2016. Demonstration of compliance with the ISO 13485:2016 standard permits manufacturers to benefit from a presumption of conformity with the corresponding quality system requirements laid down in such Annexes to EU Medical Devices Regulation. Failure to comply with such standards could subject us to enforcement actions and adversely impact our business.

Later discovery of previously unknown problems with our products, including unanticipated adverse events, adverse events of unanticipated severity or frequency, or manufacturing problems, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, a requirement to repair, replace or refund the cost of any medical device that we manufacture or distribute, fines, import refusals, product seizures, injunctions, the suspension, variation or withdrawal of regulatory clearances, approvals, certifications or other regulatory authorizations or the imposition of civil, administrative or criminal penalties or other enforcement or regulatory actions, each of which could adversely affect our business, financial condition and results of operations.

Under certain circumstances, the FDA has the authority to require a recall of medical devices if it determines that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death. Similar foreign governmental authorities, such as Health Canada and the authorities of the EU member states, also have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Moreover, notified bodies have the power to suspend, vary or withdraw our certifications in such circumstances. Manufacturers may, on their own initiative, recall a product if any material deficiency in a device is found or conduct a market withdrawal such as the correction or removal of a device to reduce a risk to health posed by the device, to remedy a minor violation of law or even if no violation of law has occurred. A government-mandated or voluntary recall by us or one of our importers or distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, manufacturing errors, other problems with design or labeling, packaging defects or other deficiencies or failures to comply with applicable regulations.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA, other applicable foreign regulatory authorities or notified bodies may require, or we may decide, that we will need to obtain new approvals, clearances, or certifications for the product before we may market or distribute the corrected product. Seeking such approvals, clearances or certifications may delay our ability to replace the recalled or withdrawn products in a timely manner. Moreover, if we do not adequately address problems associated with our products, we may face additional regulatory enforcement action, including warning letters, untitled letters, product seizure, injunctions, administrative penalties, civil or criminal fines, or other enforcement actions. Companies often are required to maintain certain records of recalls and withdrawals, even if they are not reportable to the applicable

regulatory authority. We may initiate voluntary withdrawals for our products in the future that we determine do not require notification of the FDA or other applicable foreign regulatory authorities. If such regulatory authority disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action.

Any future recalls or market withdrawals of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, business, financial condition and results of operations, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits. A future recall announcement could also potentially lead to product liability claims against us.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance, approval, or other required regulatory authorizations or certifications to commercialize our products.

We do not have the ability to independently conduct all of our clinical trials for our products without the participation of third parties. In the event that clinical trials are needed for future product clearance or approval, we will need to rely on third parties such as medical institutions and clinical investigators to conduct such trials. If these third parties do not successfully carry out their contractual duties or comply with regulatory obligations, including GCPs, or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to a failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control. In the event of such extensions, delays, suspensions or terminations, we may not be able to obtain regulatory clearance, approval or other required regulatory authorizations or certifications for, or successfully commercialize, our products on a timely basis, if at all, and our business, financial condition and results of operations may be adversely affected.

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

The ability of the FDA, foreign regulatory agencies such as Health Canada and the notified body, to review and clear, approve or certify new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees and statutory, regulatory and policy changes. Average review times at these organizations have fluctuated in recent years as a result. In addition, government funding of other government agencies that oversee clearances and approvals and that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at these agencies and bodies may slow the time necessary for new devices to be reviewed and/or cleared, approved or certified, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the global COVID-19 pandemic, in March 2020, the FDA temporarily postponed all domestic and foreign routine surveillance facility inspections. Subsequently, in July 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system and in May 2021, the FDA issued a new report outlining the agency's plan to move toward a more consistent state of inspectional capacity and priorities for domestic and foreign inspections that were not performed during the pandemic. In February 2022, the FDA announced that it will resume its domestic inspection operations. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA, other foreign regulatory authorities and certification bodies from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the

ability of the FDA, other regulatory authorities and certification bodies to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

For instance in the EU, notified bodies must be officially designated by EU member states governments to certify products and services in accordance with the EU Medical Devices Regulation. While several notified body have been designated, the COVID-19 pandemic has significantly slowed down their designation process and the current designated notified body are facing a large amount of requests with the new regulation, resulting in longer notified body review times. This situation could impact our ability to grow our business in the EU and EEA.

Any product we develop may cause or contribute to adverse medical events, which could interrupt, delay, or prevent its continued development. If certain events occur after marketing authorization or certification, we may be required to report them to the FDA or comparable regulatory authority, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. In addition, the discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

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

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. For example, in October 2019, we initiated and subsequently completed a voluntary recall of the foot pedal component of our GentleWave Console after determining that treatment fluid continuously cycled even after the foot pedal was released. The recall affected 460 foot pedals and there were no patient safety issues reported and no reports of adverse clinical events related to this issue and the issue has been corrected. Product defects or other errors may occur in the future.

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

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA or foreign regulatory bodies. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA or foreign regulatory bodies. If the FDA or foreign regulatory bodies disagree with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with clinicians and dental practitioners, potentially lead to product liability claims against us and negatively affect our sales. Any corrective

action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

The FDA and other regulatory enforcement agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory enforcement agencies strictly regulate the promotional claims that may be made about medical devices. For example, devices authorized for marketing pursuant to a 510(k) clearance cannot be marketed for any intended use beyond the cleared indications. Dentists and endodontists nevertheless may use our products on their patients in a manner that is inconsistent with the indications for use cleared by the FDA. The FDA does not interfere with, restrict or regulate a dental practitioner's use of a medical product within the practice of medicine, and we cannot prevent a dental practitioner from using our products for an off-label use. However, we cannot market for these off-label uses and we train our marketing personnel and direct sales force to not promote our devices for uses outside of the FDA-cleared indications.

The use of our products for indications other than those for which our products have been cleared by the FDA or approved, authorized or certified by a notified body or foreign regulatory enforcement authorities may not effectively treat the conditions not referenced in product indications, which could harm our reputation in the marketplace among dental practitioners and patients. If we are found to have promoted such "off-label" uses, we may become subject to significant government fines and other related liability. For example, if the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could subject us to regulatory or enforcement actions, including the issuance or imposition of a warning letter or an untitled letter, injunction, seizure, civil fine or criminal penalties, or other enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

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

We may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy laws, and consumer protection laws and regulations that govern the collection, processing, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. For example, HIPAA imposes obligations on "covered entities," including certain health care providers, health plans, and health care clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information ("PHI") for or on behalf of a covered entity, as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Entities that are found to be in violation of HIPAA, whether as the result of a breach of unsecured PHI, a complaint about privacy practices, or an audit by the Department of Health and Human Services ("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. Depending on the facts and circumstances, we could be subject to penalties if we violate HIPAA.

Even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair or deceptive acts or practices in or affecting commerce in violation of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered by the FTC as sensitive data that merits stronger safeguards.

In addition, certain state laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to protected health information than HIPAA, many of which may differ from each other, thus, complicating compliance efforts. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California enacted the CCPA, which creates individual privacy rights for California consumers (as defined in the law), including the right to opt out of certain disclosures of their information, and places increased privacy and security obligations on entities handling certain personal data of consumers or households and may apply to us in the future. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Further, the CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions went into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In order to comply, we must inform consumers of their right to opt-out of the sale of their personal information, display a "Do Not Sell" link, and timely and efficiently comply by opt-out requests. The CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the United States, as other states or the federal government may follow California's lead and increase protections for U.S. residents. Similar laws have passed in Virginia, Colorado, Connecticut, and Utah. For example, the Virginia Consumer Data Protection Act took effect on January 1, 2023. The CCPA has already prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, add layers of complexity to compliance in the U.S. market, increase compliance costs and adversely affect our business.

Foreign data protection laws, including the GDPR, which went into effect in May 2018, may also apply to our processing of health-related and other personal data regardless of where the processing in question is carried out.

The GDPR imposes stringent requirements for controllers and processors of personal data of individuals within the EEA. The GDPR applies to any company established in the EEA as well as to those outside the EEA if they collect, process, and use personal data in connection with the offering of goods or services to individuals in the EEA or the monitoring of their behavior. The GDPR, together with national legislation, regulations and guidelines of the EEA countries governing the processing of personal data, impose strict obligations and restrictions on the ability to process, collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions involve the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA to jurisdictions deemed to have inadequate, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU, and the United States remains uncertain. For

example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union (the "CJEU") in the so-called Schrems II decision. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional technical, organizational and contractual supplementary measures may need to be put in place. The nature and examples of what these supplementary measures could include since Schrems II was further discussed by the European Data Protection Board in Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data adopted on June 18, 2021. The CJEU went on to state that if a competent supervisory authority believes that the standard contractual clauses cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer of personal data. The European Commission has published revised standard contractual clauses for data transfers from the EEA: the revised clauses must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. As the timeframe for the migration of the revised clauses has now passed, and to the extent necessary, we have implemented the revised standard contractual clauses, in relation to relevant existing contracts and certain additional contracts and arrangements. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. However, with no further guidance from the European Commission, it is prudent for us to continue to rely on the revised clauses in such data transfers.

Further, from January 1, 2021, companies have to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR (*e.g.,* fines up to the greater of €20 million (£17.5 million) or 4% of global turnover). The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the United Kingdom adequacy decision will automatically expire in June 2025 unless the European Commission re- assesses and renews/extends that decision, and remains under review by the Commission during this period. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. These changes will lead to additional costs and increase our overall risk exposure. For the time being, the UK Information Commissioner has issued the UK standard contractual clauses for data transfers from the UK to third countries as an adequate transfer mechanism. Existing standard contractual clauses arrangements must be migrated to the UK revised clauses by March 21, 2024. We are working on implementing the UK revised clauses in relation to relevant existing contracts and certain additional contracts and arrangements as appropriate in each case.

Implementing mechanisms that endeavor to ensure compliance with the GDPR and relevant local legislation in EEA countries and the United Kingdom, if necessary, may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations, and prospects. While we have taken steps to comply with the GDPR where applicable, including by reviewing our security procedures, and entering into data processing agreements with relevant contractors, our efforts to achieve and remain in compliance may not be fully successful.

Further, in Canada, the Personal Information Protection and Electronic Documents Act ("PIPEDA") and similar provincial laws may impose obligations with respect to processing personal information. PIPEDA requires companies to obtain an individual's consent when collecting, using or disclosing that individual's personal information. Individuals have the right to access and challenge the accuracy of their personal information held by an organization, and personal information may only be used for the purposes for which it was collected. If an organization intends to use personal information for another purpose, it must again obtain that individual's consent. Failure to comply with PIPEDA could result in significant fines and penalties.

Compliance with applicable US and foreign data protection, privacy and security laws, regulations and standards could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can also be subject to varying interpretations. Any failure or perceived failure to comply could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity, and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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

We are exposed to the risk that our employees, collaborators, independent contractors and consultants may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these persons could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- FDA requirements, including those laws requiring the reporting of true, complete and accurate information to the FDA authorities;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations; or
- laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, incentive programs and other business arrangements. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee, contractor, or other agent, or our company, receiving an FDA debarment or exclusion by OIG could result in penalties, a loss of business from third parties, and severe reputational harm.

It is not always possible to identify and deter misconduct by our employees and other agents, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, treble damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations.

We must comply with environmental and occupational safety laws.

Our research and development programs as well as our manufacturing operations involve the controlled use of hazardous materials. Accordingly, we are subject to federal, state and local laws, as well as the laws of foreign countries, governing the use, handling and disposal of these materials. In the event of an accident or failure to

comply with environmental or occupational safety laws, we could be held liable for resulting damages, and any such liability could exceed our insurance coverage.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent or other intellectual property protection for any products we develop or for our technology, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize any products we may develop, and our technology, may be harmed.

In order to remain competitive, we must develop, maintain, and protect the proprietary aspects of our brands, technologies, data, and products. We rely on a combination of contractual provisions, confidentiality procedures, patent, copyright, trademark, trade secret, and other intellectual property laws to protect the proprietary aspects of our brands, technologies, data, and products. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Any failure to obtain or maintain patent and other intellectual property protection with respect to our products could harm our business, financial condition and results of operations.

As of December 31, 2023, our patent portfolio included 162 patents owned by us, including 36 in the United States. As of December 31, 2023, we had 64 pending patent applications globally, including 25 in the United States. We cannot assure you that our intellectual property position will not be challenged or that all patents for which we have applied will be granted. As with other medical device companies, our success depends, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, maintaining, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents or 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 proprietary rights at all. 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, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek and obtain patent protection. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our products or research and development results before it is too late to obtain patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends in part on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, the publication of discoveries in scientific literature often lags behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to file for patent protection of such inventions. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. In addition, the issuance of a patent is not conclusive as to its inventorship, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad, so even if we obtain patents, they may not provide us with adequate proprietary protection or competitive advantage against our competitors with similar products. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology or to prevent competitive technologies. In addition, the laws of foreign jurisdictions may not protect our rights to the same extent as the laws of the United States. For example, certain countries outside of the United States do not allow patents for methods of treating the human body. This may preclude us from obtaining method patents outside of the United States having similar scope to those we have obtained or may obtain in the future in the United States. 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 or validity of our intellectual property or narrow the scope of our patent protection. Additionally, we cannot predict whether the patent applications we 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 or other third parties.

Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. The strength of patent rights generally, and particularly the patent position of medical device companies, involves complex legal, factual and scientific questions and can be uncertain, and has been the subject of much litigation in recent years. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability, or scope of such patents, which may result in such patents being narrowed, invalidated, or held unenforceable. Decisions by courts and governmental patent agencies may introduce uncertainty in the enforceability or scope of patents owned by or licensed to us. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may also have blocking patents that could prevent us from marketing our own products and practicing our own technology. We may not be aware of all third-party intellectual property rights (for example, not be aware of a patent or not be aware of a patent's scope) potentially relating to our products, product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our ability to market our products without infringing third party patent rights, is highly uncertain. We cannot ensure that we do not infringe any patents or other proprietary rights held by others. If our products were found to infringe any proprietary right of another party, we could be required to pay significant damages or license fees to such party and/or cease production, marketing and distribution of those products. Litigation may also be necessary, from time to time, to defend infringement claims of third parties or to enforce patent rights we hold or protect trade secrets or techniques we own. Further, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable, or not infringed; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Our success will also depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how, and obtaining and maintaining other intellectual property rights. We rely on trade secret protection and confidentiality agreements for strategic purposes, to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. There can be no assurances that we can meaningfully protect or maintain intellectual property, trade secrets or other unpatented proprietary rights necessary to our business or in a form that provides us with a competitive advantage, or that others will not independently develop substantially equivalent proprietary products or processes or otherwise gain access to our proprietary technology. In addition, 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, clients, and other vendors who have access to such information, and could otherwise become known or be independently developed or discovered by third parties. Our intellectual property, including trademarks, could be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing other marks. If any of the foregoing occurs, we could be forced to re-brand our products, resulting in loss of brand recognition, and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Failure to obtain and maintain intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our trademarks, data, technology and other intellectual property and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated, or otherwise violated.

Additionally, we may find it necessary or prudent to acquire or obtain licenses from third-party intellectual property holders. However, we may be unable to acquire or secure such licenses to any intellectual property rights from third parties that we identify as necessary for our products or any future products we may develop. The acquisition or licensing of third-party intellectual property rights is a competitive area, and our competitors may pursue strategies to acquire or license third-party intellectual property rights that we may consider attractive or necessary, and our competitors could market competing products and technology. Our competitors may have a competitive advantage over us due to their size, capital resources and greater 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 acquire or license third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant product, and our customers may be forced to stop using the relevant product, which could harm our business, financial condition, and results of operations.

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

The medical device industry is highly competitive and 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, along with pending patent applications 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, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell, import, and/or export our products (or components thereof) or to use our technologies or our product names.

Third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes these patents. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims relating to our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending that may result in issued patents that our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates. 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. The defense of these matters can be time-consuming, costly to defend, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Vendors from which 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.

At least because 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 in court, at an administrative agency, or at the patent office, if issued, by proving that the invention was not original, was not novel, was obvious, or was obtained without disclosing all pertinent material prior art information to the patent office, among other reasons. For example, in litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons or are unenforceable due to inequitable conduct. If a court agrees, we would lose our rights to those challenged patents.

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

Further, if third party claims of patent or trademark infringement or trade secret misappropriation are successfully asserted against us, such claims may harm our business, result in injunctions preventing us from selling our products, and require payment of license fees, damages, attorneys' fees, and court costs, which may be substantial and have a material adverse impact on our business. In addition, if we are found to have willfully infringed third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties that may substantially erode our margins. Further, we may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement, and as such may need to stop selling the infringing products, which would have a significant adverse impact on our business, financial condition, and results of operations.

Similarly, interference, derivation, cancellation, and opposition proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office ("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, post-grant review, derivation, interference, supplemental examination, cancellation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Such challenges may result in loss of exclusivity or ability to make, use, and sell our products without infringing third-party intellectual property rights, or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products and techniques without payment to us, or limit the duration of the patent protection of our technology. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses or rights could prevent us from using, selling, manufacturing, or importing 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, trademarks, or other intellectual property rights, which could be expensive, time-consuming and unsuccessful. Former, current, or future licensees may violate the terms of their licenses and thereby infringe our intellectual property. Competitors may infringe our issued patents, trademarks, or other intellectual property. To counter infringement or unauthorized use by licensees, competitors, or other parties, we may be required to file infringement or misuse claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims or file administrative actions against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Furthermore, even if our patents or trademarks 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, and an adverse result in any litigation proceeding or administrative action could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition, and results of operations. In addition, although we make efforts to comply with the patent marking provisions of 35 U.S.C. § 287(a), a court may decide that we have not met the requirements of the patent marking statute, which may prevent us from obtaining monetary damages that would otherwise have been due to us if we had complied with the marking statute.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Protracted litigation to defend or prosecute our intellectual property rights could also result in our customers or potential customers deferring or limiting their purchase or use of the affected products until resolution of the litigation. 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 negative impact on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could harm our business, financial condition, and results of operations.

In addition, third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or indemnify our customers for any costs associated with their own initiation or defense of infringement claims, regardless of the merits of these claims. If any of these claims succeeds or settles, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

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

The USPTO, United States Copyright Office ("USCO") and various foreign governmental agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the application process. In addition, periodic maintenance fees, renewal fees, annuity fees and various other government fees often must be paid to the USPTO, USCO and foreign agencies over the lifetime of any registered or applied-for intellectual property rights we may obtain in the future. While an unintentional lapse of an intellectual property registration or application can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the registration or application, resulting in partial or complete loss of intellectual property rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a registration or application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the intellectual property registrations and applications covering our products, we may not be able to stop a competitor from developing or marketing products that are the same as or similar to our products, which would have a material adverse effect on our business. We also have a duty to disclose to the USPTO any prior art known to us that may be material to the patentability of our patents. If we failed to submit any such material prior art, a court or administrative agency may deem one or more of our patents unenforceable. Additionally, certain of our patent applications relate to software inventions. Software-related patents in general are susceptible to validity or patentability challenges before the USPTO or in other judicial or quasi-judicial proceedings for being directed to non-statutory subject matter under 35 U.S.C. § 101.

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

Patents have a limited lifespan. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a utility patent is generally 20 years from its earliest non-provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, voluntary disclaimer of patent term to obtain a patent's allowance, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. 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, we may be open to competition from competitive products, which may harm our business prospects. In addition, although upon issuance in the United States a patent's term can be extended based on certain delays caused by the USPTO, this extension can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we do not have sufficient patent terms to protect our products, proprietary technologies and their uses, our business would be seriously harmed. As our patents expire, the scope of our patent protection will be reduced, which may reduce or eliminate any competitive advantage afforded by our patent portfolio. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Changes in patent law or its interpretation could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a "first-to-invent" system to a "first-to-file" system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post-grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. A third-party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third-party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to file any patent application related to our products or invent any of the inventions claimed in our patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. Therefore, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U.S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. The Leahy-Smith 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, and results of operations.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot

predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

Our patent rights and other intellectual property may be subject to priority, ownership or inventorship disputes, interferences, and similar proceedings.

We may also be subject to claims that former employees, collaborators, or other third parties have an interest in our patents and patent applications or other intellectual property as an inventor or co-inventor. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents and patent applications, such co-owners' rights may be subject, or in the future subject, to assignment or license to other third parties, including our competitors. In addition, we may need the cooperation of any such co-owners to enforce any such patents and any patents issuing from such patent applications against third parties, and such cooperation may not be provided to us. Additionally, we may be subject to claims from third parties challenging our ownership interest in or inventorship of intellectual property we regard as our own, for example, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to another employer, to a former employer, or to another person or entity, despite our inclusion of valid, present-tense intellectual property assignment obligations. Litigation may be necessary to defend against claims, and it may be necessary or we may desire to enter into a license to settle any such claim.

If we or our licensors are unsuccessful in any priority, validity (including any patent oppositions), ownership or inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more of our patents, or such patent claims may be narrowed, invalidated, or held unenforceable, or through loss of exclusive ownership of or the exclusive right to use our owned or in-licensed patents. In the event of loss of patent rights as a result of any of these disputes, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. An inability to incorporate technologies, features or other intellectual property that are important or essential to our products could have a material adverse effect on our business and competitive position. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and product candidates. Even if we are successful in priority, inventorship or ownership disputes, it could result in substantial costs and be a distraction to management and other employees. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects.

We may be subject to claims that our employees, consultants, advisors, or contractors have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of a non-competition or non-solicitation agreement with our competitors, and third parties may claim an ownership interest in intellectual property we regard as our own. Such claims could harm our business, financial condition, and results of operations.

As is common in the medical device industry, our employees, consultants, and advisors may be currently or previously employed or engaged at universities or other medical device or healthcare companies, including our competitors and potential competitors. Some of these employees, consultants, advisors, 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, consultants, advisors, and contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future become subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property, including trade secrets or other proprietary information, of their current or former employers, competitors or other third parties. Also, we may in the future be subject to claims that these individuals are violating non-compete agreements with their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable

intellectual property rights or personnel, which could harm our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees, vendors, 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, may be ineffective under current or future case law, 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. Such defects in assignment or resulting claims could harm our business, financial condition, and results of operations.

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how, and other confidential and proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we generally have confidentiality and invention assignment provisions in contracts with our employees, consultants, suppliers, contract manufacturers, collaborators, and others upon the commencement of their relationship with us. However, we may not enter 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 confidential or 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 or proprietary technology and processes will not otherwise become known or independently developed by competitors. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Despite the protections we do place on our intellectual property or other confidential and 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 research and development or 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. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we

consider proprietary. 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. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions.

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 such breach.

We may not be able to enforce our intellectual property rights throughout the world.

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, may not favor the enforcement of patents, trademarks, and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent and trademark 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 and trademarks at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and many other countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

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

We rely on trademarks and trade names to build brand recognition and to promote, distinguish and market our products and services. Our current or future registered and unregistered trademarks or trade names may be challenged, opposed, infringed, circumvented or declared generic or descriptive, determined to be not entitled to registration, or determined to be infringing other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names or logos, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may

receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. We may in the future license our trademarks and trade names to third parties. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, and service marks may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Trademark litigation can be expensive, and the outcome can be highly uncertain. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. 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. If we are unable to license such technology, or if we are forced to license such technology, on unfavorable terms, our business could be harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

Moreover, some of our patents and patent applications in the future may be jointly owned with third parties. If we are unable to obtain an exclusive license to any such third party joint owners' interest in such patents or patent applications, such joint owners may be able to license their rights to other third parties, including our competitors, who could market competing products and technology. In addition, we may need the cooperation of any such joint owners in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could harm our business, financial condition and results of operations.

If our third-party manufacturers do not respect our intellectual property and trade secrets and produce or sell competitive products using our designs or intellectual property, our business, financial condition and results of operation would be harmed.

Although our agreements with third-party manufacturing partners generally seek to preclude them from misusing our intellectual property and trade secrets, or using our designs to manufacture products for our competitors, we may be unsuccessful in monitoring and enforcing our intellectual property rights and may find counterfeit goods in the market being sold as our products and any future products similar to ours produced for our competitors using our intellectual property. Additionally, any steps to stop counterfeits may not be successful and customers who purchase these counterfeit goods may experience product defects or failures, harming our reputation and brand and causing us to lose future sales. Any of the foregoing could harm our business, financial condition and results of operations.

Intellectual property rights do not necessarily address all potential threats, and limitations in intellectual property rights could harm our business, financial condition, and results of operations.

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

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our products that is in the public domain;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the applicable issued patent or pending patent application that we own now or may own or license in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or our future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any future patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our patents or patent applications omit individuals who should be listed as inventors or include individuals that should not be listed as inventors, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- claims of our patents or patent applications, if and when issued, may not cover our products or technologies or competitive products or technologies;
- the inventors of our patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; or

- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a patent covering such intellectual property.

Any of the foregoing could harm our business, financial condition, and results of operations.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be volatile or may decline steeply or suddenly regardless of our operating performance, which could result in substantial losses for purchasers of our common stock, and we may not be able to meet investor or analyst expectations.

The market price of our common stock may be highly volatile and fluctuate or decline significantly in response to numerous factors, many of which are beyond our control, including:

- variations between our actual operating results, or those of companies that are perceived to be similar to us, and the expectations of securities analysts, investors and the financial community;
- any forward-looking financial or operating information we may provide to the public or securities analysts, any changes in this information or our failure to meet expectations based on this information;
- actions of securities analysts who initiate or maintain coverage of us, changes in financial estimates by any securities analysts who follow our Company or our failure to meet these estimates or the expectations of investors;
- additional shares of our common stock being sold into the market by us or our existing stockholders, or the anticipation of such sales, including if existing stockholders sell shares into the market when applicable "lock-up" periods end;
- hedging activities by market participants;
- announcements by us or our competitors of significant products or features, technical innovations, acquisitions, strategic partnerships, joint ventures or capital commitments;
- changes in operating performance and stock market valuations of companies in our industry, including our competitors;
- changes in third-party payor reimbursement policies;
- an inability to obtain additional funding;
- general economic, industry and market conditions, including price and volume fluctuations in the overall stock market;
- expiration of market stand-off or lock-up agreements;
- lawsuits threatened or filed against us;
- developments in new legislation and pending lawsuits or regulatory actions, including interim or final rulings by judicial or regulatory bodies; and
- other events or factors, including those resulting from political conditions, election cycles, war or incidents of terrorism, or responses to these events, many of which are outside of our control.

Due to our failure to comply with the continued listing standard set forth in the New York Stock Exchange (NYSE)'s Listed Company Manual, our common stock has been suspended from trading on the NYSE effective at

the opening of business Eastern Standard Time on November 22, 2023 and may be delisted from the NYSE, which may negatively impact our stockholders and the trading price and liquidity of our common stock. We commenced trading on the OTCQX on the same day. We have subsequently appealed the NYSE's determination. The appeal is still in process and there can be no assurance that an appeal will be successful.

In addition, extreme price and volume fluctuations in the stock markets have affected and continue to affect many life sciences and technology companies' stock prices. Stock prices often fluctuate in ways unrelated or disproportionate to the companies' operating performance. In the past, stockholders have filed securities class action litigation following periods of market volatility. This risk is especially relevant for us because medical technology companies have experienced significant stock price volatility in recent years. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and seriously harm our business.

Moreover, because of these fluctuations, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failure to meet the expectations of industry or financial analysts or investors for any period. If our revenues or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings forecasts that we may provide.

An active trading market for our common stock may never develop or be sustained, and you may not be able to resell your shares at or above your purchase price.

An active trading market for our common stock may never develop or be sustained. In the absence of an active trading market for our common stock, you may not be able to sell your shares of our common stock when desired or at or above your purchase price. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially and adversely affect our business.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of March 1, 2024, we had a total of 66,778,504 shares of our common stock outstanding, assuming no exercise of outstanding options. Sales of a substantial number of shares, or the perception that such sales may occur, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

In addition, shares of our common stock issued upon the exercise of options, vesting of restricted stock units and exercise of warrants may also be sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold in the public market, the trading price of our common stock could decline. As of March 1, 2024, we had outstanding warrants to purchase total of 323,284 shares of our common stock at exercise prices ranging from $10.95 per share to $12.0 per share, and outstanding prefunded warrants to purchase total of 31,066,823 shares of our common stock at exercise price of $0.001 per share.

We do not intend to pay dividends for the foreseeable future and, as a result, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividends on our common stock and do not intend to pay any cash dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the development of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. In addition, the terms of our amended and restated credit agreement with Perceptive Credit Holdings III, LP restrict our ability to pay dividends to limited circumstances. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. It is possible that interpretation, industry practice and guidance involving estimates and assumptions may evolve or change over time. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

Future securities issuances could result in significant dilution to our stockholders and impair the market price of our common stock.

Future issuances of shares of our common stock, or the perception that these sales may occur, could depress the market price of our common stock and result in dilution to existing holders of our common stock. As of December 31, 2023, there are 31,066,823 pre-funded warrants outstanding, which are exercisable for shares of our common stock at a nominal exercise price. Also, to the extent outstanding options to purchase shares of our common stock are exercised or options, restricted stock units or other stock-based awards are issued or become vested, there will be further dilution. The amount of dilution could be substantial depending upon the size of the issuances or exercises. Furthermore, we may issue additional equity securities that could have rights senior to those of our common stock. As a result, purchasers of our common stock bear the risk that future issuances of debt or equity securities may reduce the value of our common stock and further dilute their ownership interest.

Delaware law and provisions in our amended and restated certificate of incorporation and bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

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

- establishing a classified board of directors so that not all members of our board of directors are elected at one time;
- permitting our board of directors to establish the number of directors and fill any vacancies and newly-created directorships;
- providing that directors may only be removed for cause and only by the affirmative vote of the holders of at least a majority of the voting power of all then outstanding shares of our capital stock;
- requiring the approval of holders of two-thirds of our outstanding common stock to amend some provisions in our amended and restated certificate of incorporation and bylaws;
- authorizing the issuance of preferred stock that our board of directors could use to implement a stockholder rights plan;
- prohibiting stockholders from calling special meetings of stockholders;
- prohibiting stockholder action by written consent, which has the effect of requiring all stockholder actions to be taken at a meeting of our stockholders;

- providing that the board of directors is expressly authorized to make, alter or repeal our bylaws;
- restricting the forum for certain litigation involving us to Delaware or federal courts, as applicable; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

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

The provisions of our amended and restated certificate of incorporation requiring exclusive forum in the Court of Chancery of the State of Delaware and the federal district courts of the United States for certain types of lawsuits may have the effect of discouraging lawsuits against our directors and officers.

Our amended and restated certificate of incorporation provides that, unless we otherwise consent in writing, (A) (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer, other employee or stockholder of us to the us or the our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws (as either may be amended or restated) or as to which the Delaware General Corporation Law confers exclusive jurisdiction on the Court of Chancery of the State of Delaware or (iv) any action asserting a claim governed by the internal affairs doctrine of the law of the State of Delaware shall, to the fullest extent permitted by law, be exclusively brought in the Court of Chancery of the State of Delaware or, if such court does not have subject matter jurisdiction thereof, the federal district court of the State of Delaware; and (B) the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act; however, there is uncertainty as to whether a court would enforce such provision, and investors cannot waive compliance with federal securities laws and the rules and regulations thereunder. Notwithstanding the foregoing, the exclusive forum provision shall not apply to claims seeking to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts of the United States have exclusive jurisdiction. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may also result in increased costs for stockholders to bring any such claim, which may discourage such lawsuits against us and our directors, officers, and other employees, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. Any person or entity purchasing or otherwise acquiring or holding any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our certificate of incorporation (as may be amended or restated).

Risks Related to Being a Public Company

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 are required to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, beginning with this annual report on Form 10-K, 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, unless we then qualify as a smaller reporting company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

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. We will need to continue to dedicate significant internal resources to assess and document the adequacy of our internal control over financial reporting, potentially engage outside consultants from time to time, continue to improve control processes as appropriate, and validate through testing that controls are designed and operating effectively. 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.

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

We are subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. Any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We are an emerging growth company and a "smaller reporting company," and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies and smaller growth companies could make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including:

- not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and annual report on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could be an emerging growth company for up to five years following the completion of our IPO. Our status as an emerging growth company will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have more than $1.07 billion in annual revenue;

- the date we qualify as a "large accelerated filer;"

- the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or

- the last day of the 2026 fiscal year.

We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded to emerging growth companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

We are an emerging growth company, as defined in 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. We have elected to avail ourselves of this exemption and, therefore, for new or revised accounting standards applicable to public companies, we will be subject to an extended transition period until those standards would otherwise apply to private companies. As a result, our consolidated financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

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

If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the trading price or trading volume of our common stock could decline.

The trading market for our common stock will be influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If one or more analysts initiate research with an unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline.

Regardless of accuracy, unfavorable interpretations of our financial information and other public disclosures could have a negative impact on our stock price. If our financial performance fails to meet analyst estimates, for any of the reasons discussed above or otherwise, or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our stock price would likely decline.

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

General Risks

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 clinicians' confidence and reduce long-term demand for our GentleWave System, even if the regulatory or legal action is unfounded or not material to our operations.

In the past, securities class action litigation has often been brought against companies following a decline in the market price of its securities. This risk is especially relevant for us because medical technology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

General economic and financial market conditions may exacerbate our business risks.

Global macroeconomic conditions and the world's financial markets remain susceptible to significant stresses caused by, among other things, political instability, changes in international trade relationships, inflation and rising interest rates and conflicts, such as the war in Ukraine and the Gaza Strip, which could result in reductions in available credit and government spending, economic downturn or stagnation, foreign currency fluctuations and volatility in the valuations of securities generally. Clinicians and distributors may respond to such economic pressures by reducing or deferring their capital spending or reducing staff. Furthermore, unfavorable changes in foreign exchange rates versus the U.S. dollar could increase our product and labor costs, thus reducing our gross profit.

Consumer spending habits are also affected by prevailing economic conditions, levels of employment, salaries and wage rates, debt obligations, discretionary income, consumer confidence and consumer perception of current and future economic conditions. A decrease in U.S. or certain international economies or an uncertain economic outlook would adversely affect consumer spending habits which may, among other things, result in reduced patient traffic in dental practitioners' offices or a reduction in the demand for dental services generally, which may result in dental practitioners postponing investments in capital equipment, such as our GentleWave System, and less demand for our single-use PIs, both of which would adversely affect our sales and operating results.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Cybersecurity Risk Management, Strategy, Governance, and Incident Disclosure

We manage cybersecurity threats as part of our general risk mitigation, evaluation, and oversight processes. We implement our cybersecurity program internally through established policies, standards, and the use of enterprise security services that focus on emerging and ongoing cybersecurity risks. We manage these risks to our employees, customers, stockholders, and business partners through a coordinated and consistent IT risk management process overseen by the Senior Manager, IT who assumes the role of our Chief Information Security Officer ("CISO").

Our information risk management framework is designed to manage and protect against risks in three broad categories: (i) operational risk; (ii) financial risk; and (iii) safety, environmental, and regulatory risk. We consider and evaluate reputational risk as an element of each of these risk categories.

We conduct regular security and awareness training for all new hires and for current employees. Employees are required to apply risk assessment processes and to professionally assess risks in the course of performing their job duties.

We conduct vulnerability scans of business critical systems on an annual, quarterly, and daily basis. We utilize external third parties to assist in assessing our systems, conduct scans and provide reports based on these scans and

we address vulnerabilities as they are identified. We generally review current and prospective third party service providers for cybersecurity risks.

Management, under the supervision of our Chief Information Security Officer (CISO), is directly responsible for assessing and managing cybersecurity risks and otherwise implementing our cybersecurity program, which includes our Incident Response Policy and Incident Response Procedure. The CISO reports directly to our Chief Executive Officer. Our CISO has over ten years of IT experience and nine years of significant experience managing cybersecurity threats across our industry. The CISO may call upon business and legal stakeholders across our company to manage cybersecurity threats and incidents.

The audit committee of our board of directors is responsible for oversight of the company's programs, policies, procedures, and risk management activities related to information security and data protection. The audit committee meets regularly with CISO to discuss threats, risks, and ongoing efforts to enhance cyber resiliency, as well as changes to the broader cybersecurity landscape. Management promptly updates our board of directors regarding significant threats and incidents as they arise.

Item 2. Properties.

Our corporate headquarters, which includes our manufacturing facility, is located in Laguna Hills, California, where we occupy approximately 59,000 square feet of space under a series of lease agreements. The lease agreement for our corporate headquarters expires in December 2026. We believe our current facilities are sufficient to meet our current and anticipated future needs and that suitable additional space is available as needed to accommodate expansion of our operations.

Item 3. Legal Proceedings.

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal and administrative proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We are not currently a party to any material legal proceeding.

Item 4. Mine Safety Disclosures.

Not applicable.

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

Market Information

Our common stock was listed and traded on the New York Stock Exchange (NYSE) under the symbol "SONX" from October 29, 2021 to November 21, 2023. Due to our failure to comply with the continued listing standard set forth in the NYSE's Listed Company Manual, NYSE suspended trading of our common stock effective at the opening of business Eastern Standard Time on November 22, 2023. We commenced trading on the OTCQX on the same day under the same symbol.

Holders of Record

As of March 1, 2024, we had approximately 127 holders of record of our common stock. This number does not include beneficial owners whose shares were held in street name. The actual number of holders of our common stock 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 or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters," in this Annual Report for information about our equity compensation plans.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities

None.

Use of Proceeds

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. 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" and elsewhere in this Annual Report. See "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are a commercial-stage medical technology company focused on saving teeth from tooth decay, the most prevalent chronic disease globally. We have developed and manufacture the GentleWave® System, an innovative technology platform designed to treat tooth decay by cleaning and disinfecting the microscopic spaces within teeth without the need to remove tooth structure. The GentleWave System employs a sterilized, single-use procedure instrument ("PI"), to transform root canal therapy ("RCT"), by addressing the limitations of conventional methods.

The clinical benefits of our GentleWave System when compared to conventional methods of RCT include improved clinical outcomes, such as superior cleaning that is independent of root canal complexity and tooth anatomy, high and rapid rates of healing and minimal to no post- operative pain. In addition to the clinical benefits, the GentleWave System can improve the workflow and economics of dental practices. We began scaling commercialization of our current technology in 2017 and are focused on establishing the GentleWave Procedure as the standard of care for RCT.

Our GentleWave System represents an innovative technology platform and approach to RCT. The GentleWave System is a Class II device and has received 510(k) clearance from the FDA for preparing, cleaning, and irrigating teeth indicated for RCT. The key components of our GentleWave System are a sophisticated and mobile console and a pre-packaged, sterilized, single-use PI. The GentleWave System utilizes a proprietary mechanism of action that is designed to combine procedure fluid optimization, broad-spectrum acoustic energy and advanced fluid dynamics to efficiently and effectively reach microscopic spaces within teeth and dissolve and remove tissue and bacteria with minimal or no removal of tooth structure. We have invested significant resources in establishing a broad intellectual property portfolio that protects the GentleWave Procedure and its unique mechanism of action, as well as future capabilities under development. We believe our GentleWave System transforms the patient and dental practitioner experience and addresses many of the limitations of conventional RCT.

In the United States and Canada, our direct sales force markets and sells the GentleWave System to dental practitioners performing a high volume of root canals as part of their practice. Our commercial strategy and sales model involves a focus on driving adoption of our GentleWave System by increasing our installed base of consoles and maximizing recurring PI revenue through increased utilization. We have been and will continue to expand the size of our sales and clinician support teams to support our efforts of driving adoption and utilization of the GentleWave System. We plan to pursue marketing authorizations and similar certifications to enable marketing and engage in other market access initiatives over time in attractive international regions in which we see significant potential opportunity.

As of December 31, 2023, we had an installed base of approximately 1,134 GentleWave Systems that had performed a milestone of more than 1.3 million GentleWave patient procedures since commercialization. We generated revenue of $43.9 million and a net loss of $60.9 million for the year ended December 31, 2023 compared to revenue of $41.7 million and a net loss of $57.1 million for the year ended December 31, 2022. As of December 31, 2023, we had cash and cash equivalents and short-term investments of $46.8 million, an accumulated deficit of $430.0 million, and $40.0 million in principal outstanding under our term loan facility, $24.9 million of which will be repaid by the end of 2024.

On September 27, 2022, we completed a private placement, issuing an aggregate of 23.0 million shares of common stock at a purchase price of $0.95 per share and pre-funded warrants to purchase an aggregate of 43.3 million shares of common stock at a purchase price of $0.949 per pre-funded warrant to certain institutional investors and accredited investors. The pre-funded warrants have an exercise price of $0.001 per share of common stock, are

immediately exercisable and will remain exercisable until exercised in full. The aggregate net proceeds from the private placement, after deducting placement agent fees and other offering expenses, were $59.0 million.

We expect to continue to incur net losses for the next several years. We expect to continue to make investments in our sales and marketing organization, including increasing the number of U.S. and Canadian sales representatives, expanding our international marketing programs and expanding direct to clinician digital marketing efforts to help facilitate further adoption among existing accounts and to broaden awareness and adoption of our products to new clinicians. We also expect to continue to make investments in research and development, regulatory affairs and clinical studies to develop future generations of our GentleWave products, support regulatory submissions and demonstrate the clinical efficacy of our new products. Moreover, we incur additional expenses as a result of operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance, investor relations, and other administrative and professional services expenses. As a result of these expenses, we will require additional financing to fund our operations and planned growth.

Our ability to continue as a going concern depends on our ability to continue to commercialize our products, achieve and maintain profitable operations, as well as the adherence to conditions of outstanding term loans (see Note 9 to the Consolidated Financial Statements). We will require additional financing in order to fund our future expected negative cash flows. There is a material uncertainty that raises substantial doubt about our ability to continue as a going concern and, therefore, that we may be unable to realize our assets and discharge our liabilities in the normal course of business (see *Liquidity and Capital Resources* section).

On March 1, 2024, we divested our TDO software segment by selling substantially all the assets and liabilities of TDO Software, Inc, our wholly owned subsidiary, for approximately $16.0 million, with $15.0 million received upon closing and the balance due in approximately 12 months.

Factors Affecting Our Performance and Key Business Metrics

We believe there are several important factors that impact our operating performance and results of operations. We also 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 following factors and key business metrics are important indicators of our performance:

- *Installed base of GentleWave Systems:* We have focused on driving adoption of the GentleWave Procedure among endodontists and general practitioners in the United States and Canada. To drive further adoption of our system, we will continue to restructure our team of capital sales representatives, who are focused on system placement by directly engaging with dental practitioners and educating them about the compelling value proposition of the GentleWave Procedure. Our sales force leverages third-party data of root canal procedure volumes by practitioner, in order to enable us to efficiently and effectively identify target accounts. We believe that our current targeting strategy identifies a well-defined customer base that is accessible by our direct sales organization.

- *System utilization:* Our revenue is significantly impacted by the utilization of our GentleWave System. Our objective is to establish the GentleWave Procedure as the standard of care for RCT. We intend to increase awareness of the GentleWave Procedure among dental practitioners and, in select markets where we establish a large installed base, directly with patients through various targeted direct-to-patient marketing initiatives, showcasing the benefits and points of difference of the GentleWave Procedure. We believe that once patients become aware of the GentleWave Procedure, they will seek the GentleWave Procedure over conventional RCT. We believe these initiatives will drive a greater volume of root canal procedures to dental practitioners who offer the GentleWave Procedure, thereby increasing utilization of our system.

- *Gross margins:* Our results of operations depend, in part, on our ability to increase our gross margins by more effectively managing our costs to produce our GentleWave Console and single-use PI, and to scale our manufacturing operations efficiently. We are undertaking continuous margin improvement programs, including simplifying our product offering to one PI that can be used across various platforms, implementing lean manufacturing methods and working with our suppliers to reduce material costs. We launched the CleanFlow PI in April 2022. In August 2023, we received CleanFlow's FDA clearance to include anterior teeth. CleanFlow PI includes an optimized design and enhanced matrix system for better effectiveness and ease of use. CleanFlow PI is now our leading PI and we have phased

out the legacy PI designed for molar teeth (a "Molar PI"), anteriors and premolars (an "APM PI") substantially in early 2024. We anticipate that the combination of these strategies will continue driving margin improvement.

- *Commercial organization:* As of December 31, 2023, our sales and customer support team consisted of approximately 61 employees. We intend to continue to re-prioritize our commercial organization to increase the adoption of our products among existing and new customer accounts. Successfully recruiting and training a sufficient number of sales and customer support employees is required to achieve growth at the rate we expect. The effectiveness of our commercial organization re-priotization can impact our revenue growth and our costs incurred in anticipation of such growth.

Effects of the Macroeconomic Environment

Our consolidated financial statements as of and for the year ended December 31, 2023 reflect our estimate of the impact of the macroeconomic environment, including the impact of inflation and higher interest rates. The duration and scope of these conditions cannot be predicted; therefore, the extent to which these conditions will directly or indirectly impact our business, results of operations and financial condition, is uncertain. We are not aware of any specific event or circumstance that would require an update to our estimates, judgments and assumptions or a revision of the carrying value of our assets or liabilities as of the date of this filing, except the impairment of long-lived assets disclosed in this Annual Report on Form 10-K .

Stock Listing

Due to our failure to comply with the continued listing standard set forth in the New York Stock Exchange (NYSE)'s Listed Company Manual, our common stock has been suspended from trading on the NYSE effective at the opening of business Eastern Standard Time on November 22, 2023 and may be delisted from the NYSE, which may negatively impact our stockholders and the trading price and liquidity of our common stock. We commenced trading on the OTCQX on the same day. We have subsequently appealed the NYSE's determination. The appeal is still in process and there can be no assurance that an appeal will be successful.

Components of Our Results of Operations

Revenue

Our revenue has consisted primarily of product revenue and software revenue. We generate product revenue on the capital sale of our GentleWave Console and recurring sales of our single-use PI and accessories. To a lesser extent, we also derive product revenue from service and repair and extended warranty contracts with our existing customers. We expect our product revenue to increase in absolute dollars as we increase adoption and utilization of our GentleWave System, though revenues may fluctuate from quarter to quarter. We also expect the growth of recurring sales of our single-use PI and accessories to outpace the growth of capital sale of our GentleWave Console. Software revenue relates to fees we receive for licensing our TDO practice management tool to dental practitioners. We expect our consolidated revenue to decrease as we have divested our software segment in March 2024. See discussion of the divestiture of our software segment in *Overview* in *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.*

Cost of Sales and Gross Margin

Cost of sales consists primarily of manufacturing overhead costs, material costs, and direct labor to produce our products, warranty, provisions for slow-moving and obsolete inventory, and other direct costs such as shipping and software support. A significant portion of our cost of sales currently consists of manufacturing overhead costs. These overhead costs include personnel compensation, including stock-based compensation expenses, facilities, production equipment depreciation, operations supervision, quality control, material procurement, intangible assets amortization and impairment of long-lived assets. We provide a one-year warranty on capital equipment upon initial sale, and we establish a reserve for warranty repairs based on historical warranty repair costs incurred. Provisions for warranty obligations, which are included in cost of sales, are provided for at the time of shipment. We expect our cost of sales to increase in absolute dollars for the foreseeable future primarily as, and to the extent, our revenue grows, partially offset by lower unit product costs, though it may fluctuate from period to period.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily, product mix and the resulting average selling prices, production volumes, manufacturing costs and product yields, and the implementation of cost reduction strategies. Our software gross margin is generally higher than our product gross margin. As a result of these factors and our divestiture of our software segment in March 2024, we expect gross margin to fluctuate in the short term, however, to moderately increase year over year. We are engaged in various efforts to improve our gross margin by reducing unit product costs to the extent our production volumes increase, as well as through product design improvements, reducing material costs through negotiations with suppliers and optimizing the manufacturing process and reducing the costs to service our installed base.

Operating Expenses

Selling, General and Administrative

Selling, general and administrative ("SG&A") expenses consist primarily of personnel compensation, including stock-based compensation, related to selling, marketing, professional education, administration, finance, information technology, legal, and human resource functions. SG&A expenses also include commissions, training, travel expenses, promotional activities, conferences, trade shows, professional services fees, audit fees, legal fees, insurance costs and general corporate expenses including allocated facilities-related expenses. We expect our SG&A expenses to decrease in absolute dollars for the foreseeable future as we implement our cost saving measures, re-prioritize our commercial infrastructure, become more efficient in the general and administrative functions, and have divested our software segment, though it may fluctuate from period to period.

Research and Development

Research and development ("R&D") expenses consist primarily of costs incurred for proprietary R&D programs, and include costs of product engineering, product development, regulatory affairs, consulting services, materials, and depreciation, as well as other costs associated with products and technologies being developed. These expenses include employee and non-employee compensation, including stock-based compensation, supplies, materials, consulting, related travel expenses and facilities expenses. We expect our R&D expenses to decrease in absolute dollars for the foreseeable future as we become more efficient in our effort to develop, enhance, and commercialize new products and technologies, and have divested our software segment. However, we expect our R&D expenses as a percentage of revenue to vary over time depending on the level and timing of initiating new product development efforts.

Impairment of Long-lived Assets

Long-lived assets include definite-lived intangibles, long-lived fixed assets and lease right-of-use assets. An impairment charge of long-lived assets is recognized when an assessment of potential impairment indicates that an asset's carrying amount is not recoverable. The carrying amount of the asset is reduced to its estimated fair value based on discounted cash flow analysis. An impairment analysis is subjective and assumptions regarding future growth rates and operating expense levels can have a significant impact on the expected future cash flows and impairment analysis.

Other (Expense) Income, Net

Other (expense) income, net, consists primarily of interest expense under our outstanding term loan, investment income, and recognition of an employer retention credit ("ERC") under The Coronavirus Aid, Relief, and Economic Security ("CARES") Act.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table shows our results of operations for the years ended December 31, 2023 and 2022, together with the dollar and percentage change in those items:

	Year Ended December 31,		Change	
	2023	2022	$	%
	(in thousands, except percentages)			
Revenue	$ 43,865	$ 41,656	2,209	5%
Cost of sales:				
Product and software	31,559	31,176	383	1%
Impairment of long-lived assets	1,584	—	1,584	100%
Total cost of sales	33,143	31,176	1,967	6%
Gross profit	10,722	10,480	242	2%
Gross margin	24%	25%		
Operating expenses:				
Selling, general and administrative	54,022	51,906	2,116	4%
Research and development	12,355	16,776	(4,421)	(26)%
Impairment of long-lived assets	2,088	—	2,088	100%
Total operating expenses	68,465	68,682	(217)	—
Loss from operations	(57,743)	(58,202)	459	(1)%
Other (expense) income, net:				
Interest and financing costs, net	(3,174)	(3,228)	54	(2)%
Employee Retention Credit	—	4,382	(4,382)	(100)%
Loss before income tax expense	(60,917)	(57,048)	(3,869)	7%
Income tax expense	(2)	(2)	—	0%
Net loss	$ (60,919)	$ (57,050)	(3,869)	7%

Revenue

Our breakdown of revenue for the years ended December 31, 2023 and 2022, together with the dollar and percentage change in those items:

	Year Ended December 31,		Change	
	2023	2022	$	%
	(in thousands, except percentages)			
Product revenue	$ 34,628	$ 33,280	1,348	4%
Software revenue	9,237	8,376	861	10%
Total revenue	$ 43,865	$ 41,656	2,209	5%

Total revenue increased $2.2 million, or 5%, in 2023 compared to 2022, reflecting increase in the average selling price of GentleWave PIs sold as further discussed below.

For the year ended December 31, 2023, we generated $9.2 million and $21.6 million from the sale of GentleWave Consoles and PIs, respectively, compared to $10.8 million and $18.9 million, respectively, for the year ended December 31, 2022.

Product revenue increased $1.3 million, or 4%, in 2023 compared to 2022, which was primarily driven by a $2.7 million increase in GentleWave PI sales, partially offset by a decrease from GentleWave Console sales. The increase in GentleWave PI sales was primarily driven by an approximate 11% increase in the average selling price of PIs. The decrease in GentleWave Console sales was primarily attributed to a 9% decrease in sales volumes and a 5% decrease in average selling price.

Software revenue increased $0.9 million, or 10%, in 2023 compared to 2022, which was primarily due to a higher number of customer subscriptions.

Cost of sales and Gross margin

Cost of sales increased $2.0 million, or 6%, in 2023 compared to 2022, which was primarily driven by a $1.6 million charge due to impairment of long-lived assets. The remainder of the increase in cost of sales was primarily driven by a $2.9 million charge related to inventory in 2023 due to phasing out our legacy GentleWave Console (“Gen 3”) and the phase-out of our molar and pre-molar legacy procedure instruments, partially offset by a $2.6 million decrease

attributed to lower cost per unit in the Product segment, as well as improved operational efficiencies in console service cost. There were no significant changes in the Software segment cost of sales.

Gross margin remained relatively flat year over year due to the aforementioned changes in cost of sales. We expect gross margin to fluctuate in the short term, however, to moderately increase year over year, as described in the *Components of Our Results of Operations* above.

Selling, general and administrative expenses

SG&A expenses increased $2.1 million, or 4%, in 2023 compared to 2022, which was primarily driven by an approximately $1.6 million increase in our Product segment due to higher sales and marketing employee-related compensation and benefit expenses, including stock-based compensation, as a result of the expansion of our commercial infrastructure. There were no significant changes in selling, general, and administrative expenses in the Software segment. We expect SG&A expenses to decrease as described in the *Components of Our Results of Operations* above.

Research and development expenses

R&D expenses decreased $4.4 million, or 26%, in 2023 compared to 2022, which was primarily driven by approximately $2.2 million in lower spending on product development and outside services in the Product segment, as well as a lower headcount. There were no significant changes in R&D expenses in the Software segment. We expect R&D expenses to decrease as described in the *Components of Our Results of Operations* above.

Impairment of Long-lived Assets

In the Product segment, the Company recognized in 2023 a total impairment charge of $3.7 million for long-lived assets, of which $1.6 million was recorded in cost of sales and the remainder in operating expenses.

Other (expense) income, net

Other income decreased by $4.0 million in 2023 compared to 2022, which was primarily driven by recognition of a $4.4 million ERC recognized under the CARES Act related to qualified wages paid to employees in 2022.

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 continue to incur net losses for the next several years.

On September 27, 2022, we completed a private placement (the "Private Placement"), issuing an aggregate of approximately 23.0 million shares of our common stock at a purchase price of $0.95 per share and pre-funded warrants to purchase an aggregate of 43.3 million shares of our common stock at a purchase price of $0.949 per pre-funded warrant. The pre-funded warrants have an exercise price of $0.001 per share of common stock, are immediately exerciseable and will remain exerciseable until exercised in full. The aggregate net proceeds from the Private Placement, after deducting placement agent fees and other offering expenses, were $59.0 million.

As of December 31, 2023, we had cash and cash equivalents and short-term investments of $46.8 million, an accumulated deficit of $430.0 million, and $40.0 million in principal outstanding under our term loan facility, of which $24.9 million will be repaid by the end of 2024. For the years ended December 31, 2023 and 2022, our net losses from operations were $60.9 million and $57.1 million, respectively, and our net cash used in operating activities was $46.1 million and $61.1 million, respectively.

Indebtedness

On April 6, 2022, we entered into Amendment No. 1 (the “First Amendment”) to the Amended Perceptive Loan Agreement. We borrowed the first tranche of $10.0 million on July 29, 2022 and received net proceeds of $9.9 million. We forfeited the second tranche of delayed-draw term loan of $10.0 million under the First Amendment.

As a condition to entering into the First Amendment, on April 6, 2022, we also amended the warrants previously issued to Perceptive and certain of its affiliates to purchase an aggregate of 304,105 shares of our common stock. Such warrants were amended solely to reduce the exercise price of the warrants to $12.00 per share. In August 2022, a portion of these warrants representing 153,421 shares were transferred to a third party and its affiliates.

For the years ended December 31, 2023 and 2022, the interest rate for amounts borrowed under the Amended Perceptive Loan Agreement, was the greater of the 1-month LIBOR and 2.00% plus the applicable margin of 9.25%. On January 13, 2023, we entered into Amendment No. 2 (the "Second Amendment") to the Amended Perceptive Loan Agreement to replace the existing benchmark rate from the one-month LIBOR with a one-month Secured Overnight Financing Rate ("SOFR"). All other terms remain unchanged on the original agreement.

On March 1, 2024, we entered to Amendment No. 3 (the "Third Amendment") to the Amended Perceptive Loan Agreement. Pursuant to the Third Amendment, we made a one-time $15.0 million principal repayment on March 1, 2024, and agreed to make an amortization payment of $1.8 million on the outstanding principal on March 31, 2024 and make monthly amortization payments on the outstanding principal amount each in the amount of $0.9 million on each payment date commencing on April 30, 2024.The Third Amendment also modified certain covenants included in the Amended Perceptive Loan Agreement and released all liens granted to the TDO software assets. Future principal repayments and the net carrying value of the Perceptive Loan, as of December 31, 2023, are as follows:

	Principal
	(in thousands)
2024	$ 24,900
2025	10,800
2026	4,300
Total principal payment	40,000
Debt discounts	(2,633)
Net carrying value	$ 37,367

We are permitted to make voluntary prepayments, subject to a scaled prepayment premium that ranges from 7.0% to 1.0% of the aggregate principal amount outstanding on such prepayment date for prepayments made after August 23, 2022 and before August 23, 2025. No prepayment premium is required for payments made after August 23, 2025.

The Amended Perceptive Loan Agreement contains events of default, including, without limitation, upon: (i) failure to make a payment pursuant to the terms of the agreement; (ii) violation of certain covenants; (iii) payment or other defaults on other indebtedness; (iv) material adverse change in the business or change in control; (v) insolvency; (vi) significant judgments; (vii) incorrectness of representations and warranties; (viii) regulatory matters; and (ix) failure by us to maintain a valid and perfected lien on the collateral securing the borrowing. Based on the Amended Perceptive Loan Agreement, we have granted a security interest in substantially all of our assets.

The Amended Perceptive Loan Agreement includes financial covenants that require us to (i) maintain, at all times, a minimum aggregate balance of $3.0 million in cash in one or more controlled accounts, and (ii) pursuant to the Third Amendment, satisfy certain minimum revenue thresholds, measured for the consecutive 12-month periods ending on each calendar quarter-end until June 30, 2026 as follows:

For 12-month Period Ending	Revenue	
		(in thousands)
March 31, 2024	$	39,000
June 30, 2024	$	35,500
September 30, 2024	$	33,000
December 31, 2024	$	31,500
March 31, 2025	$	31,000
June 30, 2025	$	33,000
September 30, 2025	$	35,935
December 31, 2025	$	40,160
March 31, 2026	$	44,950
June 30, 2026	$	51,500

Pursuant to the Third Amendment, the lender also waived the covenant requiring the absence of any "going concern" or like qualification or exception or any qualification or exception as to the scope of the audit, solely with respect to the fiscal year ending on December 31, 2023.

Failure to satisfy any covenants would constitute an event of default under the Amended Perceptive Loan Agreement. In the event of an event of default, the lender may terminate its commitments and declare all amounts outstanding under the Amended Perceptive Loan Agreement immediately due and payable, together with accrued interest and all fees and other obligations. The amount of such repayment will include payment of any prepayment premium applicable due to the time of such payment. In addition, upon the occurrence and during the continuance of any event of default, the applicable margin will increase by 3.00% per annum to 12.25%. As of December 31, 2023, we were in compliance with all covenants and conditions under such agreement.

Divestiture of the TDO software segment

On March 1, 2024, we divested our TDO software segment by selling substantially all assets and liabilities of TDO Software, Inc, our wholly owned subsidiary, for approximately $16.0 million, with $15.0 million received upon closing and the balance due in approximately 12 months.

Funding requirements

We expect our operating expenses to decrease for the foreseeable future as we implement our cost saving measures, re-prioritize our commercial infrastructure, become more efficient in the R&D and general and administrative functions, and have divested our software segment, though it may fluctuate from period to period. The timing and amount of our operating expenditures will depend on many factors, including:

- the degree and rate of market acceptance of our current and future products and the GentleWave Procedure;
- the scope and timing of investment in our sales force;
- the impact of the macroeconomic environment, including as a result of inflation and rising interest rates, the war in Ukraine and the Gaza strip, or any other pandemic, epidemic or infectious disease outbreak, on our business;
- the cost of our research and development activities;
- the cost and timing of additional regulatory clearances or approvals;
- the costs associated with any product recall that may occur;
- the costs associated with the manufacturing of our products at increased production levels;
- the costs of attaining, defending and enforcing our intellectual property rights;
- whether we acquire third-party companies, products or technologies;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the scope, rate of progress and cost of our current or future clinical trials and registries;
- the emergence of competing new products, technologies or alternative treatments or other adverse market developments;
- our ability to raise additional funds to finance our operations;

- debt service requirements; and
- the cost associated with being a public company.

Our consolidated financial statements included elsewhere in this Annual Report have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to our ability to continue as a going concern.

Our ability to continue as a going concern depends on our ability to continue to commercialize our products, achieve and maintain profitable operations, as well as the adherence to conditions of the outstanding term loan (see Note 9 to the Consolidated Financial Statements). Without additional financing, we will have insufficient liquidity to achieve further commercialization of our products and maintain compliance with our loan covenants. Due to these conditions, there is substantial doubt about our ability to continue as a going concern and, therefore, we may be unable to realize our assets and discharge our liabilities in the normal course of business.

We will require additional financing in order to fund future expected negative cash flows. Due to our failure to comply with the continued listing standard set forth in the New York Stock Exchange (NYSE)'s Listed Company Manual, our common stock has been suspended from trading on the NYSE effective at the opening of business Eastern Standard Time on November 22, 2023 and may be delisted from the NYSE, which may negatively impact our stockholders and the trading price and liquidity of our common stock. We commenced trading on the OTCQX on the same day. We have subsequently appealed the NYSE's determination. The appeal is still in process and there can be no assurance that an appeal will be successful.

The over-the-counter markets are a more limited market than the NYSE, and it is likely that there will be significantly less liquidity in the trading of our common stock.The suspension of trading and potential delisting of our common stock from NYSE could have material adverse effects on our business, financial condition and results of operations due to, among other things:

- reduced trading liquidity and market prices for our common and preferred stock ;
- decreased number of institutional and other investors willing to hold or acquire our stock, coverage by securities analysts, market making activity and information available concerning trading prices and volume, as well as fewer broker-dealers willing to execute trades in our stock, thereby further restricting our ability to obtain equity financing;
- resulting event of default or noncompliance under certain of our debt facilities and other agreements; and
- reduced ability to retain, attract and motivate our directors, officers and employees by means of equity compensation.

If we are unsuccessful in our appeal, the NYSE will apply to the SEC to delist our common stock upon completion of all applicable procedures. Delisting our common stock from the NYSE may adversely impact our liquidity, impair our stockholders' ability to buy and sell our common stock, impair our ability to raise capital, and the market price of our common stock could decrease. Delisting our common stock could also adversely impact the perception of our financial condition and have additional negative ramifications, including further loss of confidence by our employees, the loss of institutional investor interest and fewer business opportunities.

We have active plans to mitigate these conditions. Specifically, we plan to reduce negative cash flow through operating expense reductions. We are evaluating multiple opportunities, which may include soliciting external investment or seeking strategic partnerships. Additionally, as detailed in Note 13 to the Consolidated Financial Statements, subsequent to December 31, 2023, we closed on the sale of TDO and renegotiated our covenant requirements with our lender, among other terms, which resulted in us remitting $15 million of principal payments on our outstanding borrowings. Our plans are subject to inherent risks and uncertainties and there can be no assurance that our plans can be effectively implemented and, therefore, that the conditions can be effectively mitigated.

Summary statement of cash flows

The following table summarizes our statement of cash flows:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (46,062)	$ (61,072)
Investing activities	42,402	(74,429)
Financing activities	4	68,525
Net increase (decrease) in cash and cash equivalents	$ (3,656)	$ (66,976)

Operating Activities

Net cash used in operating activities during 2023 was $46.1 million, primarily consisting of net loss of $60.9 million as adjusted for non-cash items of $12.3 million, partially offset by a net change in our net operating assets and liabilities of $2.6 million. Non-cash items primarily consisted of $7.3 million in stock-based compensation, $3.7 million impairment of long-lived assets and $1.7 million in depreciation and amortization. Changes in our net operating assets and liabilities year-over-year, were primarily due to a $4.4 million cash receipts of ERC refund and a $3.7 million decrease in inventory due to managing production level, including a $2.9 million charge related to inventory due to phasing out our legacy Gen 3, partially offset by changes in accounts receivable, prepaid expenses, accrued compensation and accounts payable attributable to timing of payments.

Net cash used in operating activities during 2022 was $61.1 million, primarily consisting of net loss of $57.1 million as adjusted for non-cash items of $9.9 million, partially offset by a net change in our net operating assets and liabilities of $14.0 million. Non-cash items primarily consisted of $1.7 million in depreciation and amortization and $7.5 million in stock-based compensation. Changes in our net operating assets and liabilities year-over-year, was primarily due to a $7.4 million increase in inventory held due to higher production and a $3.3 million increase in accounts receivable balance due to higher sales and longer credit terms. Changes in our net operating assets and liabilities also resulted from changes in prepaid expenses and other assets, accounts payable and accrued expenses and other liabilities attributable to timing of payments.

Investing Activities

Net cash provided by and used in investing activities during 2023 and 2022 was $42.4 million and $74.4 million, respectively, as a result of purchases of available-for-sale securities and property and equipment, partially offset by proceeds from maturities of available-for-sale securities.

Financing Activities

Net cash provided by financing activities during 2023 was immaterial. Net cash provided by financing activities during 2022 was $68.5 million, primarily resulting from net proceeds of $59.0 million received from the Private Placement and $10 million in borrowings under the Amended Perceptive Loan Agreement.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, the revenue generated, and expenses incurred, and related disclosures, during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in Note 2 of our consolidated financial statements included in Part II, Item 8 of this Annual Report, we believe the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our consolidated financial statements and understanding and evaluating our reported financial results.

Revenue Recognition

We recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods and services. Specifically, we apply the following five core principles 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, we satisfy a performance obligation.

Our performance obligations primarily arise from the manufacture and delivery of the GentleWave System, single-use PIs and other accessories and services as well as software license sales related to our practice management platform. Payment terms are typically on open credit terms consistent with industry practice and do not have significant financing components.

We consider the individual deliverables in our product offering as separate performance obligations and assess whether each promised good or service is distinct. The total contract transaction price is determined based on the consideration expected to be received, based on the stated value in contractual arrangements or the estimated cash to be collected in no-contracted arrangements, and is allocated to the identified performance obligations based upon the relative standalone selling prices of the performance obligations. The stand-alone selling price ("SSP") is based on an observable price offered to other comparable customers. We estimate the SSP 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. We regularly review and update SSP as necessary. The consideration we receive in exchange for our goods or services is only recognized when it is probable that a significant reversal will not occur. The consideration to which we expect to be entitled includes a stated list price, less various forms of variable consideration. We estimate related variable consideration at the point of sale, including discounts, product returns, refunds, and other similar obligations.

Revenue is recognized over time when the customer simultaneously receives and consumes the benefits provided by our performance. Revenue is recognized at a point in time if the criteria for recognizing revenue over time are not met, and we transferred control of the goods to the customer. Product revenue is recognized at a point in time when we have transferred control to the customer, which is generally when title of the goods transfers to the customer. Revenue from support and maintenance contracts and software license revenue is recognized as the output of the service is transferred to the customer over time, typically evenly over the contract term. Revenue is recognized net of any taxes collected from customers, which are subsequently remitted to governmental authorities.

We also sell extended service contracts on the GentleWave System. Sales of extended service contracts are recorded as deferred revenue until such time as the standard warranty expires, which is generally up to two years from the date of sale. Service contract revenue is recognized on a straight-line basis over time consistent with the life of the related service contract in proportion to the costs incurred in fulfilling performance obligations under the service contract.

Revenue for technical support and other services is recognized ratably over the performance obligation period.

Valuation of Goodwill and Intangible Assets with Definite Lives

Our goodwill represents the excess of cost over fair value of identified assets acquired and liabilities we assume in an acquisition of a business. We recorded $8.5 million of goodwill in conjunction with the acquisition of TDO in October 2018.

The determination of the value of goodwill and intangible assets arising from business combinations and asset acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired. Goodwill is not amortized; however, it is assessed for

impairment using fair value measurement techniques on an annual basis or more frequently if facts and circumstance warrant such a review. The goodwill is considered to be impaired if we determine that the carrying value of the reporting unit exceeds its fair value.

We perform our goodwill impairment analysis at the reporting unit level, which aligns with our reporting structure and availability of discrete financial information. We perform our annual impairment analysis by either doing a qualitative assessment of the reporting unit's fair value from the last quantitative assessment to determine if there is potential impairment, or comparing the reporting unit's estimated fair value to its carrying amount. We may do a qualitative assessment when the results of the previous quantitative test indicated the reporting unit's estimated fair value was significantly in excess of the carrying value of its net assets and we do not believe there have been significant changes in the reporting unit's operations that would significantly decrease its estimated fair value or significantly increase its net assets. If a quantitative assessment is performed the evaluation includes management estimates of cash flow projections based on internal future projections and/or use of a market approach by looking at market values of comparable companies.

We estimate the fair value of the TDO reporting unit using the income approach and market approach. For the purposes of the income approach, fair value is determined based on the present value of estimated future cash flows, discounted at an appropriate risk-adjusted rate. Key assumptions for these projections require significant judgments by management and include revenue growth, future gross and operating margin growth, and its weighted cost of capital and terminal growth rates. The revenue and margin growth is based on increased sales of new and existing products as we maintain investment in research and development. Additional assumed value creators may include increased efficiencies from capital spending. The resulting cash flows are discounted using a weighted average cost of capital. Operating mechanisms and requirements to ensure that growth and efficiency assumptions will ultimately be realized are also considered in the evaluation. Actual results may differ from those assumed in our forecasts. We also reconcile our discounted cash flow analysis to our indicated equity value allowing for a reasonable control premium. For purposes of the market approach, fair value is determined based on the guideline public company method and utilizes a number of factors such as publicly available information regarding the market capitalization of the selected guideline companies, as well as operating results, market multiples, and present value techniques. Under the market-based fair value methodology, judgment is required in evaluating market multiples and recent transactions. Management believes that the assumptions used for its impairment test are representative of those that would be used by market participants performing similar valuations of the TDO reporting unit.

Our evaluation for goodwill impairment, which is completed annually as of October 31, consists of the TDO reporting unit from which goodwill originated. In the second half of 2023, we identified indicators of impairment related to the decline in our share price. We completed an evaluation using a quantitative method as of September 30, 2023, the annual evaluation using a qualitative method as of October 31, 2023 and an evaluation using a quantitative method as of December 31, 2023, and determined that no impairment existed at each evaluation date. Our divestiture of our software segment in March 2024 further substantiated the conclusion that no impairment existed as of December 31, 2023.

Valuation and Impairment of Long-Lived Assets

Our long-lived assets comprises definite-lived intangibles, property and equipment, and lease right-of-use assets. Our intangible assets with a finite life are primarily composed of developed technology, customer relationships, and tradenames acquired in conjunction with the acquisition of TDO in October 2018. We make significant judgments in relation to the valuation of intangible assets resulting from business combinations and asset acquisitions.

Intangible assets are generally amortized on a straight-line basis over their estimated useful lives of 5 to 10 years. We base the useful lives and related amortization expense on the period of time we estimate the assets will generate revenue or otherwise be used. We also periodically review the lives assigned to our intangible assets to ensure that our initial estimates do not exceed any revised estimated periods from which we expect to realize cash flows from the assets. If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

Property and equipment are recorded at cost, net of accumulated depreciation. The Company records depreciation over the estimated useful lives of the assets, typically three to five years, using the straight-line method, and amortizes leasehold improvements using a straight-line method over the shorter of the estimated economic lives or

the related remaining lease term. Repairs and maintenance expenditures that do not significantly add value to property and equipment, or prolong the useful lives of the assets, are charged to expense as incurred. Gains and losses on dispositions of property and equipment are included in the operating results of the related period.

We review our long-lived assets for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Factors that could trigger an impairment review include significant under-performance relative to expected historical or projected future operating results, significant changes in the manner of our use of the acquired assets or the strategy for our overall business or significant negative industry or economic trends. If this evaluation indicates that the value of the long-lived asset may be impaired, we make an assessment of the recoverability of the net carrying value of the asset over its remaining useful life. If this assessment indicates that the long-lived asset is not recoverable, based on the estimated undiscounted future cash flows of the technology over the remaining useful life, we reduce the net carrying value of the related asset to fair value and may adjust the remaining useful life. An impairment analysis is subjective and assumptions regarding future growth rates and operating expense levels can have a significant impact on the expected future cash flows and impairment analysis.

In the second half of 2023, the significant decline in our market capitalization was a triggering event, which resulted in the performance of long-lived assets impairment assessments. The assessments indicated that the carrying amount of our long-lived fixed assets in the Product segment would not be recoverable as of December 31, 2023. As a result, in the year ended December 31, 2023, the Company recognized impairment charges of $1.0 million to a definite-lived intangible, developed technology, which was recorded in operating expenses on the Consolidated Statements of Operations, and impairment charges of $2.6 million to property and equipment, of which $1.6 million was recorded in cost of sales and the remainder was recorded in operating expenses, on the Consolidated Statements of Operations. No impairment was identified in the year ended December 31, 2022.

Significant judgment is required in the forecasts of future operating results that are used in the discounted cash flow valuation models. It is possible that plans may change and estimates used may prove to be inaccurate. If our actual results, or the plans and estimates used in future impairment analyses, are lower than the original estimates used to assess the recoverability of these assets, we could incur additional impairment charges.

JOBS Act Accounting Election and Smaller Reporting Company Status

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012 (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, presenting only two years of audited financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this Annual Report, not being required to comply 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 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.

In addition, the JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to avail ourselves of this exemption and, therefore, for new or revised accounting standards applicable to public companies, we will be subject to an extended transition period until those standards would otherwise apply to private companies.

We will remain an emerging growth company until the earliest of (1) the last day of our first fiscal year (a) following the fifth anniversary of our IPO, which closed on November 2, 2021, (b) in which we have total annual gross revenues of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, as defined in Rule 12b-2 under the Exchange Act, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (2) 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 no longer qualify as 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 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700 million measured on the last business day of our second fiscal quarter.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included elsewhere in this Annual Report for additional information.

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

Not applicable.

Item 8. Financial Statements and Supplementary Data.

Sonendo, Inc.
Index to Financial Statements

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Sonendo, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has experienced recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 2013.

Irvine, California

March 11, 2024

SONENDO, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except par value and share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,009	$ 17,665
Short-term investments	32,773	73,784
Accounts receivable, net	5,081	5,798
Inventory	11,074	15,462
Prepaid expenses and other current assets	2,334	8,397
Total current assets	65,271	121,106
Property and equipment, net	664	2,860
Operating lease right-of-use assets	2,974	2,455
Intangible assets, net	661	2,292
Goodwill	8,454	8,454
Other assets	136	118
Total assets	$ 78,160	$ 137,285
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,176	$ 4,438
Accrued expenses	3,266	5,357
Accrued compensation	2,758	3,616
Operating lease liabilities	1,377	1,114
Current portion of term loan	24,900	—
Other current liabilities	1,844	2,191
Total current liabilities	35,321	16,716
Operating lease liabilities, net of current	1,423	1,095
Term loan, net of current	12,467	36,746
Other liabilities	530	773
Total liabilities	49,741	55,330
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value; authorized —10,000,000 shares; issued and outstanding - none	—	—
Common stock, $0.001 par value; authorized — 500,000,000 shares as of December 31, 2023 and 2022; issued — 63,547,467 shares as of December 31, 2023 and 49,974,281 shares as of December 31, 2022; outstanding — 63,547,467 shares as of December 31, 2023 and 49,974,281 shares as of December 31, 2022	64	50
Additional paid-in-capital	458,357	451,060
Accumulated other comprehensive gain (loss)	11	(61)
Accumulated deficit	(430,013)	(369,094)
Total stockholders' equity	28,419	81,955
Total liabilities and stockholders' equity	$ 78,160	$ 137,285

The accompanying notes are an integral part of these Consolidated Financial Statements

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

	Year Ended December 31,	
	2023	2022
Product revenue	$ 34,628	$ 33,280
Software revenue	9,237	8,376
Total revenue	43,865	41,656
Cost of sales:		
Product and software	31,559	31,176
Impairment of long-lived assets	1,584	—
Total cost of sales	33,143	31,176
Gross profit	10,722	10,480
Operating expenses:		
Selling, general and administrative	54,022	51,906
Research and development	12,355	16,776
Impairment of long-lived assets	2,088	—
Total operating expenses	68,465	68,682
Loss from operations	(57,743)	(58,202)
Other expense, net:		
Interest and financing cost, net	(3,174)	(3,228)
Employee retention credit	—	4,382
Loss before income tax expense	(60,917)	(57,048)
Income tax expense	(2)	(2)
Net loss	$ (60,919)	$ (57,050)
Other comprehensive income (loss) (net of tax):		
Unrealized gain (loss) on short-term investments	72	(61)
Comprehensive loss	$ (60,847)	$ (57,111)
Net loss per share – basic and diluted	$ (0.65)	$ (1.27)
Weighted-average shares outstanding – basic and diluted	93,988,749	44,932,952

The accompanying notes are an integral part of these Consolidated Financial Statements

SONENDO, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except shares amount)

	Common Stock		Treasury	Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Stock	Capital	Gain (Loss)	Deficit	Equity
Balance at December 31, 2021	26,336,536	$ 26	$ (51)	$ 384,132	$ —	$ (312,044)	$ 72,063
Employee stock plans	592,209	1	—	413	—	—	414
Issuance of common stock, net of issuance costs	23,045,536	23	—	20,493	—	—	20,516
Issuance of pre-funded warrants, net of issuance costs	—	—	—	38,518	—	—	38,518
Stock-based compensation	—	—	—	7,482	—	—	7,482
Revaluation of warrants	—	—	—	73	—	—	73
Unrealized loss on short-term investments	—	—	—	—	(61)	—	(61)
Retirement of treasury stock	—	—	51	(51)	—	—	—
Net loss	—	—	—	—	—	(57,050)	(57,050)
Balance at December 31, 2022	49,974,281	$ 50	$ —	$ 451,060	$ (61)	$ (369,094)	$ 81,955
Employee stock plans	1,462,872	2	—	33	—	—	35
Stock-based compensation	—	—	—	7,276	—	—	7,276
Exercise of Common Stock Warrants	12,110,314	12	—	(12)	—	—	—
Unrealized gain on short-term investments	—	—	—	—	72	—	72
Net loss	—	—	—	—	—	(60,919)	(60,919)
Balance at December 31, 2023	63,547,467	$ 64	$ —	$ 458,357	$ 11	$ (430,013)	$ 28,419

The accompanying notes are an integral part of these Consolidated Financial Statements

SONENDO, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (60,919)	$ (57,050)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,118	1,052
Amortization of intangible assets	585	664
Amortization of right-of-use lease assets	1,272	1,100
Impairment of long-lived assets	2,626	—
Impairment of intangible	1,046	—
Stock-based compensation	7,276	7,482
Amortization of debt issuance costs	621	473
Accretion of available for sale securities, net	(2,248)	(772)
Other non-cash operating activities, net	—	(70)
Changes in operating assets and liabilities:		
Accounts receivable, net	717	(3,282)
Inventory	3,769	(7,414)
Prepaid expenses and other assets	6,047	(4,845)
Accounts payable	(3,262)	1,287
Accrued expenses and other liabilities	(3,955)	17
Deferred revenue	103	46
Accrued compensation	(858)	240
Net cash used in operating activities	(46,062)	(61,072)
Cash flows from investing activities:		
Purchases of available-for-sale securities	(60,069)	(98,723)
Proceeds from maturities of available-for-sale securities	103,400	25,650
Purchases of property and equipment	(929)	(1,356)
Net cash provided by (used in) investing activities	42,402	(74,429)
Financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	—	20,516
Proceeds from issuance of pre-funded warrants, net of issuance costs	—	38,518
Proceeds from debt, net of issuance costs	—	9,850
Issuance of stock under employee stock plans	127	414
Taxes paid on vested stock awards under employee stock plans	(92)	—
Payment of common stock IPO issuance costs	—	(598)
Payment of contingent earnout	—	(117)
Principal repayments on finance lease	(31)	(58)
Net cash provided by financing activities	4	68,525
Net decrease in cash and cash equivalents	(3,656)	(66,976)
Cash and cash equivalents at beginning of year	17,665	84,641
Cash and cash equivalents at end of year	$ 14,009	$ 17,665
Supplemental disclosures of cash flow information:		
Cash paid for:		
Taxes	$ 2	$ 2
Interest	$ 5,813	$ 4,060
Supplemental schedule of non-cash investing and financing activities:		
Operating lease right-of-use assets obtained in exchange for lease liabilities	$ 1,792	$ 808

The accompanying notes are an integral part of these Consolidated Financial Statements

1. Organization and Basis of Presentation

Unless this Form 10-K indicates otherwise or the context otherwise requires, the terms "we," "our," "us," "Sonendo," or the "Company" as used in this Form 10-K refer to Sonendo, Inc**.**

Description of Business

Sonendo, Inc. was incorporated in June 2006 pursuant to the laws of the State of Delaware under the name Dentatek Corporation. In March 2011, the Company changed its name to Sonendo, Inc. The Company is a medical technology company that has developed and is commercializing the GentleWave System to treat tooth decay. The Company's principal market is the United States. The Company's products include the GentleWave System, which is cleared by the United States ("U.S.") Food and Drug Administration (the "FDA") for sale in the U.S. and approved by Health Canada in Canada, along with the system's sterilized, single-use procedure instruments ("PIs"). In addition, the Company offers practice management software to enable an integrated digital office for dental practitioners.

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements, including the accounts of Sonendo and its wholly-owned subsidiaries, Pipstek, LLC and TDO Software, Inc. ("TDO"), have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). All significant inter-company balances and transactions among the consolidated entities have been eliminated in consolidation.

Liquidity

On September 27, 2022, the Company completed a private placement (the "Private Placement"), issuing an aggregate of 23.0 million shares of its common stock at a purchase price of $0.95 per share and pre-funded warrants to purchase an aggregate of 43.3 million shares of common stock at a purchase price of $0.949 per pre-funded warrant. The pre-funded warrants have an exercise price of $0.001 per share of common stock, are immediately exercisable and will remain exercisable until exercised in full. The aggregate net proceeds from the Private Placement, after deducting placement agent fees and other offering expenses, were $59.0 million. See Note 5, *Stockholders' Equity*, for additional information.

As of December 31, 2023, the Company had cash and cash equivalents and short-term investments of $46.8 million and $40.0 million in principal outstanding under its term loan facility.

On March 10, 2023, the California Department of Financial Protection and Innovation shut down Silicon Valley Bank ("SVB") due to liquidity concerns and appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. On March, 27, 2023, SVB began operating as a division of First Citizens Bank. As of December 31, 2023, the Company held approximately $0.8 million in operating accounts at SVB. The Company's remaining cash and cash equivalents and short-term investments, consisting of money market funds, high-grade corporate securities, and U.S. government backed securities, reside in custodial accounts held by U.S. Bank. There has been no disruption to the Company's operations.

Going Concern

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 net losses and negative cash flows from operations since its inception and as of December 31, 2023 had an accumulated deficit of $430.0 million. During the year ended December 31, 2023, the Company incurred net losses of $60.9 million and used $46.1 million of cash, cash equivalents in operations. The Company will continue to incur significant costs and expenses related to its ongoing operations until it gains market acceptance of products and achieves a level of revenues adequate to support the Company's operations.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and

classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The Company's ability to continue as a going concern depends on its ability to continue to commercialize its products, achieve and maintain profitable operations, as well as the adherence to conditions of the outstanding term loan as amended in March 2024 (see Note 9). Without additional financing, the Company will have insufficient liquidity to achieve further commercialization of our products and maintain compliance with our loan covenants. Due to these conditions, there is substantial doubt about the Company's ability to continue as a going concern and, therefore, it may be unable to realize its assets and discharge its liabilities in the normal course of business.

The Company will require additional financing in order to fund its future expected negative cash flows. Due to its failure to comply with the continued listing standard set forth in the New York Stock Exchange (NYSE)'s Listed Company Manual, our common stock has been suspended from trading on the NYSE effective at the opening of business Eastern Standard Time on November 22, 2023 and may be delisted from the NYSE, which may negatively impact our stockholders and the trading price and liquidity of our common stock. The Company commenced trading on the OTCQX on the same day. The Company has subsequently appealed the NYSE's determination and there is no assurance that the appeal will be successful. The over-the-counter markets are a more limited market than the NYSE, and it is likely that there will be significantly less liquidity in the trading of our common stock. The suspension of trading and potential delisting of the Company's common stock from NYSE could have material adverse effects on its business, financial condition and results of operations.

The Company has active plans to mitigate these conditions. Specifically, the Company plans to reduce negative cash flow through operating expense reductions. The Company is evaluating multiple opportunities, which may include soliciting external investment or seeking strategic partnerships. Additionally, as detailed in *Note 13*, subsequent to December 31, 2023, the Company closed on the sale of TDO and renegotiated its covenant requirements with its lender, among other terms, which resulted in the Company remitting $15 million of principal payments on its outstanding borrowings. Its plans are subject to inherent risks and uncertainties and there can be no assurance that its plans can be effectively implemented and, therefore, that the conditions can be effectively mitigated.

Effects of the Macroeconomic Environment

The Company's consolidated financial statements as of and for the year ended December 31, 2023 reflect the Company's estimates of the impact of the macroeconomic environment, including the impact of inflation and higher interest rates. 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. See "*Impairment of Long-Lived Assets*" in Note 2, "*Summary of Accounting Policies*", for a description of the impairment charges recorded during 2023. 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.

Operating Segments

The Company has business activity and operates two operating and reportable segments: Product and Software. Operating segments are defined as components of an enterprise for which discrete financial information is available and evaluated regularly by the chief operating decision maker, who is the Company's chief executive officer ("CEO"), for the purpose of allocating resources and evaluating performance.

Emerging growth company status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (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 elected to avail itself of this exemption and, therefore, for new or revised accounting standards applicable to public companies, the Company will be subject to an extended transition period until those standards would otherwise apply to private companies.

2. Summary of Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make informed estimates, judgements and assumptions that affect the reported amounts in the consolidated financial statements and disclosures in the accompanying notes, including estimates of probable losses and expenses, as of the date of the accompanying consolidated financial statements. Actual results could differ materially from the estimates and assumptions used in the preparation of the accompanying consolidated financial statements under different assumptions or conditions.

Cash and Cash Equivalents

Cash and cash equivalents consist of cash and highly liquid investments with remaining maturities at purchase of three months or less that can be liquidated without prior notice or penalty. Cash and cash equivalents may include U.S. Treasury bills, deposits, money market funds and commercial paper.

Short-Term Investments

Short-term investments consist of available-for-sale U.S. Treasury securities, U.S. government agency securities, corporate bonds and commercial paper with original maturities greater than three months and remaining maturities of less than twelve months. These investments are recorded at fair value based on quoted prices in active markets, with unrealized gains and losses reported in other comprehensive gain (loss) in the Company's consolidated statements of operations and comprehensive loss. Purchase premiums and discounts are recognized in interest expense using the effective interest method over the terms of the securities. Realized gains and losses and declines in fair value that are deemed to be other than temporary are reflected in the statements of operations and comprehensive loss using the specific-identification method.

The Company periodically reviews all available-for-sale securities for other than temporary declines in fair value below the cost basis whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company also evaluates whether it has plans or is required to sell short-term investments before recovery of their amortized cost bases. To date, the Company has not identified any other than temporary declines in fair value of its short-term investments.

Concentration of Risks

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash, cash equivalents and accounts receivable. The Company has established guidelines to mitigate such potential risks by maintaining the Company's cash balances with entities that management believes possess high credit quality to limit the amount of credit exposure. Substantially all of the Company's cash and cash equivalents are maintained at one financial institution domiciled in the United States. Cash and cash equivalents can exceed amounts insured by the Federal Deposit Insurance Corporation of up to $250,000. The Company has not experienced any losses in its accounts and management believes it is not exposed to any significant credit risk on cash and cash equivalents. The primary objectives of the Company's investment portfolio are the preservation of capital and maintenance of liquidity.

The Company believes any concentration of credit risk in its accounts receivable is mitigated by its credit evaluation process, relatively short collection terms and the level of credit worthiness of its customers. No individual customer accounted for more than 10% of sales or accounts receivable in 2023 or 2022.

The Company sources materials and services through several vendors. Certain materials are sourced from a single vendor. The loss of certain vendors could result in a temporary disruption of the Company's commercialization efforts.

The Company's products require clearance from the FDA and foreign regulatory agencies before commercial sales can commence. There can be no assurance that the Company's products in development will receive any of these required clearances. The denial or delay of such clearances may have a material adverse impact on the Company's

business in the future. In addition, after the clearance by the FDA, there is still an ongoing risk of adverse events that did not appear during the device clearance 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 its products, product liability and the need to obtain additional financing.

Accounts Receivable, Net

Accounts receivable pertain to contracts with customers who are granted credit by the Company in the ordinary course of business and are recorded at the invoiced amount. Accounts receivable do not bear interest. Accounts receivable presented on the consolidated balance sheets are adjusted for any write-offs and net of allowance for credit losses. The Company's allowance for credit losses is developed by using relevant available information including historical collection and loss experience, current economic conditions, prevailing economic conditions, supportable forecasted economic conditions and evaluations of customer balances. 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 does not generally require collateral or other security on receivables. The allowance for credit losses is measured on a collective basis when similar risk characteristics exist. The Company's estimate of current expected credit losses was immaterial as of December 31, 2023 and 2022, respectively, and there were immaterial write-offs.

Inventory

Inventory is valued at the lower of cost or net realizable value. Cost may include materials, labor and manufacturing overhead. Cost is determined by the first in first out inventory method. The carrying value of inventory is reviewed for potential impairment whenever indicators suggest that the cost of inventory exceeds the carrying value and management adjusts the inventory to its net realizable value. The Company also periodically evaluates inventory for estimated losses from excess quantities and obsolescence and writes down the cost of inventory 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 of completion and disposal.

Property and Equipment, Net

Property and equipment are recorded at cost, net of accumulated depreciation. The Company records depreciation over the estimated useful lives of the assets, typically three to five years, using the straight-line method, and amortizes leasehold improvements using a straight-line method over the shorter of the estimated economic lives or the related remaining lease term. Repairs and maintenance expenditures that do not significantly add value to property and equipment, or prolong the useful lives of the assets, are charged to expense as incurred. Gains and losses on dispositions of property and equipment are included in the operating results of the related period.

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 (the "Commencement Date") based on the present value of lease payments over the lease term. At the inception of a contract, the Company determines whether the arrangement is or contains a lease based on the facts and circumstances present.

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. The Company elected the practical expedient to exclude short-term agreements of less than 12 months from capitalization and not to separate lease and non-lease components. The Company enters into various operating

leases for office space. The leases expire at various dates, have various options to renew, and may contain escalation provisions.

Rent expense on cancelable 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. 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. The key estimates for the Company's leases include the incremental borrowing rate used to determine the present value of lease payments and the lease term. The Company's leases generally do not include an implicit rate; therefore, management establishes a rate of interest the Company would have to pay on a collateralized borrowing, for an amount equal to the lease payments, over a similar term and in a similar economic environment.

Goodwill and Intangible Assets

Goodwill represents the excess of cost over fair value of identified assets acquired and liabilities assumed by the Company in an acquisition of a business. The determination of the value of goodwill and intangible assets arising from a business combination requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired. The Company recorded $8.5 million of goodwill in conjunction with the acquisition of TDO.

The Company performs its goodwill impairment analysis at the reporting unit level, which aligns with the Company's reporting structure and availability of discrete financial information. The Company performs its annual impairment analysis by either comparing a reporting unit's estimated fair value to its carrying amount or doing a qualitative assessment of a reporting unit's fair value from the last quantitative assessment to determine if there is potential impairment. The Company may do a qualitative assessment when the results of the previous quantitative test indicated the reporting unit's estimated fair value was significantly in excess of the carrying value of its net assets and it does not believe there have been significant changes in the reporting unit's operations that would significantly decrease its estimated fair value or significantly increase its net assets. If a quantitative assessment is performed, the evaluation includes management projections of future cash flows and/or use of a market approach by considering market values of comparable companies. Key assumptions for these projections include revenue growth, future gross and operating margin growth, and the weighted cost of capital and terminal growth rates. The revenue and margin growth is based on increased sales of new and existing products as the Company maintains investments in research and development. Additional value creators may include increased efficiencies from capital spending. The resulting cash flows are discounted using a weighted average cost of capital. Operating mechanisms and requirements to ensure that growth and efficiency assumptions will ultimately be realized are also considered in the evaluation.

The Company's evaluation for goodwill impairment, which is completed annually as of October 31, consists of the TDO reporting unit from which goodwill originated. In the second half of 2023, the Company identified indicators of impairment related to the decline in its share price. The Company completed an evaluation using a quantitative method as of September 30, 2023, the annual evaluation using a qualitative method as of October 31, 2023 and an evaluation using a quantitative method as of December 31, 2023, and determined that no impairment existed in each evaluation.

The assumptions used in the estimate of fair value are generally consistent with the past performance of the Company and are also consistent with the projections and assumptions that are used in current operating plans. The assumptions are subject to change as a result of changing economic and competitive conditions.

Definite-lived intangible assets are recorded at cost, net of accumulated amortization, and are amortized on a straight-line basis over their estimated useful life, which range from five to ten years. In determining the useful lives of intangible assets, the Company considers the expected use of the assets and the effects of obsolescence, demand, competition, anticipated technological advances, market influences and other economic factors. Trademarks and trade names that are related to products are assigned lives consistent with the period in which the products bearing each brand are expected to be sold.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets, which includes definite-lived intangibles, long-lived fixed assets and lease right-of-use assets, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Factors that could trigger an impairment review include significant under-performance relative to expected historical or projected future operating results, significant changes in the manner of the Company's use of the acquired assets or the strategy for the Company's overall business or significant negative industry or economic trends. If this evaluation indicates that the value of the long-lived asset may be impaired, the Company makes an assessment of the recoverability of the net carrying value of the asset over its remaining useful life. If this assessment indicates that the long-lived asset is not recoverable, based on the estimated undiscounted future cash flows of the technology over the remaining useful life, the Company reduces the net carrying value of the related asset to fair value and may adjust the remaining useful life. An impairment analysis is subjective and assumptions regarding future growth rates and operating expense levels can have a significant impact on the expected future cash flows and impairment analysis.

In the second half of 2023, the significant decline in the Company's market capitalization was a triggering event, which resulted in the performance of an interim long-lived assets impairment assessment. The assessment indicated that the carrying amount of the Company's definite-lived intangible and long-lived fixed assets in its Product segment would not be recoverable. As a result, the Company recognized an impairment charge of $1.0 million to a definite-lived intangible, developed technology, which was recorded in operating expenses on the *Consolidated Statements of Operations*, and an impairment charge of $2.6 million to property and equipment, of which $1.6 million was recorded in cost of sales and the remainder was recorded in operating expenses, on the *Consolidated Statements of Operations*.

No impairment was identified in the year ended December 31, 2022.

Fair Value of Financial Instruments

The Company applies fair value measurements to record fair value adjustments to certain assets and liabilities and to determine fair value disclosures. The Company's financial instruments consist principally of cash, cash equivalents, short-term investments, accounts receivable, accounts payable, operating lease liabilities, warrant liabilities, and a term loan. Fair value is measured as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. A fair value measurement assumes that the transaction to sell the asset or transfer the liability occurs in the principal market for the asset or liability or, in the absence of a principal market, the most advantageous market. 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 the Company has the ability to access.

Level 2 – Inputs (other than quoted prices included within Level 1) that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3 – Unobservable inputs that are significant to the fair value measurement and reflect the reporting entity's use of significant management judgment and assumptions when there is little or no market data. 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 periods presented.

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, and certain accrued expenses approximate fair value due to the short-term nature of these items. Accordingly, the Company estimates that the recorded amounts approximate fair market value.

Revenue Recognition

Contracts with Customers

The Company recognizes revenue when it transfers promised goods or services to customers in an amount 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 core principles 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.

Product revenue is generated from sales of the GentleWave Console and related PIs and accessories. Software revenue is generated from sales of TDO's endodontist practice management software licenses. The Company’s products are sold primarily in the United States and Canada directly to customers through its field sales force.

Performance Obligations

The Company’s performance obligations primarily arise from the manufacture and delivery of the GentleWave System, related PIs and accessories, and the delivery or license of TDO software and related ancillary services. Payment terms are typically on open credit terms consistent with industry practice and do not have significant financing components. Consideration may be variable based on volume.

The Company considers the individual deliverables in its product offering as separate performance obligations and assesses whether each promised good or service is distinct. The total contract transaction price is determined based on the consideration expected to be received, based on the stated value in contractual arrangements or the estimated cash to be collected in no-contracted arrangements, and is allocated to the identified performance obligations based upon the relative standalone selling prices of the performance obligations. The stand-alone selling price is based on an observable price offered to other comparable customers. 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. The consideration the Company receives in exchange for its goods or services is only recognized when it is probable that a significant reversal will not occur. The consideration to which the Company expects to be entitled includes a stated list price, less various forms of variable consideration. The Company estimates related variable consideration at the point of sale, including discounts, product returns, refunds, and other similar obligations.

Revenue is recognized over time when the customer simultaneously receives and consumes the benefits provided by the Company’s performance. Revenue is recognized at a point in time if the criteria for recognizing revenue over time are not met, and the Company has transferred control of the goods to the customer. Product revenue is recognized at a point in time when the Company has transferred control to the customer, which is generally when title of the goods transfers to the customer. Software is licensed via delivery to the customer or via a service arrangement under which cloud-based access is provided on a subscription basis (software-as-a-service). When a fixed up-front license fee is received in exchange for the delivery of software, revenue is recognized at the point in time when the delivery of the software has occurred. When software is licensed on a subscription basis, revenue is recognized over the respective license period.

The Company also sells extended service contracts on its GentleWave Systems. Sales of extended service contracts are recorded as deferred revenue until such time as the standard warranty expires, which is generally up to two years from the date of sale. Service contract revenue is recognized on a straight-line basis over time consistent with the life of the related service contract in proportion to the costs incurred in fulfilling performance obligations under the service contract.

Revenue for technical support and other services is recognized ratably over the performance obligation period.

The Company generally does not experience returns. If necessary, a provision is recorded for estimated sales returns and allowances and is deducted from gross product revenue to arrive at net product revenue in the period the related

revenue is recorded. These estimates are based on historical sales returns and allowances and other known factors. Actual returns and claims in any future period are inherently uncertain and thus may differ from these estimates. If actual or expected future returns and claims are significantly greater or lower than the reserves established, a reduction or increase to revenue will be recorded in the period in which such a determination is made.

All non-income government-assessed taxes (sales and use taxes) collected from the Company's customers and remitted to governmental agencies are recorded in accrued expenses until they are remitted to the government agency.

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.

Contract liabilities

The Company recognizes a contract liability when a customer pays for goods or services for which the Company has not yet transferred control. The balances of the Company's contract liabilities are as follows:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Extended service contracts	$ 920	$ 336
Subscription software licenses	—	481
Total contract liabilities	$ 920	$ 817
Less: long-term portion	302	—
Contract liabilities - current	$ 618	$ 817

Contract liabilities are included within other current liabilities and other long-term liabilities in the accompanying consolidated balance sheets. Revenue recognized during the years ended December 31, 2023 and 2022 that was included in the contract liability beginning balance of each year was $0.7 million and $0.8 million, respectively.

Disaggregation of revenue

The Company disaggregates revenue from contracts with customers by segment and by the timing of when goods and services are transferred which depicts how the nature, amount, timing and uncertainty of revenue and cash flows are affected.

The following table provides information regarding revenues disaggregated by segment and the timing of when goods and services are transferred:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Product revenue recognized at a point in time	$ 33,844	$ 32,566
Product revenue recognized over time	784	714
Software revenue recognized at a point in time	2,014	1,599
Software revenue recognized over time	7,223	6,777
Total	$ 43,865	$ 41,656

Shipping and handling costs

All customer related shipping and handling costs are expensed as incurred and are charged to cost of sales. Charges to customers for shipping and handling are credited to revenue.

Warranty Reserve

The Company provides a standard warranty on its GentleWave Systems for a specified period of time. For the years ended December 31, 2023 and 2022, GentleWave Systems sold were covered by the warranty for a period of up to two years from the date of sale. Estimated warranty costs are recorded as a liability at the time of delivery with a corresponding provision to cost of sales. Warranty accruals are estimated based on the current product costs, the

Company's historical experience, management's expectations of future conditions and standard maintenance schedules. The Company evaluates this reserve on a regular basis and makes adjustments as necessary.

The following table provides a reconciliation of the change in estimated warranty liabilities for the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
Balance at beginning of period	$ 1,930	$ 1,620
Provision for warranties issued	890	1,707
Warranty costs incurred	(1,550)	(1,397)
Balance at end of period	$ 1,270	$ 1,930

The warranty liability, current and non-current, are included in other current liabilities and other liabilities, respectively, on the consolidated balance sheets as follows:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Current portion	$ 1,187	$ 1,340
Non-current portion	83	590
Total	$ 1,270	$ 1,930

Advertising Expense

Advertising costs are expensed as incurred and amounted to $1.0 million and $0.3 million in 2023 and 2022, respectively. These expenses are included in selling, general and administrative in the Consolidated Statements of Operations and Comprehensive Loss.

Research and Development

Research and development ("R&D") expenses consist of costs incurred for proprietary R&D programs and are recorded to operating expenses when incurred. Research and development expenses primarily include (1) personnel-related costs, including compensation and benefits and stock-based compensation associated with R&D personnel, (2) costs related to clinical and pre-clinical testing of the Company's technologies under development, and (3) other R&D expenses. Costs to acquire technologies to be used in R&D that have not reached technological feasibility and have no alternative future use are also expensed as incurred.

Stock-Based Compensation

The Company periodically grants stock-based payment awards in the form of stock options to employees, directors and non-employees and records stock-based compensation expenses for awards of stock-based payments based on their estimated fair value at the grant date. The Company recognizes stock-based compensation expense for all stock-based payments, including stock options.

Stock-based compensation costs are calculated based on the estimated fair value of the underlying option using the Black-Scholes option-pricing model on the date of grant for stock options and recognized as expense in the accompanying consolidated statements of operations and comprehensive loss on a straight-line basis over the requisite service period, which is the vesting period. Determining the appropriate fair value model and related input assumptions requires judgment, including estimating the fair value of the Company's common stock, stock price volatility, and expected term:

- Prior to the Company's IPO, given the absence of a public trading market, the fair value of the Company's common stock was determined by the Company's Board of Directors (the "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 was 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 options and ESPP awards granted post-IPO, the fair value for its underlying common stock is determined using the closing price on the date of grant as reported on the New York Stock Exchange ("NYSE");

- 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;
- The expected term of "plain vanilla" options granted is calculated using the "simplified method" permitted by the SEC 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 the Company and 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 its common stock and limited data regarding company-specific historical or implied volatility of its share price.

No compensation cost is recognized for awards with performance conditions until that condition is probable of being met. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The fair values of RSUs are determined based on the closing market price of the Company's common stock on the date of the grant. The fair values of all Employee Stock Purchase Plan ("ESPP") purchase rights are estimated using Black-Scholes option-pricing model and require the input of subjective assumptions.

Employee Retention Credit

The Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), enacted on March 27, 2020, provided emergency economic stimulus package and other reliefs as a result of the COVID-19 pandemic. Employee retention credit ("ERC") is one of the reliefs that provides a refundable payroll tax credit that encouraged business to keep employees on the payroll during the COVID-19 pandemic. The ERC is based on wages and compensation paid by an eligible employer after March 12, 2020 and before January 1, 2021. The Company qualified as an eligible employer based on the Company's evaluation of this provision and the significant pandemic-related impacts to its operations in 2020 and 2021. As a result, an ERC of $4.4 million related to qualified wages paid to the employees in 2021 was recorded in other (expense) income, net in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2022. The Company received all of the $4.4 million payment of ERC in 2023.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Accordingly, deferred tax liabilities and assets are determined based on the difference between the financial statement and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to reverse. Estimates and judgments occur in the calculation of certain tax liabilities and in the determination of the recoverability of certain deferred income tax assets, which arise from temporary differences and carryforwards. A valuation allowance related to a deferred tax asset is recorded when it is more likely than not that some portion of the deferred tax asset will not be realized. Current income taxes are based on the year's taxable income for federal and state income tax reporting purposes.

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 is required to file federal and state income tax returns in the United States. The preparation of state tax returns requires the Company to interpret the applicable tax laws and regulations in effect in such jurisdictions, which could affect the amount of tax paid by the Company.

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 follows the accounting guidance on accounting for uncertainty in income taxes. The guidance prescribes a recognition threshold and measurement attribute criteria for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. As applicable, the Company recognizes accrued penalties and interest related to unrecognized tax benefits in the provision for income taxes.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss attributable to Company's stockholders by the weighted average number of common stock outstanding for the period. Diluted net loss per share is computed by giving effect to all potentially dilutive common stock equivalents to the extent they are dilutive. The pre-funded warrants are considered outstanding for the purpose of computing loss per share and are included in the calculation of basic and diluted shares outstanding.

As applicable, for purposes of this calculation, convertible preferred stock, stock options, rights to purchase shares of common stock under the ESPP and warrants are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share attributable to common stockholders as their effect is anti-dilutive for all periods presented. Diluted net loss per share is the same as basic net loss per share in periods when the effects of potentially dilutive securities are anti-dilutive.

Recent Accounting Updates

Changes to GAAP are established by the Financial Accounting Standards Board ("FASB") in the form of accounting standards updates ("ASU"). ASU's 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.

Accounting Pronouncements Recently Adopted

In October 2021, the FASB, issued Accounting Standards Update No. 2021-08, Business Combinations (Topic 805), Accounting for Contract Assets and Contract Liabilities from Contracts with Customers, which requires an entity (acquirer) to recognize and measure contract assets and liabilities acquired in a business combination in accordance with Topic 606, Revenue from Contracts with Customers. This update is effective for fiscal years beginning after December 15, 2022, and interim periods within those fiscal years, with early adoption permitted. The amendments should be applied prospectively to business combinations occurring on or after the effective date of the amendments. The Company early adopted the ASU on January 1, 2023. The adoption did not have an impact on the Company's consolidated financial statements. The Company will evaluate the impact for each business combination transaction completed hereafter.

3. Balance Sheet Components

Inventory

Inventory as of December 31, 2023 and 2022 consisted of the following:

	2023	2022
	(in thousands)	
Raw materials	$ 6,450	$ 9,269
Work in process	278	427
Finished goods	4,346	5,766
Total inventory	$ 11,074	$ 15,462

During the year ended December 31, 2023, the Company recorded a reserve for excess and obsolete inventory of $1.7 million related to reduced sales volumes of legacy GentleWave Console ("Gen3"). During the same period, the Company also recorded a charge of $1.2 million related to phasing out legacy procedure instruments, the molar and anterior pre-molar as the Company moves to the CleanFlow procedure instruments, of which $0.6 million was due to excess and obsolete inventory. The Company recorded a reserve for excess and obsolete inventory of $0.8 million and $0.5 million as of December 31, 2023 and 2022, respectively.

Property and equipment, net

Property and equipment, net as of December 31, 2023 and 2022 consisted of the following:

	2023	2022
	(in thousands)	
Laboratory and warehouse equipment and tooling	$ 469	$ 6,837
Computer equipment and software	30	1,543
Office furniture and fixtures	314	1,955
Leasehold improvements	19	2,983
Automobiles	—	29
Construction in progress	—	130
	832	13,477
Less: accumulated depreciation	(168)	(10,617)
Property and equipment, net	$ 664	$ 2,860

During 2023, the Company recorded an impairment charge of $2.6 million to property and equipment, of which, $1.6 million was recorded in cost of sales and the remainder was recorded in operating expenses on the consolidated statements of operations and comprehensive loss. During 2022, the Company did not record any impairment charges related to property and equipment.

Depreciation expense was $1.1 million for each of the years ended December 31, 2023 and 2022. During 2023, approximately $0.6 million depreciation expense was recorded in cost of sales, $0.4 million was recorded in selling, general and administrative expenses, and $0.1 million was recorded in research and development expenses in the consolidated statements of operations and comprehensive loss. During 2022, approximately $0.5 million depreciation expense was recorded in cost of sales, $0.4 million was recorded in selling, general and administrative expenses, and $0.2 million was recorded in research and development expenses in the consolidated statements of operations and comprehensive loss.

Intangible assets, net

Intangible assets as of December 31, consisted of the following:

	2023			
	Weighted Average Amortization Period	Gross	Accumulated Amortization	Net
	(in years)		*(in thousands)*	
Developed Technology (5 years)	1.6	$ 1,110	$ 1,110	—
Customer relationships (7 years)	4.0	1,910	1,421	489
Tradenames (10 years)	1.1	360	188	172
Total intangible assets	6.7	$ 3,380	$ 2,719	$ 661

	2022			
	Weighted Average Amortization Period	Gross	Accumulated Amortization	Net
	(in years)		*(in thousands)*	
Developed Technology (5 - 10 years)	4.0	$ 2,445	$ 1,123	$ 1,322
Customer relationships (7 years)	2.8	1,910	1,148	762
Tradenames (10 years)	0.8	360	152	208
Total intangible assets	7.6	$ 4,715	$ 2,423	$ 2,292

During 2023, an impairment charge of $1.0 million to developed technology was recorded in operating expenses on the consolidated statements of operations and comprehensive loss. See Note 2 *Summary of Accounting Policies*. During 2022, the Company did not record any impairment charges related to intangible assets.

For each of the years ended December 31, 2023 and 2022, amortization expense was $0.6 million, with approximately $0.2 million amortization expense recorded in cost of sales and $0.4 million recorded in selling, general, and administrative expenses as recorded in the accompanying consolidated statements of operations and comprehensive loss.

The following table presents estimated future annual amortization expense related to intangible assets, net as of December 31, 2023:

	Future Intangible Asset Amortization Expenses
	(in thousands)
2024	$ 309
2025	252
2026	36
2027	36
2028 and thereafter	28
Total future amortization expense	$ 661

Accrued Expenses

Accrued expenses as of December 31, 2023 and 2022 consisted of the following:

	2023	2022
	(in thousands)	
Vendor invoices	$ 1,711	$ 2,779
Other accrued expenses	1,555	2,578
Total accrued expenses	$ 3,266	$ 5,357

Other Current Liabilities

Other current liabilities as of December 31, 2023 and 2022 consisted of the following:

	2023	2022
	(in thousands)	
Finance lease liability	$ 39	$ 34
Warranty liability	1,187	1,340
Other current liabilities	618	817
Total other current liabilities	$ 1,844	$ 2,191

Other Liabilities

Other liabilities as of December 31, 2023 and 2022 consisted of the following:

	2023	2022
	(in thousands)	
Non-current finance lease liability	$ 145	$ 183
Other non-current liabilities	385	590
Total other liabilities	$ 530	$ 773

4. Fair Value of Financial Instruments

The following table provides the 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 value at December 31, 2023 and 2022:

	2023			
	Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(in thousands)		
Assets:				
Cash equivalents:				
Money market funds	$ 10,761	$ 10,761	$ —	$ —
Corporate Bonds	1,827	—	1,827	—
Total cash equivalents at fair value	12,588	10,761	1,827	—
Short-term investments:				
U.S. treasury securities	14,826	14,826	—	—
Commercial paper and corporate bonds	13,204	—	13,204	—
U.S. government agency bonds	4,743	—	4,743	—
Total short-term investments at fair value	32,773	14,826	17,947	—
Total assets at fair value	$ 45,361	$ 25,587	$ 19,774	$ —

	2023			
	Fair Value	Cost Basis	Amounts Recognized in Accumulated Other Comprehensive Loss	
			Unrealized Gains	Unrealized Losses
		(in thousands)		
Available-for-sale securities:				
U.S. Treasury securities	$ 14,826	$ 14,820	$ 6	$ —
Commercial paper and corporate bonds	13,204	13,197	9	(2)
U.S. government agency bonds	4,743	4,745	—	(2)
Total available-for-sale securities at fair value	$ 32,773	$ 32,762	$ 15	$ (4)

	2022			
	Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(in thousands)		
Assets:				
Cash equivalents:				
Money market funds	$ 12,253	$ 12,253	$ —	$ —
Commercial paper	1,998	—	1,998	—
U.S. government agency bonds	1,991	—	1,991	—
Total cash equivalents at fair value	16,242	12,253	3,989	—
Short-term investments:				
U.S. treasury securities	33,622	33,622	—	—
Commercial paper and corporate bonds	40,162	—	40,162	—
Total short-term investments at fair value	73,784	33,622	40,162	—
Total assets at fair value	$ 90,026	$ 45,875	$ 44,151	$ —

	2022			
	Fair Value	Cost Basis	Amounts Recognized in Accumulated Other Comprehensive Loss	
			Unrealized Gains	Unrealized Losses
		(in thousands)		
Available-for-sale securities:				
U.S. Treasury securities	$ 33,622	$ 33,676	$ —	$ (54)
Commercial paper and corporate bonds	40,162	40,169	—	(7)
Total available-for-sale securities at fair value	$ 73,784	$ 73,845	$ —	$ (61)

The Company reviews its investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, any changes to the underlying credit risk of the investment, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. The unrealized losses in the Company's investments were caused by changes in interest rates caused by changing economic conditions, and not from a decline in credit of their underlying issuers. The Company does not generally 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 which may be at maturity. As such, the Company has classified these losses as temporary in nature.

Money market funds and U.S. Treasury securities are highly 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.

Commercial paper, U.S. government agency bonds and corporate bonds 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 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.

5. Stockholders' Equity

In April 2022, the Company amended its term loan and the warrants previously issued to Perceptive Credit Holdings III, LP and certain of its affiliates to purchase an aggregate of 304,105 shares of its common stock. Such warrants were amended solely to reduce the exercise price of the warrants to $12.00 per share. The amendment resulted in revaluation of warrants that was recognized in additional paid-in capital on the consolidated statement of convertible preferred stock and stockholders' equity (deficit) as of December 31, 2022.

Warrants outstanding at December 31, included the following:

2023			2022		
Number of warrants		Purchase Price Per Share	Number of warrants		Purchase Price Per Share
19,179	$	10.95	27,398	$	10.95
54,792	$	12.00	54,792	$	12.00
249,313	$	12.00	249,313	$	12.00
323,284			331,503		

These warrants expire between June 2024 and August 2031.

On September 27, 2022, the Company completed the Private Placement, issuing an aggregate of 23.0 million shares of its common stock at a purchase price of $0.95 per share and pre-funded warrants to purchase an aggregate of 43.3 million shares of common stock at a purchase price of $0.949 per pre-funded warrant to certain institutional investors and accredited investors (the "Purchasers"). The pre-funded warrants have an exercise price of $0.001 per share of common stock, are immediately exercisable and will remain exercisable until exercised in full. The aggregate net proceeds from the Private Placement, after deducting placement agent fees and other offering expenses, were $59.0 million.

The pre-funded warrants include a provision whereby the exercisability of the warrants may be limited if, upon exercise, the warrant holder or any of its affiliates would beneficially own more than 9.99% of the Company's common stock. The threshold is subject to the Purchaser's rights under the pre-funded warrant to increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days' prior notice from the Purchaser to the Company. As of December 31, 2023, approximately 12.1 million shares have been issued pursuant to the exercise of pre-funded warrants and 31.1 million shares underlying the pre-funded warrants remain outstanding.

The pre-funded warrants were classified as equity and are accounted for as a component of additional paid-in capital at the time of issuance. The pre-funded warrants are included in the calculation of basic and diluted loss per share. Pursuant to the terms and conditions of the purchase agreements entered into by the Purchasers, the Company was obligated to file a registration statement with the SEC registering the resale by the Purchasers of the shares of common stock issued to them in the Private Placement and the shares of common stock to be issued to them upon exercise of the pre-funded warrants issued to them in the Private Placement within 45 days of the closing of the Private Placement. On November 4, 2022, the Company filed a registration statement on Form S-3 (File No. 333-268174), as required under the purchase agreements, and the registration statement was declared effective by the SEC on November 16, 2022.

6. Stock Based Compensation

2017 and 2021 Incentive Plan

During 2017, the Company adopted a stock option plan (the "2017 Plan"), which replaced the Company's 2007 stock option plan (the "2007 Plan"). Following the adoption of the 2017 Plan, no stock options were granted under the 2007 Plan. The exercise price of options granted under the 2017 Plan were set at fair market value at the date of the grant as estimated by the Company's Board with an exercise price of no less than 100% of estimated fair market value on the date of grant.

In November 2021, in connection with its IPO, the Company adopted the 2021 Equity Incentive Plan (the "2021 Plan"). The types of awards that may be granted under the 2021 Plan include stock options, including incentive stock options and nonqualified stock options, restricted stock, dividend equivalents, RSUs, stock appreciation rights, and other stock or cash awards. Under the 2021 Plan, the vesting of stock awards is typically over four years. Following the adoption of the 2021 Plan, no further awards will be granted under the 2017 Plan.

2023 Inducement Plan

During 2023, the Company adopted the 2023 Employment Inducement Incentive Award Plan (the "2023 Inducement Plan"). The 2023 Inducement Plan provides for, among other things, the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, dividend equivalents and other stock- or cash-based awards to eligible individuals. Under the 2023 Plan, the defined vesting term of stock awards typically ranges from four to five years.

Employee Stock Purchase Plan ("ESPP")

Under the Company's ESPP, eligible employees may authorize payroll deduction of up to 15% of their eligible compensation, subject to IRS limitations, during prescribed offering periods to purchase the Company's common stock at 85% of the fair market value of common stock either at the beginning of that offering period or on the exercise date, whichever is less. Each offering period is generally six months.

During 2023 and 2022, the number of shares issued and the purchase were both immaterial. In late 2023, the Company suspended future ESPP offering.

Stock-based Compensation Expenses

The following tables present the Company's stock-based compensation for stock-settled awards by type (*i.e.*, stock options and RSUs granted under the Company's incentive plans, and rights to purchase shares of common stock issued under the Company's ESPP and financial statement lines included in the accompanying consolidated statement of operations and comprehensive loss for the years ended December 31, 2023 and 2022:

	2023	2022
	(in thousands)	
Options	$ 2,829	$ 3,975
RSUs	4,297	3,407
ESPP	150	100
Total stock-based compensation expense	$ 7,276	$ 7,482

	2023	2022
	(in thousands)	
Cost of sales	$ 359	$ 562
Selling, general and administrative	6,228	5,729
Research and development	689	1,191
Total stock-based compensation expense	$ 7,276	$ 7,482

On December 2, 2022, the Company's board of directors approved a stock option modification that reduced certain employees' stock option exercise prices. The original options to purchase approximately 2.0 million shares were canceled and replaced by the same number of new options granted with an exercise price of $2.34 with no other terms modified. The modification to the existing options resulted in $1.0 million of incremental value of the stock options, $0.6 million of which was immediately recognized related to vested options as of December 31, 2022. The remaining incremental fair value of $0.4 million will be recognized over the remaining requisite service period.

Compensation cost related to unvested stock options and RSUs will generally be amortized on a straight-line basis over the remaining average service period. The following table presents the unamortized compensation cost and weighted average service period of all unvested outstanding awards as of December 31, 2023.

	Twelve Months Ended December 31,	
	Unamortized Compensation Costs	Weighted Average Service Period
	(in thousands)	*(years)*
Options	$ 2,194	1.5
RSUs	8,212	2.6
Total unamortized compensation cost	$ 10,406	

As of December 31, 2023, the unamortized compensation cost related to the ESPP was not material.

Plan Activities

The following table summarizes stock option activity under the Company's incentive plans:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life	Aggregate Intrinsic Value
			(in years)	*(in thousands)*
Options outstanding, December 31, 2021	3,119,993	$ 7.59	7.6	$ 2,325
Granted	297,516	$ 1.73		
Forfeited	(327,720)	$ 9.45		
Exercised	(262,222)	$ 5.76		
Expired	(71,199)	$ 3.54		
Options outstanding, December 31, 2022	2,756,368	$ 2.83	6.9	$ 1,510
Granted	195,120	$ 1.08		
Forfeited	(468,691)	$ 2.35		
Expired	(99,156)	$ 1.14		
Options outstanding, December 31, 2023	2,383,641	$ 2.86	6.3	$ —
Options vested and exercisable, December 31, 2023	1,922,354	$ 2.90	5.8	

The weighted-average grant-date fair value of options granted during the years ended December 31, 2023 and 2022 was $0.83 per share and $1.16 per share per share, respectively.

The following table summarizes the non-vested stock options as of December 31, 2023 and 2022:

	Number of Shares	Weighted Average Grant Date Fair Value
Non-vested Options, December 31, 2022	1,118,088	$ 6.23
Non-vested Options, December 31, 2023	461,287	$ 5.33

The total fair value of shares vested during the years ended December 31, 2023 and 2022 was $2.5 million and $6.9 million, respectively.

Certain stock option grants under the 2017 Plan allow the recipient to exercise the options prior to the options becoming fully vested. Under the 2017 Plan, the Company retains the right to repurchase common shares that have been issued upon early exercise of options at the original issue price. During the year ended December 31, 2023, the Company did not repurchase shares. There was no material number of shares of common stock subject to repurchase as of December 31, 2023. Cash received for the early exercise of unvested stock options is initially recorded as a liability and are released to equity over the vesting period. There was no early exercised stock options during 2023. During 2022, early exercised stock options vested were immaterial.

The following table summarizes RSU activity under the Company's incentive plans:

	Number of Shares	Weighted Average Grant Date Fair Value
RSUs outstanding, December 31, 2021	338,149	$ 9.37
Granted	3,547,603	$ 4.33
Vested	(440,952)	$ 5.72
Forfeited	(586,151)	$ 5.39
RSUs outstanding, December 31, 2022	2,858,649	$ 4.49
Granted	3,541,198	$ 1.57
Vested	(1,436,020)	$ 3.36
Forfeited	(1,621,206)	$ 3.02
RSUs outstanding, December 31, 2023	3,342,621	$ 2.60

In the first quarter of 2024, the Company immediately vested 589,487 outstanding RSUs granted to certain non-executive employees.

Fair Value Assumptions

The fair value of the Company's stock options awards is estimated at the date of grant or modification, using the Black-Scholes option-pricing model with the following input assumptions during the years ended December 31, 2023 and 2022:

	2023		2022	
	Range	Weighted Average	Range	Weighted Average
Expected volatility	96.65% - 96.65%	96.65%	78.37% - 85.14%	83.28%
Dividend yield	0.00%		0.00%	
Risk-free interest rates	3.92% - 3.92%	3.92%	3.13% - 4.28%	3.75%
Expected term (in years)	5.50 - 5.50	5.50	2.25 - 5.91	4.46

The fair value of the Company's RSU awards is determined based upon the closing price of the Company's stock price on the date of grant.

Stock Reserved for Issuance

As of December 31, 2023, 9.4 million shares of common stock were reserved for issuance under the Company's incentive plans.

7. Leases

The Company leases office space under operating leases with expirations ranging from March 2025 to December 2026, some of which include rent escalations or an option to extend the lease for up to three years per renewal. The exercise of lease renewal options is at the sole discretion of the Company.

As of December 31, 2023, the Company has not entered into any leases that have not yet commenced that would entitle the Company to significant rights or create additional obligations.

The Company determines whether a contract is or contains a lease at the inception of the contract. A contract will be deemed to be or contain a lease if the contract conveys the right to control and direct the use of identified property, plant, or equipment for a period of time in exchange for consideration. The Company generally must also have the right to obtain substantially all of the economic benefits from the use of the property, plant, and equipment.

The Company has elected the practical expedient to not separate its lease component from non-lease component for its real estate leases. The Company has elected the practical expedient not to apply the lease recognition requirements to short-term leases with an initial term of 12 months or less.

The Company uses either its incremental borrowing rate or the implicit rate in the lease agreement as the basis to calculate the present value of future lease payments at lease commencement. The incremental borrowing rate represents the rate the Company would have to pay to borrow funds on a collateralized basis over a similar term and in a similar economic environment.

Future minimum lease payments under these leases are as follows:

	Lease Amounts
	(in thousands)
2024	$ 1,427
2025	1,009
2026	645
Total future minimum lease payments	3,081
Less: Imputed Interest	(281)
Present value of operating lease liabilities	$ 2,800
Less: Current portion	1,377
Long-term operating lease liabilities	$ 1,423
Weighted average remaining lease term in years	2.33
Weighted average discount rate	8.82%

Variable operating lease expenses consist primarily real estate taxes and insurance. The components of lease expense and related cash flows were as follows:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Rent expense	$ 1,516	$ 1,297
Variable lease costs	83	120
Total	$ 1,599	$ 1,417
Cash paid for operating leases	$ 1,521	$ 1,387

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Cost of sales	$ 327	$ 234
Selling, general and administrative	1,272	1,183
Total	$ 1,599	$ 1,417

8. Commitments and Contingencies

Contingencies

The Company is subject to claims and assessments from time to time 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 accompanying 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. The Company's management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's business, financial condition, results of operations or cash flows.

Stock Listing

Due to our failure to comply with the continued listing standard set forth in the New York Stock Exchange (NYSE)'s Listed Company Manual, our common stock has been suspended from trading on the NYSE effective at the opening of business Eastern Standard Time on November 22, 2023 and may be delisted from the NYSE, which may negatively impact our stockholders and the trading price and liquidity of our common stock. We commenced trading on the OTCQX on the same day. We have subsequently appealed the NYSE's determination. The appeal is still in process and there can be no assurance that an appeal will be successful.

9. Term Loan

Perceptive loan

On April 6, 2022, the Company entered into Amendment No. 1 (the "First Amendment") to the Amended and Restated Credit Agreement and Guaranty with Perceptive Credit Holdings III, LP (as it may be amended, restated, supplemented or modified from time to time, the "Amended Perceptive Loan Agreement"). On July 29, 2022, the Company borrowed the first tranche of $10.0 million of delayed draw term loan under the First Amendment and received a net proceeds of $9.9 million. The Company forfeited the second tranche of delayed draw term loan under the First Amendment.

As a condition to entering into the First Amendment, on April 6, 2022, the Company also amended the warrants previously issued to Perceptive and certain of its affiliates to purchase an aggregate of 304,105 shares of its common stock. Such warrants were amended solely to reduce the exercise price of the warrants to $12.00 per share. In August 2022, a portion of these warrants representing 153,421 shares were transferred to a third party and its affiliates.

For the years ended December 31, 2023 and 2022, the interest rate for amounts borrowed under the Amended Perceptive Loan Agreement was the greater of the one-month LIBOR and 2.00% plus the applicable margin of 9.25%. On January 13, 2023, the Company entered into Amendment No. 2 (the "Second Amendment") to the Amended Perceptive Loan Agreement to replace the existing benchmark rate from the one-month LIBOR with a one-month Secured Overnight Financing Rate("SOFR"). All other terms remain unchanged on the original agreement.

For the year ended December 31, 2023 and 2022, the effective interest rate of the Amended Perceptive Loan, was 16.15% and 14.59%, respectively. As of December 31, 2023 and 2022, the fair value of the Amended Perceptive Loan approximates its carrying amount.

On March 1, 2024, the Company entered to Amendment No. 3 (the "Third Amendment") to the Amended Perceptive Loan Agreement. Pursuant to the Third Amendment, the Company made a one-time $15.0 million principal repayment on March 1, 2024, and agreed to make an amortization payment of $1.8 million on the outstanding principal on March 31, 2024 and make monthly amortization payments on the outstanding principal amount each in the amount of $0.9 million on each payment date commencing on April 30, 2024. The Third Amendment also modified certain covenants included in the Amended Perceptive Loan Agreement (also see note 13).

Pursuant to the Third Amendment, future principal repayments and the net carrying value of the Perceptive Loan as of December 31, 2023, are as follows:

	Principal
	(in thousands)
2024	$ 24,900
2025	10,800
2026	4,300
Total principal payment	40,000
Debt discounts	(2,633)
Net carrying value	$ 37,367

The Company is permitted to make voluntary prepayments, subject to a scaled prepayment premium that ranges from 7.0% to 1.0% of the aggregate principal amount outstanding on such prepayment date for prepayments made after August 23, 2022 and before August 23, 2025. No prepayment premium is required for payments made after August 23, 2025.

The Amended Perceptive Loan Agreement contains events of default, including, without limitation, upon: (i) failure to make a payment pursuant to the terms of the agreement; (ii) violation of certain covenants; (iii) payment or other defaults on other indebtedness; (iv) material adverse change in the business or change in control; (v) insolvency; (vi) significant judgments; (vii) incorrectness of representations and warranties; (viii) regulatory matters; and (ix) failure by us to maintain a valid and perfected lien on the collateral securing the borrowing. Based on the Amended Perceptive Loan Agreement, the Company has granted a security interest in substantially all of its assets.

The Amended Perceptive Loan Agreement includes financial covenants that require the Company to (i) maintain, at all times, a minimum aggregate balance of $3.0 million in cash in one or more controlled accounts, and (ii) pursuant to the Third Amendment, satisfy certain minimum revenue thresholds, measured for the consecutive 12-month periods ending on each calendar quarter-end until June 30, 2026 as follows:

For 12-month Period Ending	Revenue
	(in thousands)
March 31, 2024	$ 39,000
June 30, 2024	$ 35,500
September 30, 2024	$ 33,000
December 31, 2024	$ 31,500
March 31, 2025	$ 31,000
June 30, 2025	$ 33,000
September 30, 2025	$ 35,935
December 31, 2025	$ 40,160
March 31, 2026	$ 44,950
June 30, 2026	$ 51,500

Pursuant to the Third Amendment, the lender also waived the covenant requiring the absence of any "going concern" or like qualification or exception or any qualification or exception as to the scope of the audit, solely with respect to the fiscal year ending on December 31, 2023.

Failure to satisfy any covenants would constitute an event of default under the Amended Perceptive Loan Agreement. In the event of an event of default, the lender may terminate its commitments and declare all amounts outstanding under the Amended Perceptive Loan Agreement, immediately due and payable, together with accrued interest and all fees and other obligations. The amount of such repayment will include payment of any prepayment premium applicable due to the time of such payment. In addition, upon the occurrence and during the continuance of any event of default, the applicable margin will increase by 3.00% per annum to 12.25%. As of December 31, 2023, we were in compliance with all covenants and conditions required by the outstanding Amended Perceptive Loan Agreement.

10. Income Taxes

The income tax provision for the years ended December 31, 2023 and 2022 was immaterial. The effective tax rate was 0.0% for each of the years ended December 31, 2023 and 2022 and differs from the statutory federal income tax rate due to the deferred tax assets being subject to a full valuation allowance.

The provision (benefit) for income taxes charged to operations was as follows:

	2023	2022
	(in thousands)	
Current tax expense		
U.S. federal	$ —	$ —
State and local	2	2
Total current	2	2
Deferred tax expense:		
U.S. federal	$ —	$ —
State and local	—	—
Total deferred	—	—
Total provision for income taxes	$ 2	$ 2

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383 as well as similar state provisions, 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. In general, an "ownership change," as defined by IRC Section 382, 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. 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, 2023. 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, 2023. However, the Company has not reflected a benefit in the consolidated financial statements due to the recorded valuation allowance.

A reconciliation of the provision for income taxes with the expected income tax computed by applying the statutory federal income tax rate to loss before provision for income taxes and a reconciliation of the statutory federal rate and the effective rate was calculated as follows:

	2023		2022	
	Amount	Percent	Amount	Percent
Tax computed at federal statutory rate	$ (12,896)	21.00%	$ (11,979)	21.00%
State income tax - net of federal benefit	(1,350)	2.20%	(1,144)	2.01%
Tax credits	(351)	0.57%	(560)	0.98%
Change in valuation allowance	12,894	(21.00)%	11,637	(20.41)%
Stock-based compensation	1,623	(2.64)%	1,160	(2.03)%
Other deferred adjustments	(65)	0.11%	750	(1.31)%
Permanent items	147	(0.24)%	138	(0.24)%
Income tax provision	$ 2	0.00%	$ 2	0.00%

The significant components that comprised the Company's net deferred taxes at December 31, 2023 and 2022 are as follows:

	2023	2022
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 87,831	$ 78,276
Fixed assets and intangible assets	1,643	1,244
Lease liabilities	659	514
Accruals and reserves	1,018	1,170
Stock-based compensation	453	918
Tax credits	5,749	5,375
Employee Retention Credit	—	172
Research & Development	5,093	3,077
Other	2,261	1,346
Gross deferred tax assets	104,707	92,092
Less: valuation allowance	(104,007)	(91,113)
Net deferred tax assets	700	979
Deferred tax liabilities:		
Fixed assets and intangible assets	—	(408)
Right-of-use assets	(700)	(571)
Total gross deferred tax liabilities:	(700)	(979)
Net deferred tax asset (liability)	$ —	$ —

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.

On the basis of this evaluation, as of December 31, 2023 and 2022, a valuation allowance of $104.0 million and $91.1 million, respectively, has been recorded to recognize only the portion of the deferred tax asset that is more likely than not to be realized. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are reduced or increased or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as the Company's projections for growth.

As of December 31, 2023 and 2022, the Company had federal net operating loss carryforwards of approximately $361.2 million and $321.6 million, respectively and state net operating loss carryforwards of $205.1 million and $186.4 million, respectively. The federal and state loss carryforwards begin to expire in 2026, unless previously utilized. Due to the enactment of the Tax Cuts and Jobs Act, federal net operating losses generated beginning in 2018 are carried forward indefinitely. Therefore $244.0 million of federal net operating loss carryforwards will not expire. As of December 31, 2023 and 2022, the Company also had federal research and development tax credit carry-forwards of approximately $4.1 million and $3.7 million, respectively and state research and development tax credit carry-forwards of approximately $4.6 million and $4.4 million, respectively. The federal research and development tax credits will begin to expire in 2032. The California research and development tax credits carry-forward indefinitely.

Any uncertain tax positions would be related to tax years that remain open and subject to examination by the relevant tax authorities. The Company has no liabilities recorded for uncertain tax positions but does have unrecognized tax benefits of $2.2 million which have been recorded as a direct reduction to the deferred tax asset as of the year ended December 31, 2023. The Company has not accrued for interest or penalties associated with unrecognized tax liabilities. The Company is subject to U.S. federal tax authority examinations and U.S. state tax authority examinations for all years due to the net operating loss carryforwards. The Company files a federal U.S. tax return and several U.S. state income tax returns with varying statues of limitations.

The following changes occurred in the amount of unrecognized tax benefits:

	2023	2022
	(in thousands)	
Gross unrecognized tax benefits at the beginning of the year	$ 2,020	$ 1,791
Increases related to current year tax positions	126	207
Increases related to prior year tax positions	10	22
Gross unrecognized tax benefits at the end of the year	$ 2,156	$ 2,020

11. Segment Information

As of December 31, 2023, the Company operates and reports its results in two business segments, Product and Software. The Company reports segment information based on the management approach. The management approach designates the internal reporting used by the Company's chief operating decision maker (“CODM”) for decision making and performance assessment as the basis for determining the Company’s reportable segments. The performance measures of the Company’s reportable segments are primarily income (loss) from operations. Income (loss) from operations for each segment includes all revenues, related cost of net revenues, gross margin and operating expenses directly attributable to the segment.

The Company’s Product segment includes sales of the Company's GentleWave System console and related accessories and instruments.

The Company’s Software segment included sales of the Company's traditional software licenses for practice management software to enable an integrated digital office for endodontists. The Company divested its Software segment in March 2024.

The following tables present the Company’s segment information as of and for the years ended December 31, 2023 and 2022.

In the Product segment, for the year ended December 31, 2023, the Company recognized a total impairment charge of $3.7 million for long lived assets, of which $1.6 million was recorded in cost of sales and the remainder in operating expenses. In addition to the impairment charges, cost of sales included a $2.9 million charge related to

inventory due to phasing out the Company's legacy GentleWave Console ("Gen 3") and molar and pre-molar legacy procedure instruments during 2023.

	2023			2022		
	(in thousands, except percentage data)					
	Product	Software	Total	Product	Software	Total
Revenue	$ 34,628	$ 9,237	$ 43,865	$ 33,280	$ 8,376	$ 41,656
Cost of sales:						
Product and software	28,375	3,184	31,559	28,193	2,983	31,176
Impairment of long-lived assets	1,584	—	1,584	—	—	—
Total cost of sales	29,959	3,184	33,143	28,193	2,983	31,176
Gross profit	4,669	6,053	10,722	5,087	5,393	10,480
Gross margin	13%	66%	24%	15%	64%	25%
Operating expenses:						
Selling, general and administrative	51,639	2,383	54,022	49,859	2,047	51,906
Research and development	10,207	2,148	12,355	15,002	1,774	16,776
Impairment of long-lived assets	2,088	—	2,088	—	—	—
Total operating expenses	63,934	4,531	68,465	64,861	3,821	68,682
Income (loss) from operations	$ (59,265)	$ 1,522	$ (57,743)	$ (59,774)	$ 1,572	$ (58,202)

Segment Assets:

	2023	2022
	(in thousands)	
Product	$ 67,290	$ 125,713
Software	10,870	11,572
Total	$ 78,160	$ 137,285

12. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders for the periods presented:

	Year Ended December 31,	
	2023	2022
	(in thousands, except shares and per share data)	
Numerator:		
Net loss	$ (60,919)	$ (57,050)
Denominator:		
Weighted-average shares outstanding – basic and diluted	93,988,749	44,932,952
Net loss per share – basic and diluted	$ (0.65)	$ (1.27)

The pre-funded warrants as discussed in Note 5 are considered outstanding for the purposes of computing loss per share and are included in the calculation of basic and diluted shares outstanding above.

The following potentially dilutive securities were excluded from the computation of diluted net loss per share calculations for the periods presented because the impact of including them would be anti-dilutive:

	Year Ended December 31,	
	2023	2022
Stock options	2,383,641	2,756,368
RSUs	3,342,621	2,858,649
Warrants	323,284	331,503
Total	6,049,546	5,946,520

13. Subsequent Event

On March 1, 2024, the Company entered into an Asset Purchase Agreement by and among TDO, Valsoft Corporation Inc., a Quebec corporation, and Aspire USA LLC, a Delaware limited liability company and affiliate of Valsoft (collectively "Valsoft"), pursuant to which TDO agreed to sell to Valsoft substantially all the assets and liabilities relating to the Company's software segment. As consideration for the transaction, Valsoft agreed to pay TDO approximately $16.0 million, with $15.0 million paid on March 1, 2024 and the balance due in approximately 12 months. In connection with the transaction, Valsoft agreed to make offers of employment to certain employees of the Business on terms that are comparable to those currently in effect for such employees. The Agreement contains certain representations, warranties and covenants of each of TDO and Valsoft. Each of TDO and the Valsoft has agreed to indemnify the other for certain losses arising out of breaches of representations and covenants and for certain losses arising out of retained liabilities or assumed liabilities relating to the TDO business, as applicable, subject to customary limitations.

The assets and liabilities of the Company's software segment did not meet the held for sale criteria as of December 31, 2023 and therefore were not classified as held for sale in the Company's Consolidated Balance Sheet as of December 31, 2023.

On March 1, 2024, the Company entered to Amendment No. 3 (the "Third Amendment") to the Amended Perceptive Loan Agreement. Pursuant to the Third Amendment, the Company made a one-time $15.0 million principal repayment on March 1, 2024, and agreed to make an amortization payment of $1.8 million on the outstanding principal on March 31, 2024 and make monthly amortization payments on the outstanding principal amount each in the amount of $0.9 million on each payment date commencing on April 30, 2024. The Third Amendment also modified certain covenants included in the Amended Perceptive Loan Agreement (also see note 9) and released all liens granted to the TDO software assets.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our principal executive and principal financial officers, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended, as of the end of the period covered by this Annual Report. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (b) to include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management’s Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting refers to a process designed by, or under the supervision of, the principal executive and principal financial officer and effected by the board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Under the supervision and with the participation of senior management, including the Chief Executive Officer and Chief Financial Officer, the Company carried out an evaluation of the effectiveness of its internal control over financial reporting, as of December 31, 2023, based on the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based upon this evaluation, management concluded that, as of December 31, 2023, the Company's internal control over financial reporting was effective in providing reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect all misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate due to changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Attestation Report of the Independent Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting due to an exemption established by the JOBS Act for “emerging growth companies” and because we qualify as a “non-accelerated filer” (i.e., we do not qualify as either an “accelerated filer” or a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act).

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the quarter ended December 31, 2023, none of the Company's directors or officers adopted, modified or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (each as defined in Item 408 of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Incorporated herein by reference is the information to be provided under the captions "Board of Directors and Corporate Governance - The Board of Directors," "Family Relationships," "Executive Officers," "Code of Ethics," and "Committees of the Board of Directors - Audit Committee" in our definitive proxy statement to be filed with the Securities and Exchange Commission (the "SEC") within 120 days after December 31, 2023 (the "2024 Proxy Statement").

Item 11. Executive Compensation.

Incorporated herein by reference from our 2024 Proxy Statement is the information to be set forth under the caption "Executive and Director Compensation."

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

Incorporated herein by reference from our 2024 Proxy Statement is the information to be set forth under the caption "Equity Compensation Plan Information" and "Ownership of the Company."

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

Incorporated herein by reference from our 2024 Proxy Statement is the information to be set forth under the caption "Certain Relationships and Related Party Transactions" and "Board of Directors and Corporate Governance - Director Independence."

Item 14. Principal Accounting Fees and Services.

Incorporated herein by reference from our 2024 Proxy Statement is the information to be set forth under the caption "Relationship with Independent Registered Public Accounting Firm."

PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

(1) Financial Statements. See Item 8 "Financial Statements and Supplemental Information" elsewhere in this Annual Report on Form 10-K.

(2) Financial Statement Schedules. None. Financial statement schedules have been omitted because they are not applicable.

(3) Exhibits. The following exhibits are filed (or incorporated by reference herein) as part of this Annual Report on Form 10-K:

Exhibit Number	Description	Incorporated by Reference				Filed / Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation	8-K	001-40988	3.1	11/2/2021	
3.2	Amended and Restated Bylaws	8-K	001-40988	3.2	11/2/2021	
4.1	Form of Certificate of Common Stock	S-1/A	333-260136	4.1	10/25/2021	
4.2	Fifth Amended and Restated Voting Agreement by and among Sonendo, Inc. and the investors listed therein	S-1/A	333-260136	4.2	10/25/2021	
4.3	Third Amended and Restated Investors' Rights Agreement by and among Sonendo, Inc. and the investors listed therein	S-1	333-260136	4.3	10/8/2021	
4.4	Warrant to purchase Series C-1 preferred stock, issued to Oxford Finance LLC on December 31, 2013	S-1	333-260136	4.4	10/8/2021	
4.5	Warrant to purchase Series C-1 preferred stock, issued to Oxford Finance LLC on June 30, 2014	S-1	333-260136	4.5	10/8/2021	
4.6	Warrant to purchase Series C-1 preferred stock, issued to Oxford Finance LLC on December 31, 2014	S-1	333-260136	4.6	10/8/2021	
4.7	Warrant to purchase Series D preferred stock	S-1	333-260136	4.7	10/8/2021	
4.8	Warrant to purchase Series E preferred stock (2018)	S-1	333-260136	4.8	10/8/2021	
4.9	Warrant to purchase Series E preferred stock (2019)	S-1	333-260136	4.9	10/8/2021	
4.10	Warrant to purchase Series E preferred stock (2021)	S-1	333-260136	4.10	10/8/2021	
4.11	Description of Common Stock	10-K	001-40988	4.11	3/23/2022	
4.12	Form of Credit Agreement Warrant to Purchase Common Stock (April 2022)	8-K	001-40988	4.1	4/7/2022	
4.13	Schedule to Exhibit 4.12 - Holders of Credit Agreement Warrant to Purchase Common Stock (April 2022)	8-K	001-40988	4.2	4/7/2022	
4.14	Form of Credit Agreement Warrant to Purchase Stock (Warberg entities)	10-Q	001-40988	4.12	8/10/2022	

4.15	Schedule to Exhibit 4.14 - Holders of Credit Agreement Warrants to Purchase Common Stock (Warberg entities)	10-Q	001-40988	4.13	8/10/2022
4.16	Form of Indenture for Senior Debt Securities	S-3	333-270366	4.6	3/8/2023
4.17	Form of Indenture for Subordinated Debt Securities	S-3	333-270366	4.7	3/8/2023
10.1	Form of Indemnification Agreement	S-1/A	333-260136	10.1	10/25/2021
10.2	Amendment No. 5 to Credit Agreement and Guaranty, dated August 23, 2021, between Sonendo, Inc., Perceptive Credit Holdings, LP and Perceptive Credit Holdings III, LP	S-1	333-260136	10.8	10/8/2021
10.3	Amended and Restated Credit Agreement and Guaranty, dated August 23, 2021, between Sonendo, Inc. and Perceptive Credit Holdings III, LP	S-1	333-260136	10.9	10/8/2021
10.4	2007 Stock Plan	S-1	333-260136	10.10	10/8/2021
10.5	2017 Sonendo, Inc. Stock Incentive Plan and related form agreements	S-1	333-260136	10.11	10/8/2021
10.6	2021 Incentive Award Plan	S-1/A	333-260136	10.12	10/25/2021
10.6.1	Form of Restricted Stock Unit Agreement pursuant to 2021 Incentive Award Plan	S-1/A	333-260136	10.12.1	10/25/2021
10.6.2	Form of Option Agreement pursuant to 2021 Incentive Award Plan	S-1/A	333-260136	10.12.2	10/25/2021
10.7	Sonendo, Inc. 2021 Employee Stock Purchase Plan	S-1/A	333-260136	10.13	10/25/2021
10.8	Non-Employee Director Compensation Program	S-1/A	333-260136	10.18	10/25/2021
10.9	Executive Severance Plan	S-1/A	333-260136	10.19	10/25/2021
10.10	Employment Offer Letter by and between Sonendo, Inc. and Bjarne Bergheim, effective July 1, 2012	S-1	333-260136	10.14	10/8/2021
10.11	Employment Offer Letter by and between Sonendo, Inc. and Mehrzad Khakpour, effective September 26, 2014	S-1	333-260136	10.16	10/8/2021
10.12	Standard Business Park Lease, dated July 15, 2020, by and between Sonendo, Inc. and Laguna Cabot Road Business Park, LP	S-1	333-260136	10.2	10/8/2021
10.13	Amendment No.1 to Amended and Restated Credit Agreement and Guranty, dated as of April 6, 2022, by and among Sonendo, Inc. and Perceptive Credit Holdings III, LP	8-K	001-40988	10.1	4/7/2022
10.14	Form of Institutional Investor Securities Purchase Agreement by and between Sonendo, Inc. and the Purchasers named therein (September 2022)	8-K	001-40988	10.1	9/23/2022
10.15	Form of Retail Investor Securities Purchase Agreement by and between Sonendo, Inc. and the Purchasers named therein (September 2022)	8-K	001-40988	10.2	9/23/2022
10.16	Form of Pre-Funded Warrant (September 2022)	8-K	001-40988	10.3	9/23/2022
10.17	Amendment No. 2 to Amended and Restated Credit Agreement and Guaranty, dated as of January 13, 2023, by and	8-K	001-40988	10.1	1/17/2023

	between Sonendo, Inc. and Perceptive Credit Holdings III, LP					
10.18	Asset Purchase Agreement, between TDO Software, Inc., Valsoft Corporation Inc. and Aspire USA LLC, effective as of March 1, 2024	8-K	001-40988	10.2	3/5/2024	
10.19	Amendment No. 3 to Amended and Restated Credit Agreement and Guaranty, dated as of March 1, 2024, by and between Sonendo, Inc. and Perceptive Credit Holdings III, LP	8-K	001-40988	10.2	3/5/2024	
21.1	List of Subsidiaries	10-K	001-40988	21.1	3/23/2022	
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.					*adver
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.					*
97.1	Policy for Recovery of Erroneously Awarded Compensation					
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 with embedded Linkbases document					*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					*

+ The information contained in Exhibits 32.1 and 32.2 shall not be deemed “filed” for purposes of Section 18 of the Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act (including this Annual Report on Form 10-K), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

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.

Sonendo, Inc.

Date: March 11, 2024

By: /s/ Bjarne Bergheim

Bjarne Bergheim
President, Chief Executive Officer and Director

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/ Bjarne Bergheim **Bjarne Bergheim**	President, Chief Executive Officer and Director (principal executive officer)	March 11, 2024
/s/ Michael P. Watts **Michael P. Watts**	Chief Financial Officer (principal financial and accounting officer)	March 11, 2024
/s/ Anthony P. Bihl III **Anthony P. Bihl III**	Director	March 11, 2024
/s/ Carolyn Beaver **Carolyn Beaver**	Director	March 11, 2024
/s/ Olav Bergheim **Olav Bergheim**	Director	March 11, 2024
/s/ Karen McGinnis **Karen McGinnis**	Director	March 11, 2024
/s/ Raj Pudipeddi **Raj Pudipeddi**	Director	March 11, 2024
/s/ Sadie Stern **Sadie Stern**	Director	March 11, 2024