2023 Annual Report

Inspire®

No mask. No hose. Just sleep.™

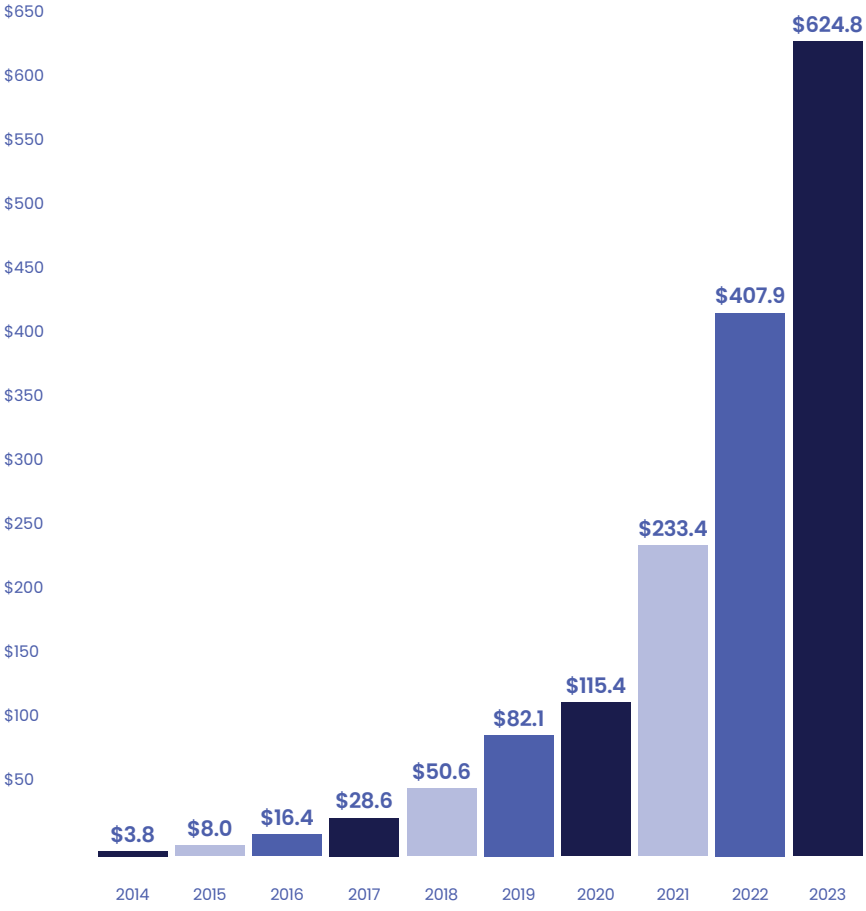
A Letter from the CEO

Dear Inspire Shareholders,

Timothy P. Herbert
President & Chief Executive Officer

We celebrate another record-breaking year of financial and operational performance driven by the continued growth in the adoption of Inspire therapy. These results were driven by our relentless focus on our core growth strategies of ensuring strong and consistent patient outcomes, promoting awareness of Inspire therapy among patients and providers, and methodically expanding our sales and marketing organization. I am proud of the Inspire team for all that they accomplished in 2023 and look forward to the future as we work to enhance the quality of life for patients struggling with obstructive sleep apnea (OSA).

Revenue (in millions)



$624.8M revenue
in 2023

53% revenue growth
in 2023 over 2022

Our disciplined approach to operating our business generated exceptional financial results in 2023, including full-year revenue of $624.8 million, representing growth of 53% over the $407.9 million generated in 2022, as well as our first quarter with operating profits. We gained operating leverage on our direct-to-consumer spend,

(continued on page 2)

84.5%
gross margin
in 2023

which, complemented by increased utilization at existing centers and interest income on our cash and investments, led to a profitable fourth quarter in 2023. The full-year gross margin in 2023 was 84.5%, as compared to 83.8% in 2022. The increase was driven by improved manufacturing yields and higher volumes.

The past year was filled with many important milestones. First, we were proud to receive Food and Drug Administration (FDA) authorization to provide therapy to certain pediatric patients with Down syndrome, to increase the upper limit of the Apnea Hypopnea Index from 65 to 100 events per hour, and to increase the Body Mass Index warning from 32 to 40.

We continued to make technology investments that we expect will further enhance patient outcomes and product performance. During 2023, we submitted the PMA supplement for the Inspire V neurostimulator to the FDA. We anticipate approval in the back half of 2024 with full launch in 2025. We also received FDA approval for our new connected physician programmer, called the SleepSync™ programmer, and are currently in the process of launching that product in the U.S. We finished enrolling 5,000 patients in our ADHERE registry, which will serve as the baseline for our real-world evidence strategy going forward. We also finished enrollment in the PREDICTOR study and expect to publish results once the full data set has been analyzed. If the results are favorable, the PREDICTOR will be an important step towards replacing the required drug-induced sleep endoscopy with an office-based measurement for certain patients less likely to have concentric collapse, improving the patient experience and increasing capacity for surgeons.

We ended the year with over 1,000 team members and strengthened our executive leadership team with the additions of Carlton Weatherby as our Chief Strategy Officer and Dr. Charisse Sparks as our Chief Medical Officer. As we continue to expand our business, we need strong leadership to focus on increasing the adoption of Inspire therapy in the OSA market. OSA is a large and underpenetrated market, and we believe we have many years of sustained, healthy organic growth ahead. Carlton joins us from Medtronic where he was general manager of their spinal division. He brings a wealth of talent and experience that will be invaluable as we continue to scale our business. Dr. Sparks is a board-certified physician with extensive business and leadership experience including direct experience with Inspire as a board director. She leads Inspire's clinical program, provides executive oversight to ensure high-quality patient outcomes, and serves as a liaison for the ENT and sleep physician communities.

In connection with her appointment, Dr. Sparks transitioned from her role on the Inspire Board of Directors.

We also welcomed Dr. Myriam Curet, Executive Vice President and Chief Medical Officer of Intuitive Surgical, to our Board of Directors. Dr. Curet brings significant experience in developing and commercializing scalable solutions for minimally invasive surgery and we look forward to her guidance, expertise, and contributions to our board as we advance Inspire therapy to treat the many patients affected by OSA.

Since our FDA approval in 2014, we have continued to execute our commercial strategy focusing primarily on driving growth in the U.S. and in select international markets. As we continue to grow and scale our business, we expect to focus our efforts to drive a greater percentage of our growth through increased utilization at existing centers. This is evidenced by our continued improvement in utilization from 1.7 units per center per month in the first quarter of 2023 to 2.1 units per center per month in the fourth quarter of 2023.

As far as expanding the number of centers offering Inspire therapy, in 2023 we activated 280 new U.S. centers, ending the year with a total of 1,180 U.S. centers, up 30% year-over-year. While we prioritize leveraging higher utilization at existing centers, we also aim to continue to expand the number of centers offering Inspire therapy.

In order to succeed in our focus areas, we must ensure that we have adequate support in the field, as well as a training team equipped to add additional centers, all while maintaining strong patient outcomes, which is aways our top priority. The rate at which we open new sales territories is directly proportional to the rate at which we open new centers. As such, in 2023 we opened 62 new U.S. territories, ending the year with 287 U.S. territories. We also increased the field support teams, including Field Clinical Representatives who specialize in case coverage and programming training.

Our market access team continues to work in collaboration with the Centers for Medicare and Medicaid Services, commercial payers, and sleep and ENT physicians to ensure that coverage policies are clear and appropriate and, in 2023, we made significant progress updating our commercial coverage policies for our expanded FDA label. Additionally, we facilitate patient access to Inspire therapy by providing our customers with assistance in obtaining coverage decisions from payors, including with respect to prior authorization. In this regard, during 2023, we expanded our prior authorization

(continued on page 4)

280 new U.S. centers
initiated Inspire programs in 2023

1,180 U.S. centers
in total at the end of 2023

62 new U.S. territories
opened in 2023

287 U.S. territories
in total at the end of 2023

team and onboarded a third-party vendor to enhance our ability to provide this assistance.

A key to our success is our ability to drive awareness of Inspire therapy through our direct-to-consumer marketing programs. As such, we were excited to launch a new and improved www.inspiresleep.com website in December which features increased education around the procedure and healing process, as well as physician testimonials. Our website had over 13 million visits in 2023 and continues to educate patients on Inspire therapy and assist patients to find a qualified healthcare provider. Additionally, our call center, the Advisor Care Program (ACP), is a resource for patients to learn more about Inspire therapy and to connect them with a qualified healthcare professional. After initiating a direct digital scheduling program for our ACP in 2022, we made steady progress expanding this capability to additional centers in 2023 and ended the year with over 100 centers using direct digital scheduling.

In addition to our emphasis on the U.S. market, we are pleased with the recent growth in the adoption of Inspire therapy in Europe and the Asia Pacific region. Our European business saw significant acceleration in the back half of 2023 until we ran into supply shortages associated with European Union Medical Device Regulation labeling requirements for our new silicone-based sensing and stimulation leads. Despite these challenges, we are making excellent progress toward resolution, and, as a contingency, applied for and obtained derogation authorization in the Netherlands, Germany, Belgium, and Switzerland, enabling us to ship product in those countries. Our strategy is to focus our commercial activities in countries that have established reimbursement, primarily Germany, Switzerland, the Netherlands, and Belgium. Going forward, we plan to continue to pursue positive reimbursement decisions in other key European countries which we expect will allow us to further grow therapy adoption in markets such as France and the United Kingdom.

We hired and trained our direct sales team in Japan, continued to see strong traction in Singapore, and performed the first reimbursed cases in Hong Kong. We look forward to further expansion in Japan, as well as Singapore, Hong Kong, and other select countries throughout the Asia Pacific region.

The Inspire team continues to be fully committed to delivering positive and consistent outcomes for patients with untreated OSA. Monitoring and reporting on these outcomes provide an opportunity for continued education of ENT surgeons and sleep physicians, which, in turn, can lead to enhanced patient outcomes. To this end, in 2023,

independent and company-supported researchers authored over 40 peer-reviewed publications on Inspire therapy, increasing the total number of such publications to over 280. These articles were published in leading ENT and sleep medicine journals.

Over 280 peer-reviewed papers

documenting the safety and efficacy of Inspire therapy

Looking ahead, we have a strong balance sheet to support our growth objectives, with cash, cash equivalents and investments totaling $470 million as of December 31, 2023. Given the strength of our balance sheet and our disciplined approach to capital allocation, we believe that we are well-positioned for the future and intend to remain focused on expanding the capacity of our sales organization to meet the growing demand for Inspire therapy and advance our key research and development projects.

In December, we issued our 2023 Environmental, Social, and Governance (ESG) Report. We are dedicated to transparent reporting that demonstrates where we are today and strive to expand upon our sustainability programs and reporting in the years ahead. We understand our responsibilities as a corporate citizen and are focused on developing ESG programs and initiatives that are sustainable and have real impact.

In 2023, we launched InspireGives, Inspire's community outreach program aimed at serving the communities in which we live and operate through financial donations and volunteerism. Our contributions provide crucial assistance to charities treating critical illnesses, combating poverty and homelessness, easing hardship for people affected by disasters, eliminating barriers to equal opportunity, and supporting underserved communities to address inequities in health outcomes.

Our employees are passionate about improving the lives of others, so we provide channels for our team members to identify opportunities to engage with new organizations and events in our communities. In 2023, we contributed to 15 local and national organizations, including healthcare charities and causes such as community assistance, disaster relief, and diversity, equity, and inclusion.

In closing, while 2023 presented some challenges, our team remained committed to helping patients and clinicians and showed tremendous resolve, which resulted in a very successful year that saw us surpass 60,000 patients receiving Inspire therapy and achieve our second profitable quarter in the company's history. On behalf of the entire Inspire team, we look forward to helping more

(continued on page 6)

people discover the potentially life-changing impact that Inspire therapy can offer patients with OSA and their loved ones. We sincerely thank all our investors for their support and remain firmly committed to creating additional long-term stakeholder value.

Sincerely,

Timothy P. Herbert
President & Chief Executive Officer

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**

For the transition period from to

Commission File Number: 001-38468

Inspire Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-1377674**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
5500 Wayzata Blvd., Suite 1600 Golden Valley, MN	**55416**
(Address of principal executive offices)	(Zip Code)

(844) 672-4357
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common stock, $0.001 par value	**INSP**	**New York Stock Exchange**

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

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

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

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

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

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

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

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

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

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 Act). Yes ☐ No ☒

As of June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $9,352,188,865, based on the closing price of the registrant's common stock as reported on the New York Stock Exchange on such date.

As of February 1, 2024, the registrant had 29,585,104 shares of common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2024 annual stockholders' meeting, which is to be filed within 120 days of the registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements, including, without limitation, statements regarding our future results of operations and financial position, business strategy, the impact of macroeconomic trends on our business, financial results and financial position, prospective products, international product approvals and commercializations, our expectations regarding the final reimbursement levels for Inspire therapy procedures, research and development costs, timing and likelihood of success, other insurance providers' plans to begin approving our Inspire therapy, human capital initiatives, environmental, social, and governance reporting, and the plans and objectives of management for future operations.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “can,” “continue,” “could,” “designed,” “estimate,” “expect,” “forecast,” “goal,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would,” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. The forward-looking statements in this Annual Report on Form 10-K are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of known and unknown risks, uncertainties and assumptions, including, but not limited to the factors described in "Part I, Item 1. Business," "Part I, Item 1A. Risk Factors," and "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Unless the context requires otherwise, references to “Inspire,” the “Company,” “we,” “us,” and “our,” refer to Inspire Medical Systems, Inc.

Summary Risk Factors

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

- our history of operating losses and dependency on our Inspire system for revenues;
- commercial success and market acceptance of our Inspire therapy;
- our ability to achieve and maintain adequate levels of coverage or reimbursement for our Inspire system or any future products we may seek to commercialize;
- competitive companies and technologies in our industry;
- the impact on our business, financial condition, and results of operation from COVID-19, or any other pandemic, epidemic or outbreak of an infectious disease;
- our ability to expand our indications and develop and commercialize additional products and enhancements to our Inspire system;

- future results of operations, financial position, research and development costs, capital requirements, and our needs for additional financing;
- our ability to forecast customer demand for our Inspire system and manage our inventory;
- our dependence on third-party suppliers, vendors, and contract manufacturers;
- risks related to consolidation in the healthcare industry;
- our ability to expand, manage, and maintain our direct sales and marketing organization, and to market and sell our Inspire system in markets outside of the United States;
- our ability to manage our growth;
- our ability to hire and retain our senior management and other highly qualified personnel;
- risks related to product liability claims and warranty claims;
- our ability to address quality issues that may arise with our Inspire system;
- our ability to successfully integrate any acquired business, products or technologies;
- changes in global macroeconomic conditions;
- any failure of key information technology systems, processes or sites or damage to or inability to access our physical facilities;
- our ability to commercialize or obtain regulatory approvals or certifications for our Inspire therapy and system, or the effect of delays in commercializing or obtaining regulatory approvals or certifications;
- any violations of anti-bribery, anti-corruption, and anti-money laundering laws;
- our ability to use our net operating losses and research and development carryforwards;
- risks related to the increasing and evolving focus on sustainability and environmental, social and governance initiatives;
- U.S. Food and Drug Administration ("FDA") or other United States or foreign regulatory actions affecting us or the healthcare industry generally, including risks associated with regulatory approvals, certifications or healthcare reform measures in the United States and international markets;
- our ability to establish and maintain intellectual property protection for our Inspire therapy and system or avoid claims of infringement;
- changes in U.S. and foreign tax laws; and
- risks related to our common stock.

PART I

Item 1. Business.

Overview

We are a medical technology company focused on the development and commercialization of innovative, minimally invasive solutions for patients with obstructive sleep apnea ("OSA"). Our proprietary Inspire system is the first and only FDA-approved neurostimulation technology that provides a safe and effective treatment for moderate to severe OSA. We have developed a novel, closed-loop solution that continuously monitors a patient's breathing and delivers mild hypoglossal nerve stimulation to maintain an open airway. A significant body of clinical data, which includes a publication in the *New England Journal of Medicine*, multiple publications in leading respiratory, ear, nose and throat ("ENT") and sleep medicine journals, and more than 280 peer-reviewed publications, supports the safety and efficacy of Inspire therapy. Inspire therapy received premarket approval ("PMA") from the FDA in 2014 and has been commercially available in certain European markets since 2011. Japan's Ministry of Health, Labour and Welfare ("MLHW") approved Inspire therapy to treat moderate to severe OSA in 2018. Inspire therapy is indicated for patients with moderate to severe OSA who do not have significant central sleep apnea and do not have a complete concentric collapse of the airway at the soft palate level. In addition, patients in the United States ("U.S."), Japan, and Singapore must have been confirmed to fail or be unable to tolerate positive airway pressure ("PAP") treatments, such as continuous positive airway pressure ("CPAP"), and be 18 years of age or older, though there are no similar requirements for patients in Europe. Physicians have treated more than 60,000 patients with Inspire therapy at over 1,300 medical centers across the U.S., Europe, and Asia.

Sleep apnea is a serious and chronic disease that negatively impacts a patient's sleep, health, and quality of life. OSA is the most common form of sleep apnea. OSA occurs when a person's breathing is interrupted during sleep by a partially or completely blocked airway and affects patients of all ages, sexes, and body types. The severity of OSA is measured by the number of partial or complete airway blockages that a patient experiences in an hour, referred to as the apnea-hypopnea index ("AHI"). Moderate OSA patients have an AHI of 15 to 30 events per hour, while severe OSA patients have an AHI of 30 more events per hour. Left untreated, OSA increases the risk of high blood pressure, hypertension, heart failure, stroke, coronary artery disease, and other life-threatening diseases.

CPAP is the leading therapy for patients with moderate to severe OSA. CPAP is delivered through a face or nasal mask that connects through a hose to a bedside air pump. In order for CPAP to be most effective, the mask must form an airtight seal on the patient's face or nose and the mask must be worn every night. The effectiveness of CPAP has been limited by low patient compliance as many patients find the mask or treatment cumbersome, uncomfortable, and loud. When CPAP fails or cannot be tolerated, patients' remaining treatment options consist primarily of invasive surgical procedures developed to modify or remove existing tissue in an attempt to create free air flow. These invasive surgical procedures have limited or unpredictable clinical benefit, are irreversible, and can be extremely painful.

We believe that there is both an urgent clinical need and a strong market opportunity for an alternative to CPAP that is effective and minimally invasive. Patients with CPAP intolerance are at risk of higher mortality and healthcare utilization. Two recent findings published in 2022 from large healthcare outcome databases, including Medicare and the French national healthcare insurance database, have demonstrated, in a large national cohort, the risks and costs of CPAP intolerance. Specifically, Medicare patients with untreated OSA had $20,000 in higher healthcare costs prior to their OSA diagnosis compared to those without OSA, and those with CPAP intolerance had higher risks of new cardiovascular events than those who were adherent. Similarly, the French national reimbursement database showed that in over 176,000 patients, CPAP non-adherent patients had a higher risk for mortality and new onset of heart failure than those who were adherent. These findings show the urgency of treating CPAP-intolerant OSA to improve outcomes and reduce healthcare utilization.

Inspire therapy is an innovative, closed-loop, minimally invasive solution that provides comfort and convenience, resulting in high compliance for patients with moderate to severe OSA. Once implanted, the Inspire system delivers electrical stimulation that causes a slight forward movement of the back of the tongue, which helps to

maintain an open airway, enabling the patient to inhale freely without interruption. We believe our Inspire therapy provides the following benefits:

- **Safe, effective, and durable treatment** supported by compelling clinical data, including long-term efficacy results out to five years from initial treatment.

- **Closed-loop system** that uses a proprietary algorithm to continuously monitor patients' breathing and provide electrical stimulation during the inspiratory phase.

- **Comfortable and convenient therapy resulting in high patient satisfaction** that was reported to be 90% in patients who were followed an average of 12 months from initial treatment, according to the most recent publication of our ongoing global patient registry.

- **Strong patient compliance**, with 80% of patients reporting continued nightly use through five years from initial treatment in our Stimulation Therapy for Apnea Reduction ("STAR") trial.

- **Minimally invasive outpatient procedure** with short recovery time.

- **Long-lasting solution** with a battery designed to last approximately 11 years without charging or maintenance.

The results from multiple clinical studies, which include seven sponsored and more than 100 independent clinical studies that evaluated several thousand patients, have shown that our Inspire therapy provides statistically significant and sustained reduction in the severity of patients' OSA, improvement in sleep-related quality of life and reduction in snoring, as well as high patient compliance rates and a strong safety profile.

Our pivotal STAR trial was designed to demonstrate longitudinal therapy efficacy and included a randomized controlled therapy withdrawal study. The longitudinal study demonstrated an approximately 70% reduction in the median AHI in patients with moderate to severe OSA from a baseline of 29.3 events per hour to 9.0 events per hour at 12 months following initial treatment. STAR trial follow-up has shown results similar to the initial data at 18 months, three years, and five years. At five years, median AHI in patients with moderate to severe OSA remained low at 6.2 events per hour. The effectiveness of Inspire therapy was further demonstrated by the results of the randomized controlled therapy withdrawal study, in which patients in the therapy withdrawal group regressed to near-baseline AHI levels while patients in the control group that continued therapy experienced sustained therapeutic benefits.

We sell our Inspire system to hospitals and ambulatory surgery centers ("ASCs") in the U.S. and in select countries in Europe through a direct sales organization, and we sell our Inspire system in Japan and Singapore through distributors. As of December 31, 2023, we had 287 sales territories in the U.S. and 19 outside of the U.S. Our direct sales force engages in sales efforts and promotional activities focused on ENT physicians, and sleep centers. In addition, we highlight our compelling clinical data and value proposition to increase awareness and adoption amongst referring physicians. We build upon this top-down approach with strong direct-to-consumer marketing initiatives to create awareness of the benefits of our Inspire system and drive demand through patient empowerment. This outreach helps to educate thousands of patients on our Inspire therapy.

Our U.S. customers are generally reimbursed for the cost of patient treatment by various third-party payors, such as commercial insurance providers and Medicare. We have secured positive coverage policies with many U.S. commercial payors, including virtually all large national commercial insurers, encompassing approximately 260 million covered lives in the U.S. We are in active discussions with regional commercial insurers to establish additional positive coverage policies, as well as modify existing positive coverage policies to support reimbursement of Inspire therapy. In parallel, a subset of our 28-person reimbursement team, which we refer to as our market access team, is focused on assisting patients and physicians in obtaining prior authorization approvals from commercial payors on a case-by-case basis in advance of treatment with our Inspire therapy. In addition, all seven Medicare Administrative Contractors ("MACs") provide coverage of Inspire therapy when certain coverage criteria are met. We also have a U.S. government contract for patients who are treated by the Veterans Health Administration.

Reimbursement in other countries can often be established through a combination of private (commercial insurance) and public funding sources, or at the hospital level through innovation budgets.

Our Competitive Strengths

We believe the continued growth of our company will be driven by the following competitive strengths:

- ***First to market with an innovative, closed-loop, minimally invasive solution.*** We have developed the first and only FDA-approved neurostimulation technology that provides a safe and effective treatment for patients with moderate to severe OSA who have been confirmed to fail or cannot tolerate PAP treatments, such as CPAP. We received a PMA from the FDA in 2014 for our Inspire therapy. Unlike CPAP, which is limited by low patient compliance primarily due to patient discomfort with the mask or device, our innovative, closed-loop, minimally invasive solution is designed to provide comfort and convenience, resulting in high compliance for patients with moderate to severe OSA. We believe we have a significant first mover advantage and momentum over future competitors, as physicians have treated more than 60,000 patients with Inspire therapy.

- ***Significant body of strong clinical data.*** We have developed a significant body of clinical data that demonstrates the safety and effectiveness, therapy adherence, and long-term sustained benefits of our Inspire therapy. The benefits of treatment with Inspire therapy have been consistent across seven sponsored and more than 100 independent clinical studies that evaluated several thousand patients and have been highlighted in more than 280 peer-reviewed publications. Data reported in these clinical studies also demonstrated a high level of overall patient satisfaction. We believe this favorable data provides us with a significant competitive advantage and will continue to support increased adoption of our Inspire therapy.

- ***Holistic and targeted approach to market development and patient engagement.*** We have established a methodical approach to market development which centers on active engagement across three key stakeholders in the OSA treatment paradigm: physicians, sleep centers, and patients. Our sales force is focused on building long-lasting relationships with ENT physicians and sleep centers as we support physicians through all aspects of a case-from diagnosis to surgical support to patient follow-up. In addition, we are highlighting our compelling clinical data set and value proposition to increase awareness and adoption amongst referring physicians. We build upon this top-down approach with a strong direct-to-consumer marketing initiative that further drives demand through patient empowerment. This outreach helps to educate thousands of patients on our Inspire therapy. Our patient call center, the Advisor Care Program, assists patients with making a connection with a qualified healthcare provider based on their specific needs. We are confident that this holistic approach to engagement across multiple constituents will continue to drive increased awareness of and demand for our Inspire therapy.

- ***Dedicated team focused on providing market access for patients and providers.*** We have a refined, efficient approach to advance patients, once identified, to placement of the Inspire system. When required, our dedicated market access team helps patients and providers work with payors to secure prior authorization approvals in advance of initial treatment. In addition, this team proactively works with payors to establish positive coverage policies when needed by highlighting the compelling clinical data and the value of our Inspire therapy. This highly effective team has been successful in helping to secure reimbursement from hundreds of commercial payors to date, and positive coverage policies from most U.S. commercial payors, including virtually all large national payors.

- ***Strong research and development capabilities and comprehensive intellectual property portfolio.*** Our commitment to driving innovation has allowed us to achieve continuous, significant improvements of our Inspire therapy. For example, in 2023, we submitted a premarket approval ("PMA") supplement to the FDA for our next generation Inspire system. Also in 2023, we received approval from the FDA on an expanded indication which includes an increase on the upper limit of the AHI to 100 events per hour from 65, and raises the Body Mass Index ("BMI") warning in the labeling to 40 from 32. We also received FDA approval of our new physician programmer, called the SleepSync™ programmer, which we expect to formally launch in the U.S. in 2024, and we received FDA approval to offer Inspire therapy to certain

pediatric patients with Down syndrome. In 2022, we received FDA approval for additional magnetic resonance imaging ("MRI") scan conditions for use with Inspire therapy. This full-body MRI approval expanded the Inspire use labeling that previously allowed only head, neck, and extremity MRI scans. Also in 2022, the FDA approved new silicone-based stimulation and sensing leads, which provides improved manufacturability, easier system implantation, increased long-term performance, and enhanced reliability. We have a comprehensive patent portfolio to protect our intellectual property and technology, with rights as of December 31, 2023 to 80 issued U.S. patents, 55 issued foreign patents, 81 pending U.S. patent applications, and 79 pending foreign patent applications that cover aspects of our Inspire system and future product concepts.

Our Strategy

Our goal is to be a global leader in providing clinically proven innovative solutions that improve sleep, quality of life, and health of patients with moderate to severe OSA. We believe the following strategies will play a critical role in achieving this goal and our future growth:

- ***Foster strong and consistent patient outcomes.*** Patient outcomes remain the single most important focus for Inspire as we scale our business, and we have a dedicated patient outcomes team furthering this mission. Our Surgical Implant Trainers are tasked with conducting physician trainings and proctoring implants. Care Pathway Specialists develop and promote consistent post-implant care protocols. Our team of Sleep Support Specialists educate and oversee local sleep lab titrations. We believe these teams are critical to ensuring that outcomes continue to improve even as implant volumes increase around the world.

- ***Improve the customer experience.*** We believe that by enhancing interconnectivity, simplifying the care pathway, and closely tracking outcomes, we can optimize the customer experience and improve therapy adherence. We have invested in initiatives that we believe will drive higher quality patient flow to reduce time to treatment and increase the capacity of providers to treat and manage more patients. We expect that this will allow patients and health care providers to more efficiently realize the proven benefits of Inspire therapy. We also continue to invest in our SleepSync™ platform, a cloud-based patient management system which allows patients and physicians alike to remotely monitor key compliance and outcomes measures for connected and coordinated care management, thereby optimizing therapy.

- ***Promote awareness among patients, ENT physicians, sleep centers, and referring physicians.*** We believe that many patients who have failed or cannot tolerate CPAP are unaware of our Inspire therapy as a safe and effective alternative treatment for moderate to severe OSA. We intend to continue to promote awareness of our therapy through training and educating ENT physicians, sleep centers, key opinion leaders, and various medical societies on the proven clinical benefits of Inspire therapy. In addition, we intend to continue to publish additional clinical data in various industry and scientific journals and online, and to present at various industry conferences. We also plan to continue building patient awareness through our direct-to-consumer marketing initiatives, which include paid online search, radio, social media, television, and online videos.

- ***Expand our sales and marketing organization to facilitate adoption of our Inspire therapy.*** We plan to continue to expand our sales and marketing organization and seek to recruit and train exceptionally talented sales representatives in existing and new markets in the U.S. and in Europe to help facilitate further adoption and broaden awareness of our Inspire therapy. Our success to date in developing new markets has been primarily due to our ability to identify new regions with high volume medical centers, educate ENT and sleep physicians, help generate steady patient demand, and provide sufficient support staff to our sales representatives. We believe investing in a scalable, efficient direct sales force and continuing the development of our marketing efforts will help us broaden adoption of our Inspire therapy and drive revenue growth.

- ***Invest in research and development to drive innovation and expand indications.*** Our foundational commitment to driving innovation and improving patient lives fuels our desire for continuous product development. We intend to invest in existing and next generation technologies to further improve our

products and clinical outcomes, optimize patient acceptance and comfort, and broaden the patient population that can benefit from our Inspire therapy. Recent examples of our product innovation include the next generation of the Inspire system, which was submitted to the FDA for approval in June 2023, and FDA approval of our SleepSync™ programmer as discussed above. We have launched a cloud-based patient management system called the SleepSync™ platform (formerly referred to as Inspire Cloud), which allows physicians to monitor patient compliance and more efficiently coordinate patient care, and in 2020, we launched the Inspire Sleep app for patients' smartphones. In 2021, the FDA approved our new patient remote control which is Bluetooth® enabled. A recent example of our efforts to expand our label indications for the Inspire system include obtaining FDA approval to offer Inspire therapy to certain pediatric patients with Down syndrome in 2023, which was approved in 2023. Additionally in 2023, we received approval from the FDA on an expanded indication which includes an increase on the upper limit of the AHI to 100 events per hour from 65, and raises the BMI warning in the labeling to 40 from 32.

- ***Further penetrate and expand into existing and new international markets.*** We plan to continue to establish and strengthen our presence internationally. Our goal is to further increase sales of our Inspire therapy in existing international markets in Europe, including Germany and the Netherlands, and in the Asia Pacific region, including Japan, Singapore, and Hong Kong. We plan to expand our reach to markets in new regions, such as Australia, South Korea, and China. We plan to strategically invest in new markets based on our assessment of market size and opportunity and prospects for compelling reimbursement coding and coverage.

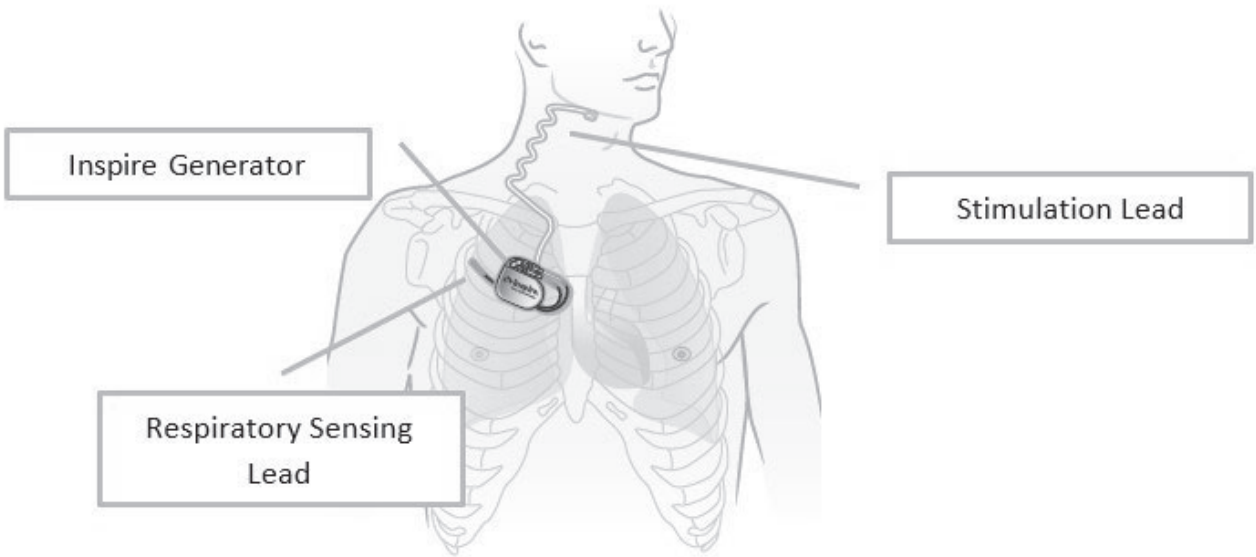
Our Solution for OSA

Overview of Inspire Therapy

Our proprietary Inspire system is the first and only FDA-approved closed-loop neurostimulation technology that provides a safe and effective treatment for moderate to severe OSA. Our Inspire system consists of a remote control and three implantable components:

- a pressure sensing lead, which detects when the patient is attempting to breathe;
- a neurostimulator, which houses the electronics and battery power for the device; and
- a stimulation lead, which delivers electrical stimulation to the hypoglossal nerve.

The image below depicts the location of the Inspire system under the patient’s skin:



A pressure sensing lead is used to monitor the patient's breathing. Our proprietary algorithm tracks breathing patterns and the neurostimulator delivers electrical stimulation at the start of inspiration. This electrical stimulation of the hypoglossal nerve causes a slight forward movement of the back of the tongue that helps maintain an open airway, thereby preventing obstructive events and enabling the patient to inhale freely.

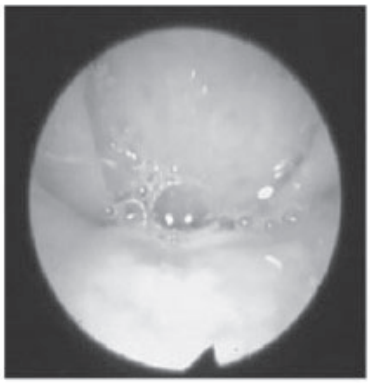
To receive the Inspire system, patients undergo a short outpatient surgical procedure, typically lasting about 90 minutes, during which the neurostimulator, sensing lead, and stimulation lead are implanted. The procedure is minimally invasive and performed with two small incisions. Patients typically recover quickly and are able to resume normal activities in just a few days. Initial activation of the system occurs 30 days after the implantation. After the initial activation, the patient is instructed to use the therapy each night by turning on their Inspire system before going to sleep using their remote control.

The following pictures depict the Inspire neurostimulator, shown with a quarter for scale, and the patient remote control, shown in hand for scale.

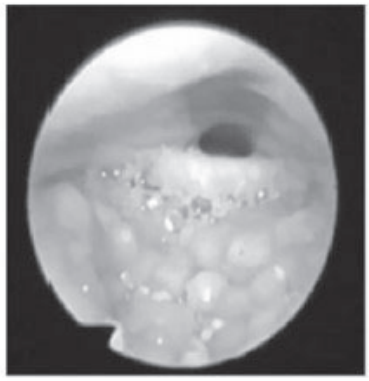
Patients turn their Inspire system on when they plan to go to sleep and turn it off when they awaken. The device has a programmed delay, typically 30 minutes, to allow patients to fall asleep naturally before the device activates. It then monitors the patient's breathing and delivers mild stimulation to the hypoglossal nerve at the start of the inspiratory phase, causing a slight forward movement at the back of the tongue to maintain an open airway during the inspiratory phase of respiration. The therapy is designed to provide stimulation for each breath to prevent obstructive events.

The following pictures depict the anatomy of a patient experiencing an OSA event. The patient's soft palate and the base of the patient's tongue are obstructing the patient's airway and limiting airflow to the lungs.

Obstructed Airway



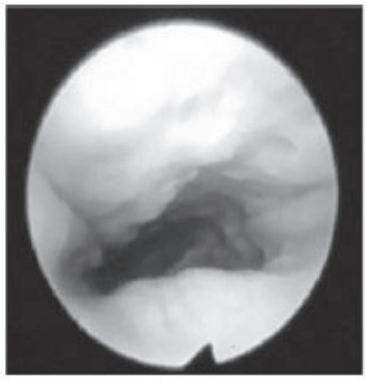
Palate



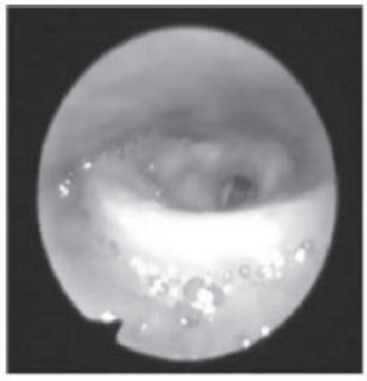
Tongue Base

The following pictures depict the anatomy of the patient after mild stimulation of the hypoglossal nerve, which caused the patient's tongue to move forward slightly, opening the patient's airway and restoring airflow to the lungs.

Open Airway



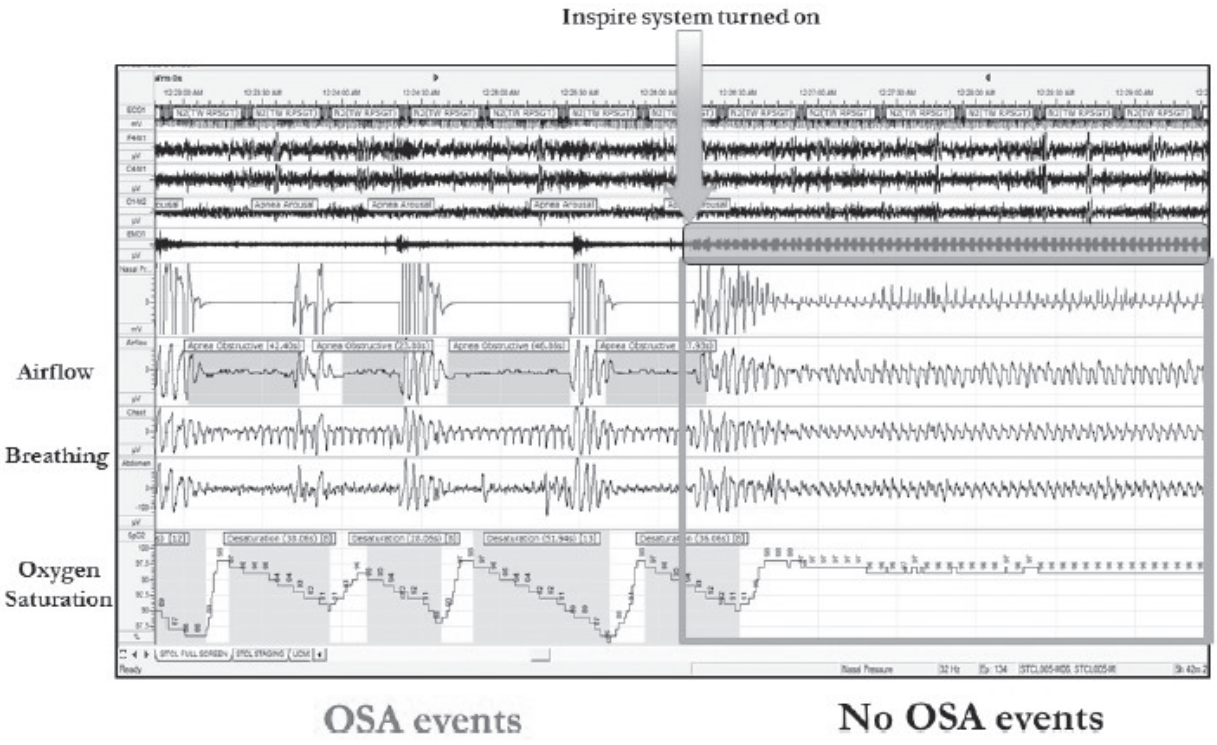
Palate



Tongue Base

The effectiveness of Inspire therapy to relieve OSA is objectively measured during a sleep study or polysomnogram. A sleep study records a patient’s breathing, airflow, and blood oxygen levels before and after activating the device. Before activation, the patient experiences multiple periods of interrupted breathing, and oxygen levels repeatedly drop before the patient experiences a transient arousal that allows air intake. The polysomnogram below shows that after activating Inspire therapy, the patient exhibited a more regular breathing pattern, higher and more consistent blood oxygen levels, and fewer or no transient arousals.

Polysomnogram Before and After Activation of Inspire System



Benefits of Inspire Therapy

We believe our Inspire therapy overcomes many of the limitations of CPAP and other current treatments of moderate to severe OSA by providing the following key benefits:

- **Safe, effective, and durable treatment.** Results from our clinical studies provide compelling safety and efficacy data regarding the clinical benefits of Inspire therapy as many as five years after initial treatment. The results from our STAR trial, a five-year follow-up phase III pivotal trial, demonstrated an approximately 70% reduction in the median AHI from a baseline of 29.3 events per hour to 9.0 events per hour at 12 months following initial treatment. STAR trial follow-up has shown similar results to the initial data at 18 months, three years, and five years. At five years, median AHI remained low at 6.2 events per hour.

- **Closed-loop system.** The Inspire system uses a proprietary algorithm to continuously monitor a patient's breathing and provide electrical stimulation during the inspiratory phase, working with the body's natural actions to keep the airway open during the breathing cycle.

- **Comfortable and convenient therapy resulting in high patient satisfaction.** Data reported in the most recent publication of our ongoing ADHERE patient registry, which we established to follow patients who have been implanted with an Inspire system, demonstrated that patients used Inspire therapy an average of 5.7 hours per night an average of 12 months after initial treatment, with overall patient satisfaction reported to be at 90%.

- **Strong patient compliance.** Results from our STAR trial demonstrated that 80% of patients continue to use Inspire therapy on a nightly basis five years after initial treatment.

- **Similar outcomes and usage as CPAP.** Several independent clinical studies demonstrating Inspire therapy has similar improvements in symptoms, and similar nightly usage as CPAP.

- **Minimally invasive outpatient procedure.** The Inspire system's implantable components are placed during an approximately 90-minute outpatient procedure. The procedure is minimally invasive and performed with two small incisions. Patients typically recover quickly and are able to resume normal activities within a few days.

- **Long-lasting solution.** Our Inspire system uses a battery designed to last approximately 11 years without charging or maintenance.

Commercialization of Inspire Therapy

In the U.S., before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive FDA clearance or approval. We obtained PMA for our Inspire system in 2014. Additionally, we received a certificate of conformity for commercialization of our Inspire system in the European Union ("EU") in 2010 which allowed us to affix the CE mark on our device. Japan's MLHW approved Inspire therapy to treat moderate to severe OSA in 2018 and was formally added to the Japan National Health Insurance Payment Listing in 2021. Reimbursement in Singapore is handled through hospital innovation budgets or private health insurance sources. In 2020, the Australian Therapeutic Goods Administration approved Inspire therapy to treat moderate to severe OSA, and we are currently seeking reimbursement coverage in Australia.

To commercialize our Inspire system, in the U.S., Europe, and Japan, we focus on physician and patient awareness and adoption of our Inspire therapy. To achieve this, our commercialization strategy primarily consists of our direct sales force engaging in sales efforts and promotional activities focused on ENT physicians and sleep centers and highlighting our compelling clinical data and value proposition. Our direct sales force utilizes strong direct-to-consumer marketing initiatives to create awareness of the benefits of our Inspire system. We intend to make significant investments building our sales and marketing organization by increasing the number of U.S. sales representatives and continuing our direct-to-consumer marketing efforts in existing and new markets throughout the U.S. and Europe.

In Singapore and Hong Kong, our commercialization approach is through exclusive distribution partners, who are responsible for local sales and promotional activities focused on ENT physicians, sleep centers, and community awareness. We work closely with the distributors to ensure a globally consistent approach and effective employee and customer training are in place.

In addition, a significant part of our commercialization effort consists of supporting our customers through the reimbursement process. Most commercial U.S. insurers now cover Inspire therapy. For those payors that do not have a positive policy, Inspire provides assistance to patients and physicians in obtaining appropriate prior authorization approvals in advance of treatment. Medicare also has positive coverage for all states, and we have a U.S. government contract for patients who are treated by the Veterans Health Administration.

Treatment with Inspire Therapy

Patient Selection

Inspire therapy is indicated for patients with moderate to severe OSA (AHI of 15 to 100) who do not have significant central sleep apnea and do not have a complete concentric collapse of the airway at the soft palate level. Patients undergo a drug-induced sleep endoscopy performed by an ENT surgeon in order to confirm that they satisfy this anatomical requirement. In addition, patients in the U.S. and Japan must have been confirmed to fail or be unable to tolerate PAP treatments, such as CPAP, and be 18 years of age or older, though there are no similar requirements for patients in Europe. Patients who fail PAP are those that are not able to eliminate moderate to severe OSA despite PAP usage. Patients who cannot tolerate PAP treatments are those who either are unable to use PAP more than five nights per week for at least four hours per night, or who are unwilling to use PAP treatment.

Implantation

The Inspire system is implanted under general anesthesia through two small incisions. One incision is under the lower jaw, where the stimulation lead is attached around a distal branch of the hypoglossal nerve that is responsible for forward movement of the tongue. A second incision in the upper right chest below the clavicle is used to implant the neurostimulator, which houses all the electronics and battery power for the device, and a pressure sensing lead to monitor the breathing cycle. The functionality of the Inspire system is tested in the operating room to verify proper placement of the stimulation and pressure sensing leads. The wires for the electrodes are tunneled under the skin and the incisions are closed. The Inspire system is powered by an internal battery that is designed to last approximately 11 years without needing to be recharged. After this time, the neurostimulator is replaced during a simple outpatient procedure.

The implantation procedure is performed in an outpatient setting and surgery is completed in approximately 90 minutes. Patients may experience mild discomfort and swelling at the incision sites for a few days that is usually managed with over-the-counter pain medications. Patients can return home and resume a normal diet shortly after completion of the procedure and resume most daily activities within a few days. The only restriction on their activity is to avoid strenuous activities until the incisions have had time to heal.

Activation

Patients are allowed to heal for a month before the Inspire system is activated through a wireless connection to the device in the clinician's office. The initial activation is performed by the clinician using a programming tablet that is able to turn the system on as well as change various parameters such as the strength, timing, and duration of the stimulation pulse, the stimulating electrode configuration, and the sensitivity of respiration detection. With the exception of pulse strength, the factory default settings are used in the majority of patients. The pulse strength is initially adjusted to the lowest level required to move the tongue forward.

Patients receive a remote control that they use to turn their Inspire system on when they plan to go to sleep and to turn it off when they awaken. The device has a programmed delay, typically 30 minutes, to allow patients to fall asleep naturally before the device activates. It then delivers mild stimulation to the hypoglossal nerve, causing the tongue to move as the patient is inhaling. The remote enables patients to adjust the strength of the stimulation to optimize their therapy and comfort. The range of control given to patients is limited to avoid setting the strength of the stimulation to an ineffective or excessively high level. Patients also have the ability to temporarily pause therapy if they awaken during the night.

Clinical Results and Studies

A significant body of published clinical evidence, which includes seven sponsored and more than 100 independent clinical studies that evaluated several thousand patients, supports the safety and effectiveness of Inspire therapy. The results of the STAR trial, our phase III pivotal clinical trial that served as the basis for the FDA approval of our PMA application, were published in the *New England Journal of Medicine*, and the results of additional clinical studies have been published in more than 280 peer-reviewed publications. We have established a global patient registry, which we refer to as our ADHERE patient registry, to collect data on safety, effectiveness, weekly usage, overall compliance, and satisfaction from patients who have been implanted with an Inspire system. The table below highlights key findings from certain of these studies and data from our ADHERE patient registry, including significant improvements in objective sleep measures and patient-reported quality of life measures, strong therapy compliance, and a favorable safety profile.

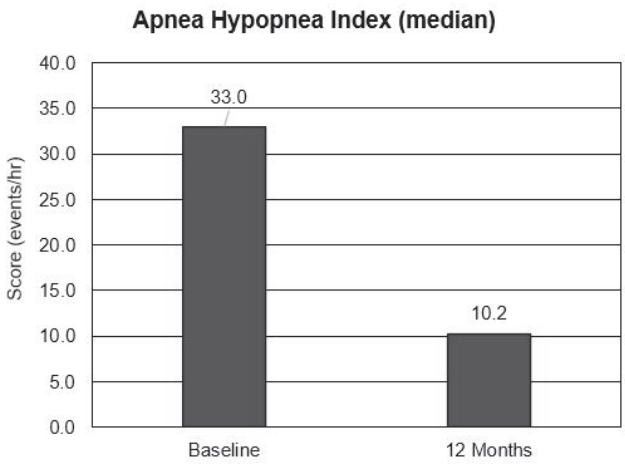
	STAR Trial[1]		German Post-Market Study[1]	ADHERE Patient Registry[1]	TJUH and UPMC Evaluation[2]
Number of Inspire therapy patients	124	97	56	1,963	97
Time following implantation	12 months	5 years	12 months	12 months	3 months
AHI—Baseline	29.3	29.3	28.6	33.0	35.6
AHI—Therapy	9.0	6.2	9.5	10.2	6.3
ESS—Baseline	11	11	13	11	11
ESS—Therapy	6	6	7	6	6
FOSQ—Baseline	14.6	14.6	13.7	*	*
FOSQ—Therapy	18.2	18.7	18.6	*	*
Therapy compliance	86% daily; 93% 5+ days weekly	80% daily	Average 39 hours per week; 89% ≥20 hours per week	Average 5.7 hours per night	Average >45 hours per week

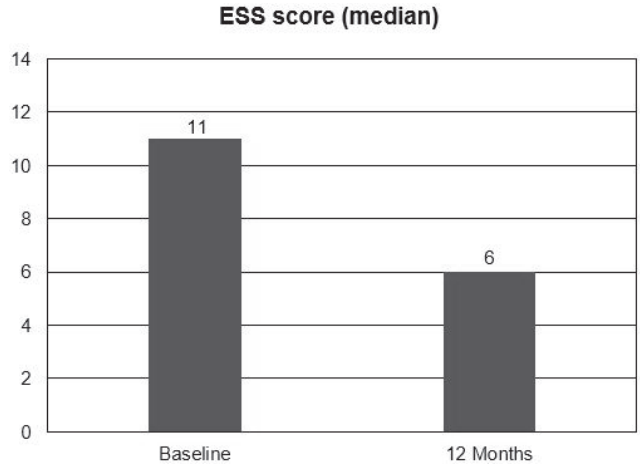
* Not measured
(1) Median results
(2) Thomas Jefferson University Hospital ("TJUH") and University of Pittsburgh Medical Center ("UPMC"). Mean results

Select Recent Clinical Results and Studies

ADHERE Patient Registry

We established our ADHERE patient registry to follow patients who have been implanted with an Inspire system, with a goal of collecting data on a group of at least 5,000 patients. Data gathered on the first 1,963 patients published in the *Journal of Clinical Sleep Medicine* in 2022 showed that patients used Inspire therapy an average of 5.7 hours per night when measured an average of 12 months after implantation. Median AHI was reduced from 33.0 events per hour to 10.2 events per hour and median ESS score improved from 11 to 6 over the same period. Overall satisfaction with Inspire therapy was reported by patients to be 90%, with 92% of patients reporting that they would choose the procedure again. In addition, 91% of patients reported a better experience than CPAP. This same study demonstrated comparable outcomes across five disease severity groups.

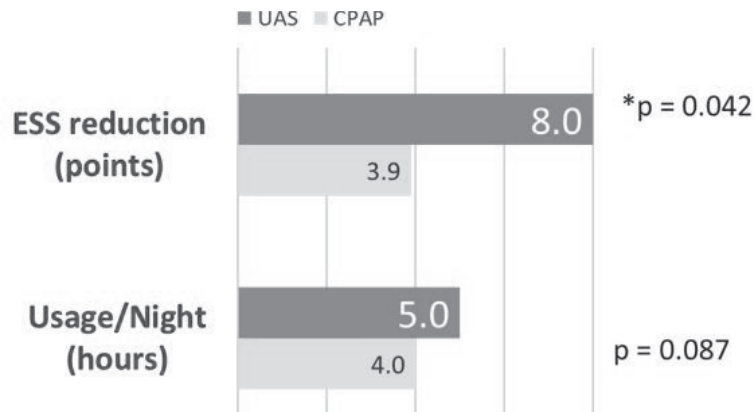




Inspire Therapy Improves Patient Symptoms Similarly as CPAP

In 2021, the Cleveland Clinic published the first comparison of patient-reported outcomes between Inspire therapy and CPAP. These results showed that Inspire therapy and CPAP had a similar improvement in patient symptoms of sleepiness, daytime energy, depression, and insomnia. The results also showed that Inspire therapy patients were more likely to have a more clinically meaningful improvement in symptoms than CPAP patients. This high degree of improvement was maintained through at least one-year in the Inspire therapy patients.

A second study, published by Dr. Clemens Heiser and team at the Technical University of Munich in the *Journal of Sleep and Breathing* in 2022, compared two similar parallel cohorts of patients who were initiating use of Inspire therapy (n=63) or CPAP (n=63). They found that Inspire therapy patients had larger improvements in sleepiness (an eight-point reduction in Epworth Sleepiness Scale ("ESS") with Inspire therapy versus a four point reduction in ESS with CPAP), and numerically higher usage in Inspire therapy patients versus CPAP patients (five hours per night with Inspire therapy versus four hours per night with CPAP). Additionally, the objective AHI outcomes were similar in both arms. Taken together, we believe these results suggest that Inspire therapy may be superior to CPAP at improving disease.



There are now multiple studies in which Inspire showed equivalent improvements in OSA outcomes as CPAP, and similar, if not potentially higher usage than CPAP. We believe these observed improvements could translate to better disease alleviation in patients unable to tolerate CPAP.

Large-scale Insights of Over Three Million Patient Nights from Inspire's SleepSync™ Patient Database Showing Real-World Results

Inspire's SleepSync™ patient management system helps physicians track therapy usage and outcomes, and the results of the first three million patient nights of data were presented by Dr. Jordan Weiner at the 2022 American Academy of Otolaryngology conference and Dr. Deborah Goss at the 2022 American Association of Sleep Medicine meeting. These data, the largest to date evaluating outcomes from Inspire therapy, show the results of 3.7 million patient-nights in 12,017 patients across 491 practices. These data showed that, in real-world use, Inspire therapy continued to show highly effective outcomes similar to the early clinical trials. Objective outcomes such as AHI and ESS were in the normalized ranges, and very high therapy usage of seven hours per night in the first 90 days, demonstrate high usage despite a previous history of CPAP intolerance.

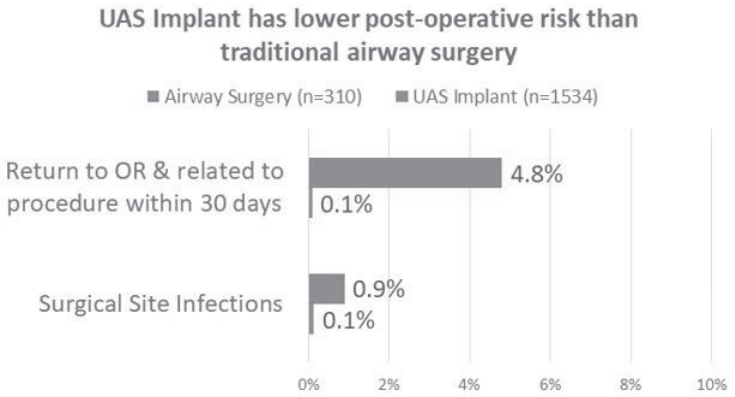
Inspire Therapy Outcomes are Consistent in Both Majority and Minority Populations

Two 2022 publications increased our focus on evaluating Inspire efficacy across a broader range of patient race and ethnicity by leveraging the ADHERE registry, which is a database of real-world Inspire therapy outcomes. The first publication from Dr. Meena Khan and team, published in the *Journal of Clinical Sleep Medicine*, demonstrated that both White and Non-White patients had similar improvements in sleep apnea severity, with no notable differences in usage, AHI, or sleepiness. Similarly, a second analysis by Dr. Linda Magaña, presented at the 2022 meeting of the American Academy of Otolaryngology, examined the differences between Hispanic / Latino and non-Hispanic / non-Latino patients, and found that it demonstrated comparable outcomes. While there is an opportunity to continue to improve the adoption of Inspire therapy in minority populations, given the higher

incident rates and under diagnosis in these groups, we believe these two analyses provide additional evidence that Inspire therapy is equally effective across race and ethnicity.

Comparison of Sleep Surgery Complication Rates versus Inspire Therapy

A 2021 paper published in *Otolaryngology – Open Journal* found that Inspire therapy had a lower complication rate and shorter hospital length of stay compared with sleep surgery, despite the fact that the Inspire population was older and had more co-morbidities. Combined with previous studies on sleep surgery outcomes, we believe these data demonstrate that Inspire therapy may improve outcomes compared to traditional sleep surgery in selected patients.



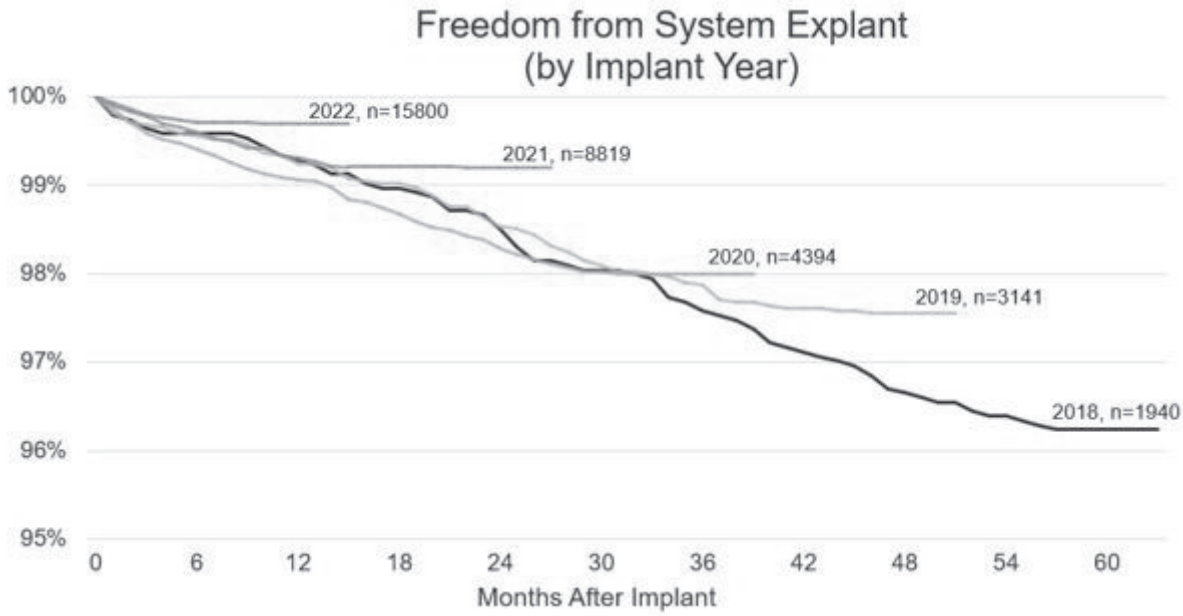
In 2022, a larger analysis was repeated on a national outcomes database, comparing post-operative operative safety and complication rates between Inspire therapy implants (n=1,201) versus palate surgery (n=3,364), which was the predominant OSA surgery prior to the introduction of Inspire therapy (Dr. Ryan Nord, *Otolaryngology – Open Journal*, 2022). This analysis found that Inspire therapy was safer than palate surgeries. Inspire therapy implantation had a much lower risk of emergency room readmission and complication rates in the first 90 days after surgery.

We believe a reduction in post-operative complication rates may help reduce clinical utilization costs versus traditional sleep surgery. Taken together, we believe these data suggest that Inspire therapy should be considered first prior to any traditional airway surgery.

Long-term Therapy Efficacy and Reliability Data

In 2023, two new findings were published showing the positive long-term effects of Inspire therapy. The first publication titled, “Long-Term Generator Replacement Experience in Hypoglossal Nerve Stimulator Therapy Recipients With CPAP-Intolerant Obstructive Sleep Apnea” was published in the *Otolaryngology–Head and Neck Surgery* journal in October 2023. In this paper, a team led by Dr. Linda Magana at the University of Pittsburgh followed the initial patients from the STAR trial for approximately eight years after initial implant, making it the longest follow-up to date of Inspire therapy. The findings reflect that these patients showed stable AHI outcomes consistent with the initial one-year outcomes, and high therapy usage of 7.2 hours per night.

Additionally, an abstract demonstrating the real-world evaluation of Inspire therapy system survival was presented at the SLEEP 2023 meeting in Indianapolis by Dr. Colin Huntley from Thomas Jefferson University. It showed that under real-world conditions, in over 20,000 device implants since January 2018, device explant and revision rates remained low and improved over time, despite increasing utilization. Furthermore, the abstract suggested that these survival rates were reported to be at least similar to, if not slightly better than other implantable active medical devices.



Sales and Marketing

We have established a methodical approach to market development which centers on active engagement across three key stakeholders in the OSA treatment paradigm: patients, physicians, and sleep centers.

We sell our Inspire system through a direct sales force that primarily targets ENT physicians and sleep centers in the U.S., Europe, and Japan, and through distributors in Singapore and Hong Kong. The implant procedure for our Inspire therapy is typically performed by an ENT physician or in some cases by a neurosurgeon. We also focus on sleep centers because they diagnose and manage large volumes of patients with sleep apnea and are often an important referral base for ENT physicians. In addition, because OSA is sometimes diagnosed during other procedures, we have developed programs to help educate general practitioners and specialists in other fields, such as cardiovascular surgeons, electrophysiologists, and dentists, regarding our Inspire therapy.

We have 287 sales territories in the U.S. and 19 outside of the U.S. We seek to recruit sales representatives with strong sales backgrounds, direct experience developing markets with new technologies, and core knowledge of medical device coding, reimbursement, and the prior authorization process. In certain Asian markets, we rely on our distribution partners for local sales and promotional activities.

We also utilize direct communication channels to inform and educate patients about Inspire therapy and to enable them to connect with active clinical sites that offer our Inspire systems. Our primary methods of patient outreach are Facebook, Google ad placements, radio advertisements (either local or satellite), and television advertisements (either local or national). The objective of this outreach is to bring patients to our website, where they can find educational materials and videos on sleep apnea and the use and benefits of our Inspire therapy, contact information for physicians and clinical sites, and information regarding community awareness events.

We believe our patient outreach efforts have been effective in bringing potential patients to our website and facilitating contact with our clinical sites. During 2023, we had nearly 13.4 million visits to our website, which generated approximately 65,000 contacts with physicians throughout the year.

In 2020, we launched the Inspire Sleep app for patients' smartphones. This app is an educational tool for patients and also interfaces with our SleepSync™ platform to allow physicians to collect clinical data from patients directly. We continue to enhance the functionality of this app as part of our overall digital platform development. Since launch, over 110,000 copies of the app have been downloaded to smartphones.

Commercial Activities Outside of the U.S.

Our general practice is to limit commercial investments in countries until such time as there is a determined reimbursement pathway. We have 19 sales territories in Europe and Japan, and we sell our products through distributors in Singapore and Hong Kong. We provide consistent training in geographies outside of the U.S. as is conducted in the U.S. and have established a support team in Europe and Japan for patient outreach and education, implant support, and device programming. In Singapore and Hong Kong, we assist our distribution partners with patient outreach and education initiatives. We expect to continue to scale our commercial activities in Europe as we continue to develop country-wide reimbursement in additional markets. We continue to work on the reimbursement process in Australia and hope to commercialize Inspire therapy there.

Third-Party Reimbursement

Our market access team is responsible for all of our reimbursement processes and initiatives. Our team includes 28 professionals who are focused on all key aspects of reimbursement, which include coding, payment, coverage, and prior authorization.

Coding and Payment

In the U.S., we sell our products to hospitals and ASCs. These customers in turn bill various third-party payors, such as commercial payors and Medicare, for the cost required to treat each patient.

Third-party payors require physicians and hospitals to identify the service for which they are seeking reimbursement by using Current Procedural Terminology (“CPT") codes, which are created and maintained by the American Medical Association. The procedures performed to implant, revise, or explant our device are described for billing purposes using Category I CPT codes (64582, 64583, and 64584, respectively) to identify hypoglossal nerve stimulator services. A Category I code (42975) is used for DISE, which is a required procedure to determine which patients are appropriate for Inspire therapy.

Physician reimbursement under Medicare is based on a defined fee schedule, the Medicare Physician Fee Schedule, through which payment amounts are determined by the relative values of the professional service rendered. Medicare provides reimbursement to our hospital customers under the hospital outpatient prospective payment system ("OPPS") which provides bundled amounts generally intended to reimburse the hospital for all facility costs related to procedures performed in the hospital outpatient setting.

Reimbursement rates from commercial payors vary depending on the procedure performed, the commercial payor, contract terms, and other factors.

Commercial Payor and Government Program Coverage

A core pillar of our reimbursement strategy involves broadening our third-party payor coverage when possible. We continue to have active discussions with commercial payors to establish new and modify existing positive coverage policies by highlighting our compelling and robust clinical data, increased patient demand, and support from leading medical societies and key opinion leaders. We have been successful in obtaining prior authorization approvals from most commercial payors for the Inspire device and procedure. Historically, commercial payors cover approximately 65% to 70% of Inspire implants in the U.S. We estimate that the majority of patients who meet the FDA indication for Inspire therapy are covered by commercial insurance companies and we have secured coverage policies with virtually all major national commercial payors.

All seven MACs provide coverage of Inspire therapy when certain coverage criteria are met. Medicare beneficiaries have historically accounted for approximately 25% to 30% of all Inspire system implantations in the U.S. In addition, we have a contract with the U.S. government that covers implantations of our Inspire system performed in Veterans Affairs and military hospitals, which account for approximately 5% of all Inspire system implantations historically in the U.S.

Prior Authorization Approval Process

A second pillar of our reimbursement strategy includes leveraging our market access team to assist patients and physicians in obtaining appropriate prior authorization approvals in advance of treatment. We believe our market access team is highly effective in working with patients and physicians to obtain prior authorizations for our Inspire system, including assisting with the appeals process. Additionally, in late 2023, we engaged a third-party vendor to assist our internal team with prior authorization submissions in order to increase our capacity to meet patient demand. We have received hundreds of prior authorization approvals from all of the largest commercial payors, for example Anthem, Cigna, Blue Cross Blue Shield, United Healthcare, and Humana. We believe we will continue to benefit from this efficient prior authorization process.

Reimbursement Outside of the U.S.

Outside the U.S., reimbursement levels vary by country and by region within some countries. Reimbursement is obtained from a variety of sources, including government-sponsored and private health insurance plans, and combinations of both. Some countries require additional clinical data before granting or expanding coverage and reimbursement for our products. In general, obtaining broad-based reimbursement and adequate payment for new technologies is more difficult in these markets than in the U.S. Some countries require new medical technologies to not only be safe and effective, but also to be able to demonstrate clinical benefits that outweigh the costs when compared to the standard of care. As in the U.S., reimbursement decisions can change, resulting in the elimination or reduction of reimbursement payments, which could adversely affect our financial results and our ability to invest in and grow our business.

We currently have country wide reimbursement in Germany, the Netherlands, Switzerland, Belgium, the United Kingdom, and Japan. We are in the final process to have the Inspire system included in the French Haute Autorité De Santé listing of products and services qualifying for reimbursement (LPPR) of approved technologies for reimbursement across the French health system. We continue to pursue permanent reimbursement in target markets across the Asia Pacific and Europe, including Spain and the Nordic region.

Research and Development

Product Evolution and Next Generation Products

The first Inspire device was developed by Medtronic Inc. (now Medtronic Public Limited Company), or Medtronic, in the early 1990s as a radio frequency controlled device that required an external apparatus to deliver electrical stimulation to the hypoglossal nerve. The first fully implantable, respiration-sensing, closed-loop Inspire system was developed shortly thereafter. Based on the initial clinical trial results, which were published in 2001, Medtronic began developing what became known as our Inspire II system, introducing a new, more durable stimulation lead and lower-power neurostimulator, and relocating the respiratory sensing lead to between the intercostal muscle layers.

After our 2007 inception and contemporaneous spin-off of the Inspire business from Medtronic, our primary focus was to requalify the Inspire II system and resume clinical trial activity. We completed a phase I feasibility trial along with a phase II dosing or patient selection trial in 2009. In 2011, we began our phase III pivotal STAR trial. The STAR trial was completed and published in the *New England Journal of Medicine* in 2014 and we received PMA in 2014. Additionally, the device was CE marked for commercialization in the EU in 2010.

We continue to invest in advancing our Inspire system with the goal of providing patients more effective and less invasive therapy for OSA. In 2017, we released the Inspire IV neurostimulator, which is 40% smaller than the previous version while maintaining approximately 11 years of battery life. The Inspire IV device was launched in the U.S. in 2017, and in Europe in 2018.

Our next generation of the Inspire neurostimulator was submitted to the FDA for approval in June 2023, and our SleepSync™ programmer was approved by the FDA in 2023. Our Bluetooth®-enabled patient remote control was approved by the FDA in 2021 and the initial commercial launch occurred in 2022. We have launched a cloud-based patient management system called the SleepSync™ platform, which allows physicians to monitor patient

compliance and more efficiently coordinate patient care. In 2020, we launched the Inspire Sleep app for patients' smartphones. The first version of the app was an educational tool, and the second version interfaces with the Inspire Cloud and allows physicians to collect clinical data from patients directly. We continue to enhance the functionality of this app as part of our overall digital platform development.

The SleepSync™ platform and our app are initial steps in establishing interconnectivity between the patient and their healthcare provider with a long-term plan to improve outcomes by tracking patient activity and adherence, and monitoring for any issues with device use.

Additional Indications

We have sought and continue to seek to expand the approved indications for our Inspire therapy. For instance, in 2023, we received FDA authorization to provide Inspire therapy to the pediatric population with Down syndrome. Also in 2023, the FDA approved an indication expansion to increase the upper limit of AHI to up to 100 events per hour from the original 65 events per hour, and to raise the BMI warning for patients with a BMI of up to 40 from the previous limit of 32.

Our research and development team focuses on our products currently under development, including our clinical studies involving efforts to improve patient selection, expand indications, and simplify patient management, as well as feasibility studies in which we are evaluating new ways to deliver neuromodulation for OSA therapy and different design configurations to enhance product functionality for future generations of the Inspire system. One example is our PREDICTOR study, which completed enrollment of 600 patients in early 2024, and which aims to remove the DISE requirement for patients less likely to have concentric collapse.

Competition

Our industry is subject to rapid change from the introduction of new products and technologies and other activities of industry participants. We compete as a second-line therapy in the OSA treatment market for patients with moderate to severe OSA.

We consider our primary competition to be other neurostimulation technologies designed to treat OSA, though we are currently the only such technology approved for commercialization in the U.S. by the FDA. Outside the U.S., we compete with LivaNova and Nyxoah. LivaNova, which markets an open-loop neurostimulation device, is currently conducting clinical trials of its device in the U.S. Nyxoah markets an open-loop bilateral hypoglossal nerve stimulation device in certain countries outside the U.S. and is conducting its first pivotal trial as it seeks FDA approval in the U.S. A drug candidate produced by Apnimed is entering a Phase 3 clinical trial to assess the viability of its pharmaceutical to treat OSA. We believe other emerging businesses are in the early stages of developing neurostimulation devices or early-stage pharmaceutical approaches.

We also compete, both within and outside of the U.S., with invasive surgical treatment options such as UPPP, maxillomandibular advancement ("MMA") and robotic tongue reduction surgery, and, to a lesser extent, oral appliances, which are primarily used in the treatment of mild to moderate OSA. We do not believe we directly compete with CPAP or other types of PAP devices because in the U.S., Inspire therapy is only indicated for patients who have been confirmed to fail or cannot tolerate PAP treatments, such as CPAP.

We believe that the primary competitive factors in the OSA treatment market are:

- company, product, and brand recognition;
- product safety, efficacy, reliability, and durability;
- quality and volume of clinical data;
- effective marketing to and education of patients, physicians, and sleep centers;
- product ease of use and patient comfort;

- sales force experience and access;
- product support and service;
- technological innovation, product enhancements, and speed of innovation;
- pricing and revenue strategies;
- procedure costs to patients;
- effectiveness of reimbursement teams and strategies; and
- dedicated practice development and clinical training teams.

Some other OSA treatments against which we compete, such as oral appliances, MMA, and UPPP, have a greater penetration into the OSA treatment market. Oral appliances and some other surgical treatments are better known to ENT physicians, sleep centers and the other physicians on whom we rely for referrals, but we believe physician awareness of our Inspire therapy is increasing.

We also compete with other medical technology companies to recruit and retain qualified personnel.

Intellectual Property

We rely on a combination of patent, copyright, trademark and trade secret laws, and confidentiality and invention assignment agreements to protect our intellectual property rights. As of December 31, 2023, we had rights to 80 issued U.S. patents, which will expire between 2029 and 2041 assuming all required fees are paid, 81 pending U.S. patent applications, 55 issued foreign patents, and 79 pending foreign patent applications. Our patents cover aspects of our current Inspire system and future product concepts. Some of the issued foreign patents and pending foreign patent applications preserve an opportunity to pursue patent rights in multiple countries.

There is no active patent litigation involving any of our patents and we have not received any notices of patent infringement.

As of December 31, 2023, we had 175 pending and registered trademark filings worldwide, some of which may apply to multiple countries.

We also rely, in part, upon unpatented trade secrets, know-how and continuing technological innovation, and may in the future rely upon licensing opportunities, to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality and assignment agreements with suppliers, employees, consultants, and others who may have access to our proprietary information.

Our pending patent applications may not result in issued patents, and we cannot ensure that any current or subsequently issued patents will adequately protect our products or provide us with any competitive advantage. While there is no active litigation involving any of our patents or other intellectual property rights and we have not received any notices of patent infringement, we may be required to enforce or defend our intellectual property rights against third parties in the future. See Part I., "Item 1A. Risk Factors — Risks Related to Intellectual Property Matters” for additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us.

License Agreement with Medtronic

In 2007, we entered into an assignment and license agreement with Medtronic ("the Assignment and License Agreement") pursuant to which Medtronic assigned certain patents and trademarks to us and granted to us a worldwide, royalty-free license to certain other patents and technical information to make, use, import and sell products, and to practice methods in the field of electrical stimulation of the upper airway for the treatment of OSA ("the Field"). We share co-exclusive rights with Medtronic under this license; however, Medtronic may not exercise

its rights unless we make an assignment for the benefit of our creditors, file or have filed against us a bankruptcy petition or go into receivership. We also granted to Medtronic certain worldwide, royalty-free, exclusive licenses to the patents Medtronic assigned to us, as well as other intellectual property (including but not limited to Technical Information (as defined in the Assignment and License Agreement)) that applies to a device and methods with certain specifications for use in the Field, to make, use, import and sell products, and to practice methods outside of the Field. The licenses granted are perpetual and irrevocable.

Manufacturing and Supply

We rely on third-party suppliers to manufacture our Inspire system and its components. Outsourcing manufacturing reduces our need for capital investment and reduces operational expense. Additionally, outsourcing provides expertise and capacity necessary to scale up or down based on demand for our Inspire system. We select our suppliers to help ensure that our Inspire system and its components are safe and effective, adhere to all applicable regulations, are of the highest quality, and meet our supply needs. We employ a rigorous supplier assessment, qualification, and selection process with the goal of selecting and retaining suppliers that meet the requirements of the FDA and the International Organization for Standardization and quality standards based on our internal policies and procedures. Our quality assurance process seeks to monitor and maintain supplier performance through qualification and periodic supplier reviews and audits.

Certain components used in our Inspire system are supplied by single-source suppliers. Our suppliers manufacture the components they produce for us and test our components and devices to our specifications. We intend to maintain sufficient levels of inventory to enable us to continue our operations while we obtain another supplier in the event that one or more of our single-source suppliers were to encounter a delay in supply or end supply.

We have experienced and continue to experience supply disruptions that began during the COVID-19 pandemic, but to date we have managed to avoid major delays in implant procedures due to those issues. During the third quarter of 2023, we began experiencing an inventory supply issue related to our polyurethane-based stimulation leads, one component of the Inspire system currently used only in the European market. We continue to expect delays to implant procedures. These delays have impacted, and are expected to continue to impact our revenue, however, to a lesser extent than in prior year periods as a result of the derogations received thus far, and we believe would be further improved if we receive certification under the EU MDR. See Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Overview” for additional information.

Government Regulation

Our products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the U.S., as well as comparable authorities in the European Economic Area ("EEA"), Japan, and in Australia (where our products are approved for sale but where we have not yet commercialized them). In the U.S., our products are subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA") as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to help ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition to U.S. regulations, we are subject to a variety of regulations in the EEA governing clinical studies and the commercial sales and distribution of our products. Whether or not we have or are required to obtain FDA clearance or approval for a product, we will be required to obtain authorization before commencing clinical studies and to obtain marketing authorization, approval or certification of our products under the comparable regulatory authorities of countries outside of the U.S. or notified bodies before we can commercialize our products in those countries. The approval/certification process varies from country to country and the time may be longer or shorter than that required for FDA clearance or approval.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the U.S. requires either FDA clearance of a 510(k) premarket notification or 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 FCA's Quality System Regulation ("QSR"), facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. 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. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is "substantially equivalent" to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or another legally marketed device that was cleared through the 510(k) process.

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 Inspire products are Class III devices which have received PMA.

PMA Pathway

In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical studies. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR.

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

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the

device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

Clinical Studies

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

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board ("IRB") for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical studies may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical study after obtaining approval for the study by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements.

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

Expedited Development and Review Programs

Following passage of the 21st Century Cures Act, the FDA implemented the Breakthrough Devices Program, which is a voluntary program offered to manufacturers of certain medical devices and device-led combination products, including ours, that may provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and health care providers with more timely access to qualifying devices by expediting their development, assessment and review,

while preserving the statutory standards for FDA marketing authorization. The program is available to medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and that the device meets one of the following criteria: (i) the device represents a breakthrough technology, (ii) no approved or cleared alternatives exist, (iii) the device offers significant advantages over existing approved or cleared alternatives, or (iv) the availability of the device is in the best interest of patients. Breakthrough Device designation provides certain benefits to device developers, including more interactive and timely communications with FDA staff, use of post-market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design, and prioritized review of premarket submissions.

Post-market Regulation

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

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced, provide adequate directions for use, and that all claims are substantiated, and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of a supplement for certain modifications to PMA 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;
- complying with the laws and regulations requiring Unique Device Identifiers (UDI) on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database (GUDID);
- 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 public health or to provide additional safety and effectiveness data for the device.

Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities, 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, our facilities, records, and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR or other

applicable regulatory requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

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

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

Foreign Regulation

In order for us to market our products in countries outside the U.S., we must obtain regulatory approvals or certifications and comply with extensive product and quality system regulations in other countries. These regulations, including the requirements for approvals, clearance or certifications and the time required for regulatory review, vary from country to country. Some countries have regulatory review processes that are substantially longer than U.S. processes. Failure to obtain regulatory approval or certification in a timely manner and meet all of the local requirements including language and specific safety standards in any foreign country in which we plan to market our products could prevent us from marketing products in such countries or subject us to sanctions and fines.

Regulation of Medical Devices in the European Union

The European Union (“EU”) has adopted specific directives and regulations regulating the design, manufacture, clinical investigation, conformity assessment, labeling and adverse event reporting for medical devices.

Until May 25, 2021, medical devices were regulated by Council Directive 93/42/EEC (the “EU Medical Devices Directive”), and Directive 90/385/EEC (“AIMDD”) which have been repealed and replaced by Regulation (EU) No 2017/745 (the “EU Medical Devices Regulation”). Our current certificates have been granted under the EU Medical Devices Directive and the AIMDD whose regime is described below. However, as of May 26, 2021, some of the EU Medical Devices Regulation requirements apply in place of the corresponding requirements of the EU Medical Devices Directive and the AIMDD with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements. Pursuing marketing of medical devices in the EU will notably require that our devices be certified under the new regime set forth in the EU Medical Devices Regulation.

Medical Devices Directive

In the EU, there is currently no premarket government review of medical devices. However, all medical devices placed on the EU market must meet the essential requirements, including the requirement that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of

patients, or the safety and health of users and others. In addition, the device must achieve the performance intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner.

Compliance with the essential requirements is a prerequisite for CE mark without which medical devices cannot be marketed or sold in the EU. To demonstrate compliance with the essential 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 non-sterile, non-measuring devices), where the manufacturer can self-assess the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), 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 essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU.

Throughout the term of the certificate of conformity, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant certificate(s).

Medical Devices Regulation

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

The EU Medical Devices Regulation became effective on May 26, 2021. In accordance with its recently extended transitional provisions, both (i) devices lawfully placed on the market pursuant to the EU Medical Devices Directive or the AIMDD prior to May 26, 2021 and (ii) legacy devices lawfully placed on the EU market after May 26, 2021 in accordance with the EU Medical Devices Regulation transitional provisions may generally continue to be made available on the market or put into service, provided that the requirements of the transitional provisions are fulfilled. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the EU Medical Devices Regulation, in particular the obligations described below.

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

All manufacturers placing medical devices 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 ("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 EEA which consists of the 27 EU member states plus Norway, Liechtenstein, and Iceland.

Brexit

Since January 1, 2021, the Medicines and Healthcare Products Regulatory Agency (“MHRA”) has become the sovereign regulatory authority responsible for Great Britain (i.e. England, Wales and Scotland) medical device market according to the requirements provided in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) that sought to give effect to EU Medical Devices Directive and AIMDD whereas Northern Ireland continues to be governed by EU rules according to the Northern Ireland Protocol. Following the end of the Brexit transitional period on January 1, 2021, new regulations require medical devices to be registered with the MHRA before being placed on the Great Britain market. Manufacturers based outside the United Kingdom ("UK") need to appoint a UK Responsible Person that has a registered place of business in the UK to register devices with the MHRA.

On June 26, 2022, the MHRA published its response to a 10-week consultation on the post-Brexit regulatory framework for medical devices and diagnostics. MHRA seeks to amend the UK Medical Devices Regulations 2002 (which are based on EU legislation, primarily the EU Medical Devices Directive and the EU In Vitro Diagnostic Medical Devices Directive 98/79/EC), in particular to create new access pathways to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform IVD regulation, and foster sustainability through the reuse and remanufacture of medical devices. Regulations implementing the new regime were originally scheduled to come into force in July 2023, but the MHRA has confirmed that the core aspects of the new regime are expected to apply by July 1, 2025. Devices bearing CE marks issued by EU notified bodies under the EU Medical Devices Regulation, the EU Medical Devices Directive or AIMDD are now subject to transitional arrangements. The MHRA has introduced legislation which provides that CE marked medical devices may be placed on the Great Britain market along following timelines:

- general medical devices compliant with the EU Medical Devices Directive or (EU) AIMDD with a valid declaration and CE marking can be placed on the Great Britain market up until the sooner of the expiration of the certificate or June 30, 2028; and

- general medical devices, including custom-made devices, compliant with the EU Medical Devices Regulation can be placed on the Great Britain market up until June 30, 2030.

Following these transitional periods, it is expected that all medical devices will require a UK Conformity Assessed ("UKCA") mark. Manufacturers may choose to use the UKCA mark on a voluntary basis prior to the mandatory deadlines. However, UKCA marking will not be recognized in the EU. The rules for placing medical devices on the market in Northern Ireland, which is part of the UK, differ from those in the rest of the UK. Compliance with this legislation is a prerequisite to be able to affix the UKCA mark to our products, without which they cannot be sold or marketed in Great Britain.

In addition, the Trade Deal between the UK and the EU generally provides for cooperation and exchange of information between the parties in the areas of product safety and compliance, including market surveillance, enforcement activities and measures, standardization-related activities, exchanges of officials, and coordinated product recalls. As such, processes for compliance and reporting should reflect requirements from regulatory authorities.

Similarly, we are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of:

- design, development, manufacturing, and testing;
- product standards;
- product safety;
- product safety reporting;
- marketing, sales, and distribution;
- packaging and storage requirements;
- labeling requirements;
- content and language of instructions for use;
- clinical studies;
- record keeping procedures;
- advertising and promotion;
- recalls and field corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- import and export restrictions;
- tariff regulations, duties, and tax requirements;
- registration for reimbursement; and
- necessity of testing performed in country by distributors for licensees.

The time required to obtain clearance or certification required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

Federal, State, and Foreign Fraud and Abuse Laws

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

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value, including stock, stock options, and the compensation derived through ownership interests.

Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct

per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply more broadly to items or services covered by any third-party payor, including commercial insurers and self-pay patients.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The federal civil False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the civil federal civil False Claims Act. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. In addition, private parties may initiate "qui tam" whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit. The government may further prosecute conduct constituting a false claim under the federal criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious or fraudulent and, unlike the federal civil False Claims Act, requires proof of intent to submit a false claim.

The Civil Monetary Penalty Law imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") also created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. For example, the advertising and promotion of medical devices is subject to some general principles set forth in EU legislation. According to the EU Medical Devices Regulation, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example, requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at a national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals. These laws, which vary between jurisdictions (thus making compliance more complex), may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Many EU member states have adopted

specific anti-gift statutes that further limit commercial practices for our products, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national “Sunshine Acts” which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs. Also, many U.S. states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs.

Additionally, there has been a recent trend of increased foreign, federal, and state regulation of payments and transfers of value provided to healthcare professionals or entities. In the U.S., the federal Physician Payments Sunshine Act imposes annual reporting requirements on certain drug, biologics, medical supplies and device manufacturers for which payment is available under Medicare, Medicaid or CHIP for payments and other transfers of value provided by them, directly or indirectly, to physicians, as defined by statute, certain other non-physician practitioners such as physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Manufacturers must submit reports by the 90th day of each calendar year. Many EU member states have adopted national “Sunshine Acts” which impose similar reporting and transparency requirements (often on an annual basis) on certain drug, biologics and medical device manufacturers. Certain foreign countries and U.S. states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation, and other remuneration to healthcare professionals and entities.

Violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to device manufacturers may result in significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if the entity becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of operations.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations, and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. For example, the General Data Protection Regulation (the "GDPR"), imposes strict requirements for processing the personal data of individuals within the European Economic Area, or the EEA. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Healthcare Reform

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

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

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect into 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the Medicare Access and CHIP Reauthorization Act of 2015 enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

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

Anti-Bribery and Corruption Laws

Our U.S. operations are subject to the FCPA. We are required to comply with the FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials for the purpose of obtaining or retaining business or other benefits. In addition, the FCPA imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made. We also are subject to similar anticorruption legislation implemented in Europe through EU member state laws and under the Organization for Economic Co-operation and Development's Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

Segment Information

We globally manage our business within one reportable segment. Segment information is consistent with how management reviews our business, makes investing and resource allocation decisions, and assesses our operating performance.

Seasonality

Historically, we have experienced seasonality in our first and fourth fiscal quarters, and we expect this trend to continue. In the U.S., we have experienced, and may in the future experience, higher sales in the fourth quarter as a result of patients having paid their annual insurance deductibles in full, thereby reducing their out-of-pocket costs. Conversely, in the first quarter, many U.S. patients' insurance deductibles reset, requiring more out-of-pocket costs, which negatively impacts our sales during this period.

Human Capital

We pride ourselves on our innovative and collaborative work environment, which we believe has driven our success and which we seek to uphold by fostering an inclusive workforce, generous compensation and benefits, open communication, a focus on employee health, wellbeing and engagement, and robust training and development programs.

Employees

As of December 31, 2023, we had 1,011 employees, of which 960 are in the U.S., 45 are in Europe and six are in Japan. We increased the number of employees by 34% during 2023 to support the rapid growth of our business.

None of our employees are currently subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Code of Business Conduct and Ethics

Inspire is committed to conducting business in accordance with the highest ethical standards and applicable laws. We maintain, and all of our employees are expected to adhere to our Code of Business Conduct and Ethics (the "Code of Conduct"), which serves as the foundation of our company's culture. All employees must certify they understand and comply with the expectations contained in the Code of Conduct. We also maintain an anonymous hotline for employees to report concerns regarding violations of the Code of Conduct. In addition, our employees complete training and education at least annually on a range of important topics related to our Code of Conduct.

Compensation and Benefits

Our human capital strategies, initiatives, and outcomes are reviewed on a regular basis with our Board's Organization and Compensation Committee to provide alignment with the company's overall business strategies. The Committee has engaged an independent consulting firm to assess the market competitiveness of our compensation programs and offerings. We believe strongly in providing employees with the opportunity to participate as owners of the company. All of our full-time employees are eligible to receive annual grants of stock awards, which may include stock options, restricted stock units, or performance stock units, and can elect to participate in our employee stock purchase program. Additionally, beginning in 2022, we incorporated a 401(k)-employer match for all U.S.-based employees.

Talent Management

With our aggressive growth objectives, it is imperative that we continue to hire exceptional talent and invest in the growth and development of our existing employees. Inspire's growth has required several strategies to attract talent and meet our headcount plans. We have a strong internal referral network in which between 50-60% of all hires have been from internal referrals. This is supplemented with search partners, who meet with our talent acquisition team on a quarterly basis to review and provide the most up-to-date public information to ensure potential candidates fully understand the potential Inspire can offer.

We seek to foster a culture where learning is continuous. We believe in our people and their ability to accept new responsibilities and challenges, and to grow with us to contribute to our success. Growth is fostered through professional development and learning programs, as well as practical experience leading projects or teams. Over 50% of our leadership promotions have been from within. To support newly promoted leaders, we have a leadership program entitled, "Boss to Coach," which is specially designed to help them succeed in their expanded roles. Additionally, we provide leadership coaching opportunities through external partners. On an annual basis, our leadership team participates in a talent review and succession planning exercise to identify organizational needs, development opportunities, and potential future leaders. This enables us to identify the resources and skill sets needed to meet our growth objectives.

To encourage further professional development of our employees, in 2022 we introduced a tuition reimbursement program for those pursuing an advanced degree.

Diversity, Equity, and Inclusion

We strive to create a culture in which all employees feel heard, respected, and valued. All new employees participate in training focused on appropriate, respectful, and inclusive workplace behavior. In 2020, we created an engaging training initiative for all employees which encourages awareness of unconscious bias and microaggressions. The goals of these programs are to encourage broad and diverse viewpoints to achieve the best outcomes for our patients, customers, and employees, and to build awareness of how our own behaviors impact our colleagues. Since then, we have developed our programs to provide engaging, virtual harassment and bias re-training to all global employees.

In addition to new employee training focused on creating a harassment-free work environment, leaders are provided information and tools annually to allow them, with the assistance of our Human Resources team, to investigate and address issues. The program, entitled “Humanity is our Superpower,” continued to expand in 2023. Following the program, leaders meet as a team and review ideas for creating an environment where inclusion prospers.

During talent acquisition, our recruiting team reinforces with hiring managers the importance of seeking and engaging with candidates from all backgrounds. We actively seek diverse candidates to participate in our Internship Program and routinely host recruiting events at college campus career fairs.

As of December 31, 2023, 48% of our workforce identified as female, and 15% identified as a member of minority racial group.

Charitable Giving

As a medical technology company, we are committed to enhancing the lives of patients through innovation. In 2023, we launched InspireGives, Inspire’s community outreach program aimed at serving the communities in which we live and operate through financial donations and volunteerism. Our contributions seeks to provide crucial assistance to charitable organizations striving to treat critical illnesses, combat poverty and homelessness, ease hardship for people affected by disasters, eliminate barriers to equal opportunity, and support underserved communities to address inequities in health outcomes.

Our employees are passionate about improving the lives of others so we provide channels for our team members to identify opportunities to engage with new charitable organizations and events in our communities. In 2023, we contributed nearly $85,000 to 15 local and national charitable organizations including healthcare charities and charitable organizations addressing other related causes.

Environmental, Social, and Governance

As our business continues to grow and develop, we recognize the importance of making responsible business decisions for the benefit of our stakeholders, including our stockholders, customers, employees, partners, the communities in which we work and live, as well as the planet. To that end, we have implemented a corporate Environmental, Social and Governance ("ESG") program and set short, intermediate and long-term ESG objectives. We published our second ESG Report in December 2023, which is available on our website, and expect to continue reporting on our progress to our various stakeholders annually.

Available Information

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements, amendments to such documents and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at *http://www.sec.gov*. We also make these filings available, free of charge, under the Investor Relations section of our website at *www.inspiresleep.com* as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. Our Corporate Governance Guidelines, Code of Business Conduct and Ethics, ESG Report, and the charters for the committees of our Board of Directors are also available free of charge at *https://investors.inspiresleep.com.* Information on our

website, including our Corporate Governance Guidelines, Code of Business Conduct and Ethics, ESG Report, and committee charters, is not part of this or any other report we file with, or furnish to, the SEC.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. These risks include, but are not limited to, those described below, each of which may be relevant to an investment decision. You should carefully consider the risks described below, together with the other information included or incorporated by reference in this Annual Report on Form 10-K. The realization of any of the following risks could have a significant adverse effect on our reputation, business, financial condition, results of operations, growth, and our ability to accomplish our strategic objectives. In that event, the trading price of our common stock could decline. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our reputation, business, financial conditions, results of operations, growth, and our ability to accomplish our strategic objectives.

Risks Related to Our Business

We have incurred significant operating losses since inception, we may incur operating losses in the future and we may not be able to achieve or sustain profitability.

We have incurred net losses since our inception in 2007. For the years ended December 31, 2023, 2022, and 2021, we had net losses of $21.2 million, $44.9 million, and $42.0 million, respectively. As of December 31, 2023, we had an accumulated deficit of $345.4 million. To date, we have financed our operations primarily through sales of our Inspire system, private placements of our convertible preferred securities, amounts borrowed under our credit facility, the initial public offering of our common stock that closed in May 2018 ("IPO"), and the three follow-on offerings of our common stock that closed in December 2018, April 2020, and August 2022. We have devoted significant resources to research and development activities related to our Inspire system, including clinical and regulatory initiatives to obtain marketing approval, and sales and marketing activities.

Since 2011, our revenue has been derived, and we expect it to continue to be derived, primarily from sales of our Inspire system. Because of its recent commercial introduction, in particular in Hong Kong, our Inspire system has limited product and brand recognition, particularly in new markets. In addition, demand for our Inspire system may decline or may not increase as quickly as we expect. Our ability to generate revenue from sales of our Inspire system, or from any products we may develop in the future, may not be sufficient to enable us to transition to profitability and generate positive cash flows.

We expect that our operating expenses will continue to increase as we continue to build our commercial infrastructure, invest in research and development, and develop, enhance, and commercialize new products. As a result, we may continue to incur operating losses for the foreseeable future and may never achieve profitability. Furthermore, even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition, results of operations, and cause the market price of our common stock to decline. In addition, failure of our Inspire system to significantly penetrate existing or new markets would negatively affect our business, financial condition, and results of operations.

Our revenue is primarily generated from sales of our Inspire system and we are, therefore, highly dependent on it for our success.

We began selling our Inspire system in 2011 in certain European countries, in 2014 in the U.S., and in 2021 in certain Asia Pacific regions. Sales of our Inspire system accounted for primarily all of our revenue for the years ended December 31, 2023, 2022, and 2021. We expect that sales of our Inspire system will continue to account for the substantial majority of our revenue going forward. Our ability to execute our growth strategy and become profitable will therefore depend upon the adoption by patients, physicians, and sleep centers, among others, of

our Inspire therapy to treat moderate to severe OSA in patients who are unable to use or get consistent benefit from CPAP.

We cannot ensure that our Inspire therapy will achieve or maintain broad market acceptance among physicians and patients. Any failure of the Inspire system to satisfy physician or patient demand or to achieve meaningful market acceptance will harm our business and future prospects.

If patients or physicians are not willing to change current practices to adopt our Inspire therapy to treat moderate to severe OSA, our Inspire therapy may fail to gain increased market acceptance, and our business will be adversely affected.

Our primary strategy to grow our revenue is to drive an increase in the adoption of our Inspire therapy to treat patients with moderate to severe OSA who are unable to use or get consistent benefit from CPAP. While the number of physicians prescribing our Inspire therapy has increased, there is a significant group of physicians who have not yet adopted our Inspire therapy, and additional physicians may choose not to adopt our Inspire therapy for a number of reasons, including, for example:

- lack of availability of adequate third-party payor coverage or reimbursement;
- lack of experience with our products and with upper airway neurostimulation as a treatment alternative;
- our inability to convince key opinion leaders to provide recommendations regarding our Inspire therapy, or to convince physicians, patients, and healthcare payors that our Inspire therapy is an attractive alternative to other treatment options;
- perceived inadequacy of evidence supporting clinical benefits or cost-effectiveness of our Inspire therapy over existing alternatives;
- challenges in obtaining prior authorization;
- a perception among some physicians of patients' inability to tolerate the surgical procedure required to implant our Inspire system;
- liability risks generally associated with the use of new products and procedures; and
- the training required to use new products.

Physicians and other medical professionals commonly screen and treat patients with moderate to severe OSA and are likely to prescribe more conventional second-line treatment methods for patients who are unable to use or obtain consistent benefit from CPAP. We believe that educating physicians in appropriate disciplines and other medical professionals about the clinical merits and patient benefits of our Inspire therapy as a treatment for moderate to severe OSA is a key element of increasing the adoption of our Inspire therapy. If additional physicians or other medical professionals do not adopt, or existing physician customers cease prescribing our Inspire therapy for any reason, including those listed above, our ability to execute our growth strategy will be impaired, and our business may be adversely affected.

In addition, patients may not be able to adopt or may choose not to adopt our Inspire therapy if, among other potential reasons, their airway anatomy would not allow for effective treatment with Inspire therapy, they are reluctant to receive an implantable device as opposed to an alternative, non-implantable treatment, they are worried about potential adverse effects of our Inspire system, such as infection, discomfort from the stimulation or tongue soreness or weakness, or they are unable to obtain adequate third-party coverage or reimbursement.

If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our Inspire system, or any future products we may seek to commercialize, our commercial success may be severely hindered.

We currently derive all of our revenue from sales of our Inspire system and expect this to continue for the foreseeable future. The primary customers for our products are hospitals and ASCs. Our customers typically bill various third-party payors to cover all or a portion of the costs and fees associated with the procedures in which our products are used and bill patients for any deductibles or co-payments. Because there is often no separate reimbursement for supplies used in surgical procedures, the additional cost associated with the use of our products can affect the profit margin of the hospital or surgery center where the procedure is performed. Some of our target customers may be unwilling to adopt our products in light of the additional associated cost. Further, any decline in the amount payors are willing to reimburse our 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 price 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.

Several 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 covered, they are reimbursed primarily on a per-patient prior authorization basis for patients covered by commercial insurers, under Local Coverage Determinations for patients covered by Medicare, and under U.S. government contract for patients who are treated by the Veterans Health Administration. Customers who perform the procedure may be subject to reimbursement claim denials upon submission of the claim. Customers 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. Our customers typically must directly bill patients enrolled with these third-party payors for the costs and fees associated with the procedures in which our products are used.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, no uniform policy of coverage and reimbursement for procedures using our products exists among third-party payors. Therefore, coverage and reimbursement for procedures using our products can differ significantly from payor to payor. 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. If we are not successful in reversing existing non-coverage policies, or if third-party payors that currently cover or reimburse our products and related procedures reverse or limit their coverage in the future, or if other third-party payors issue similar policies, this could have a material adverse effect on our business.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the U.S. and in international markets. In Europe, reimbursement is entirely regulated at the member state level, varies significantly between member states, and member states are facing increased pressure to limit public healthcare spending. Third-party coverage and reimbursement for procedures using our products or any of our products in development for which we may receive regulatory approval or certification may not be available or adequate in either the U.S. or international markets, which could have an adverse effect on our business, financial condition and results of operations, and impair our ability to grow our business.

We currently compete and will in the future continue to compete against other companies, some of which have longer operating histories, more established products or greater resources than we do, which may prevent us from achieving increased market penetration and improved operating results.

The medical technology industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. Our competitors have historically dedicated and will continue to dedicate significant resources to promoting their products or developing new products or methods to treat moderate to severe OSA. We consider our primary competition to be other neurostimulation technologies designed to treat OSA. Though we are currently the only such technology approved for commercialization in the

U.S. by the FDA, we currently compete outside the U.S. with LivaNova, which produces an open-loop neurostimulation device and is currently conducting clinical trials of its device in the U.S. We also compete outside the U.S. with Nyxoah, which markets a bilateral hypoglossal nerve stimulation device in certain countries outside the U.S., and is conducting its first pivotal trial as it seeks FDA approval in the U.S. We believe other emerging businesses are in the early stages of developing neurostimulation devices designed to treat OSA. In addition, we also compete, both within and outside of the U.S., with invasive surgical treatment options such as UPPP and MMA and, to a lesser extent, oral appliances, which are primarily used in the treatment of mild to moderate OSA.

In addition, our Inspire therapy is approved for use as a second-line therapy in the treatment of moderate to severe OSA in patients who cannot use or obtain consistent benefit from CPAP. If one or more CPAP device manufacturers successfully develop a CPAP device that is more effective, better tolerated or otherwise results in better compliance by patients, or if improvements in other first or second-line therapies make them more effective, cost effective, easier to use or otherwise more attractive than our Inspire therapy, sales of our Inspire system could be significantly and adversely affected, which could have a material adverse effect on our business and financial condition and results of operations. In addition, if other companies are successful in developing neurostimulation devices that are approved for a broader range of indications than our Inspire system, we will be at a further competitive disadvantage, which could also affect our business, financial condition and results of operations.

During 2023, glucagon-like peptide 1 ("GLP-1s"), a class of drug indicated for diabetes and obesity, continued to gain popularity as a weight-loss drug. Use of GLP-1s, or similar treatments, for these clinical indications may directly or indirectly treat OSA. Additionally, GLP-1s are currently being clinically evaluated as a potential treatment for OSA. Although we believe that there could be a benefit to our business as a result of GLP-1s, there can be no assurance of such benefit. If GLP-1s are successful in treating OSA in an indication for which Inspire therapy is approved, demand for our Inspire system could be reduced.

Many of the companies against which we compete may have competitive advantages with respect to primary competitive factors in the OSA treatment market, including, for example:

- greater company, product, and brand recognition;
- superior product safety, reliability, and durability;
- better quality and larger volume of clinical data;
- more effective marketing to and education of patients, physicians, and sleep centers;
- greater product ease of use and patient comfort;
- more sales force experience and greater market access;
- better product support and service;
- more advanced technological innovation, product enhancements, and speed of innovation;
- more effective pricing and revenue strategies;
- lower procedure costs to patients;
- more effective reimbursement teams and strategies;
- dedicated practice development; and
- more effective clinical training teams.

Most of the other OSA treatments against which we compete have a greater penetration into the OSA treatment market. Oral appliances and other surgical treatments are better known to ENT physicians, sleep centers, and the other physicians on whom we rely for referrals.

We also compete with other medical technology companies to recruit and retain qualified sales, training, and other personnel, including members of our in-house prior authorization team.

In addition, though there are currently no pharmacologic therapies approved to treat OSA, we may in the future face competition from pharmaceutical companies that develop such therapies. We also expect to experience increased competition in the future as other companies develop and commercialize competing neurostimulation devices. Any of these companies may also have the competitive advantages described above.

We are involved, and may become involved in the future, in disputes and other legal or regulatory proceedings that, if adversely decided or settled, could materially and adversely affect our business, financial condition, and results of operations.

We are, and may in the future become, party to litigation, regulatory proceedings or other disputes. In general, claims made by or against us in disputes and other legal or regulatory proceedings can be expensive and time-consuming to bring or defend against, requiring us to expend significant resources and divert the efforts and attention of our management and other personnel from our business operations. These potential claims may include but are not limited to personal injury and class action lawsuits, intellectual property claims and regulatory investigations relating to the advertising and promotional claims about our products and services and employee claims against us based on, among other things, discrimination, harassment or wrongful termination. Any one of these claims, even those without merit, may divert our financial and management resources that would otherwise be used to benefit the future performance of our operations. Any adverse determination against us in these proceedings, or even the allegations contained in the claims, regardless of whether they are ultimately found to be without merit, may also result in settlements, injunctions or damages that could have a material adverse effect on our business, financial condition and results of operations.

Additionally, securities class action litigations are often brought against companies following periods of volatility in the overall market and in the market price of a company's securities. On December 22, 2023, we and certain of our executive officers were named in a putative class action lawsuit. The complaint was filed on behalf of a potential group of similarly situated investors who purchased our common stock between May 3, 2023 and November 7, 2023. The complaint alleges that we and/or our executive officers made false and/or misleading statements regarding the effectiveness of our Acceleration Program, a program designed to facilitate customers' receiving prior authorizations from doctors with the goal of increasing demand for our Inspire therapy. This lawsuit and any future lawsuits to which we may become a party are subject to inherent uncertainties and could result in very substantial costs, divert our management's attention and resources and materially harm our business, operating results and financial condition.

Our business, financial condition, results of operations and growth have been and could in the future be significantly harmed by the effects of public health crises, such as pandemics.

The occurrence or reoccurrence of regional epidemics, a global pandemic or other public health crises, such as COVID-19, may adversely affect our operations, financial condition, and results of operations. The extent to which such health crises impact our business going forward will depend on factors such as the duration and scope; governmental, business, and individuals' actions in response to such public health crises; and the impact on economic activity, including the possibility of recession or financial market instability. The disruption to global financial markets or a recession or market correction resulting from a public health crisis could materially affect our business. The occurrence of any such events may lead to reduced disposable income and access to health insurance which could adversely affect the number of Inspire systems sold.

Our long-term growth depends on our ability to enhance our Inspire system, expand our indications, and develop and commercialize additional products.

It is important to our business that we continue to enhance our Inspire system and develop and introduce new products. Developing products is expensive and time-consuming and could divert management's attention away from our core business. The success of any new product offering or product enhancements to our Inspire system will depend on several factors, including our ability to:

- properly identify and anticipate physician and patient needs;
- develop and introduce new products and 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 preclinical studies and clinical studies;
- obtain the necessary regulatory clearances, approvals or certifications for expanded indications, new products or product modifications;
- be fully FDA-compliant with marketing of new devices or modified products and be fully compliant with foreign requirements to market our new devices or modified products;
- provide adequate training to potential users of our products;
- receive adequate coverage and reimbursement for procedures performed with our products; and
- develop an effective and dedicated sales and marketing team.

If we are not successful in expanding our indications and developing and commercializing new products and product enhancements, our ability to increase our revenue may be impaired, which could have a material adverse effect on our business, financial condition, and results of operations.

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

Our quarterly and annual results of operations have in the past and may in the future vary significantly and future period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Such factors may include, for example, seasonal variations in our sales or required postponements of elective surgical procedures effected during a health crisis, as was the case with COVID-19. We generally experience and may in the future experience higher sales in the U.S. during the fourth quarter as a result of patients having paid their annual insurance deductibles in full, thereby reducing their out-of-pocket costs. Alternatively, in the first quarter, many U.S. patients' insurance deductibles reset, requiring more out-of-pocket costs, which negatively impacts our sales during this period.

Other factors that may cause fluctuations in our quarterly and annual results include, but are not limited to:

- changes in coverage policies by third-party payors that affect the reimbursement of procedures using our products;
- challenges experienced by patients in obtaining positive coverage and reimbursement decisions from payers, including necessary prior authorization approvals in advance of treatment;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;

- unanticipated pricing pressure;
- the hiring, retention, and continued productivity of our sales representatives;
- our ability to expand the geographic reach of our sales and marketing efforts;
- our ability to obtain regulatory clearance, approval, or certification for any products in development or for our current products for additional indications or in additional countries outside the U.S.;
- results of clinical research and studies on our existing products and products in development;
- delays in receipt of anticipated purchase orders; and
- positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry.

Because our quarterly and annual results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing. These fluctuations may also increase the likelihood that we will not meet our forecasted performance, which could negatively affect the market price for our common stock.

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

To ensure adequate inventory supply, we must forecast inventory needs and place orders with our suppliers based on our estimates of future demand for our Inspire system. Our ability to accurately forecast demand for our Inspire system 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 customer demand for our Inspire system or for products of our competitors, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters, and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand 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 customer demand for our Inspire system, our third-party contract manufacturers may not be able to deliver products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers or our third-party manufacturers may not be able to allocate sufficient capacity in order to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for our Inspire system and our results of operations.

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions. As a result, we are subject to the risk that a portion of our inventory will become obsolete or expire, which could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

We have experienced and continue to experience supply disruptions which began during the COVID-19 pandemic and have continued as a result of not having received certification of silicone-based leads under the EU Medical Devices Regulation (See Part I., "Item 1A. Risk Factors — We may not receive the necessary approvals or certifications for our future products or expanded indications, and failure to timely obtain necessary approvals or certifications for our future products or expanded indications would adversely affect our ability to grow our business."). Our efforts to maintain higher levels of inventory to protect ourselves from supply interruptions may not be successful in avoiding significant supply and inventory issues or delay in implant procedures. As a result, we are subject to the risk of inventory obsolescence and expiration, which could lead to inventory impairment charges. For example, during the three months ended September 30, 2022, we recorded a charge of $2.8 million for obsolete inventory and component parts related to product introductions which were completed in October 2022, including the new silicone leads and the Bluetooth®-enabled patient remote.

We rely on a limited number of third-party suppliers and contract manufacturers for the manufacture and assembly of our products, and a loss or degradation in performance of these suppliers and contract manufacturers could have a material adverse effect on our business, financial condition, and results of operations.

We rely on third-party suppliers and contract manufacturers for the raw materials and components used in our Inspire system and to manufacture and assemble our products. The suppliers that provide certain materials and components are sole suppliers. These sole suppliers, and any of our other suppliers or our third-party contract manufacturers, may be unwilling or unable to supply the necessary materials and components or manufacture and assemble our products reliably and at the levels we anticipate or that are required by the market. Our ability to supply our products commercially and to develop any future products depends, in part, on our ability to obtain these materials, components, and products in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. While our suppliers and contract manufacturers 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 their products or prevent delays in the delivery of their products, which could be adversely affected due to, for example, natural and man-made disasters, public health emergencies such as COVID-19, product quality issues, other catastrophic events, the macroeconomic environment including supply chain constraints, higher inflation and interest rates, the nature of our agreements with our contract manufacturers, our relative importance to such manufacturers as a customer or a contract manufacturer's decision to discontinue or reduce the level of business they conduct with us. If we are required to change contract manufacturers due to any change in or termination of our relationships with these third parties, or if our manufacturers are unable to obtain the materials they need to produce our products at consistent prices or at all, we may lose sales, experience manufacturing or other delays, incur increased costs or otherwise experience impairment to our customer relationships. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all.

Establishing additional or replacement suppliers for any of these materials, components or services, if required, could be time-consuming and expensive, may result in interruptions in our operations and product delivery, may affect the performance specifications of our Inspire system or could require that we modify its design. Even if we are able to find replacement suppliers or third-party contract manufacturers, we will be required to verify that the new supplier or third-party manufacturer maintains facilities, procedures, and operations that comply with our quality expectations and applicable regulatory requirements. Furthermore, our contract manufacturers could require us to move to another one of their production facilities or use alternative materials or components. Any of these events could require that we obtain a new regulatory authority approval or notified body certification before we implement the change, which could result in further delay and which may not be obtained at all. While we seek to maintain sufficient levels of inventory as discussed above, those inventories may not fully protect us from supply interruptions.

If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our Inspire system, the supply of our products to customers, and the development of any future products will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition, and results of operations.

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

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our Inspire system to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as delivery delays or loss, damage or destruction of any systems, such occurrences may damage our reputation and lead to decreased demand for our Inspire system and increased cost and expense to our business. Similarly, strikes, severe weather, natural disasters, public health crises or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our Inspire system on a timely basis.

Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell our products at prices necessary to support our current business strategies.

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

If we are unable to expand, manage and maintain our direct sales and marketing organization we may not be able to generate revenue growth.

We currently sell our Inspire system through a direct sales force that targets ENT physicians and sleep centers in the U.S., Europe, and Japan, and also utilize various direct-to-consumer marketing initiatives, including paid online search, radio, television, social media, and online videos. In certain Asia Pacific markets, we sell our products through distributors. As of December 31, 2023, our direct sales and marketing organization, including reimbursement personnel, consisted of 728 employees, having increased from 129 employees as of December 31, 2018. Our operating results are directly dependent upon the efforts of these employees. If our direct sales force fails to adequately promote, market and sell our Inspire system, our revenue may be adversely affected.

In order to generate future revenue growth, we plan to continue to expand the size and geographic scope of our direct sales organization. This growth may require us to split or adjust existing sales territories, which may adversely affect our ability to retain customers in those territories. Additionally, our future success will depend largely on our ability to continue to hire, train, retain, and motivate skilled sales and reimbursement personnel with significant industry experience and technical knowledge of implantable devices and related products. Because the competition for their services is high, we cannot ensure that we will be able to hire and retain additional personnel on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales and reimbursement personnel would prevent us from expanding our business and generating revenue. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our Inspire system, which could have an adverse effect on our business, financial condition, and results of operations.

To successfully market and sell our Inspire system in markets outside of the U.S., we must address many international business risks.

Sales in markets outside of the U.S. accounted for approximately 3.0%, 3.2%, and 5.3% of our revenue for the years ended December 31, 2023, 2022, and 2021, respectively. Our strategy is to increase our international presence in Europe, including Germany and the Netherlands, as well as other international markets, such as Japan, Singapore, and Hong Kong. This strategy is subject to a number of risks, including:

- difficulties in staffing and managing our international operations;
- increased competition as a result of more products and procedures receiving regulatory approval or otherwise free to market in international markets;
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable;
- reduced or varied protection for intellectual property rights in some countries;
- trade export restrictions, trade regulations, and foreign tax laws;

- fluctuations in currency exchange rates;
- foreign certification and regulatory clearance or approval requirements;
- difficulties in developing effective marketing campaigns in unfamiliar foreign countries;
- customs clearance and shipping delays;
- political, social, and economic instability abroad, terrorist attacks, and security concerns in general;
- preference for locally produced products;
- potentially adverse tax consequences, including the complexities of foreign value-added tax systems, tax inefficiencies related to our corporate structure, and restrictions on the repatriation of earnings;
- the burdens of complying with a wide variety of foreign laws and different legal standards; and
- increased financial accounting and reporting burdens and complexities.

If one or more of these risks are realized, our business, financial condition, and results of operations could be adversely affected.

We primarily rely on our own direct sales force for our Inspire system, which may result in higher fixed costs than our competitors and may slow our ability to reduce costs in the face of a sudden decline in demand for our products.

We primarily rely on our own direct sales force, which as of December 31, 2023, covered 287 territories in the U.S. and 19 outside of the U.S., to market and sell our Inspire system. Some of our competitors rely predominantly on independent sales agents and third-party distributors. A direct sales force has in the past and may in the future subject us to higher fixed costs than those of companies that market competing products through independent third parties, due to the costs that we bear associated with employee benefits, training, and managing sales personnel. As a result, we could be at a competitive disadvantage. Additionally, these fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our Inspire system, which could have a material adverse effect on our business, financial condition, and results of operations.

We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. This risk exists even if a device is cleared, approved, or certified for commercial sale by the FDA or foreign regulatory authorities or notified bodies and manufactured in facilities regulated by the FDA or an applicable foreign regulatory authority. Our Inspire system is designed to affect, and any future products will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our Inspire system could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if our Inspire system causes, or is alleged to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Product liability claims may be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with our Inspire system, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- costs of litigation;
- distraction of management's attention from our primary business;

- the inability to commercialize our Inspire system or new products;
- decreased demand for our Inspire system;
- damage to our business reputation;
- product recalls or withdrawals from the market;
- withdrawal of clinical study participants;
- substantial monetary awards to patients or other claimants; or
- loss of sales.

We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have a material adverse effect on our business, financial condition and results of operations.

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

If the quality of our Inspire system does not meet the expectations of physicians or patients, then our brand and reputation or our business could be adversely affected.

In the course of conducting our business, we must adequately address quality issues that may arise with our Inspire system, including defects in third-party components included in our Inspire system. There can be no assurance that we will be able to eliminate or mitigate occurrences of quality issues and associated liabilities. In addition, even in the absence of quality issues, we may be subject to claims and liability if the performance of our Inspire system does not live up to the expectations of physicians or patients as a result of the patient's use of the product. For example, battery life will vary based on usage and therapy settings. Based on STAR trial therapy settings at the 12-month endpoint, the battery in our current generation neurostimulator is generally expected to last for approximately 11 years, but it may not last that long if a patient's use of the device or chosen level of stimulation is greater than expected. The minimum estimated longevity based on STAR trial results is seven years. If the quality of our Inspire system does not meet the expectations of physicians or patients, then our brand and reputation with those physicians or patients, or our business, financial condition and results of operations, could be adversely affected.

If we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or to successfully integrate them in a cost-effective and non-disruptive manner.

Our success depends, in part, on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures and advances in technologies. Accordingly, we may in the future pursue the acquisition of, or joint ventures relating to, complementary businesses, products or technologies instead of developing them ourselves. We do not know if we will be able to successfully complete any future acquisitions or joint ventures, or whether we will be able to successfully integrate any acquired business, product or technology or retain any key employees related thereto. Integrating any business, product or technology we acquire could be expensive and time-consuming, disrupt our ongoing business and distract our management. If

we are unable to integrate any acquired businesses, products or technologies effectively, our business will be adversely affected. In addition, any amortization or charges resulting from the costs of acquisitions could increase our expenses.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Factors such as geopolitical events (including the ongoing wars in Ukraine and Israel), inflationary pressures, impacts from COVID-19, and U.S. election cycles have caused extreme volatility and disruptions in the capital and credit markets. These global economic conditions could result in a variety of risks to our business, including weakened demand for our Inspire system, and adversely impact our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy has strained in the past and may in the future strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely affect our business.

Failure of a key information technology system, process or site, cyberattacks, or other deficiencies in our cybersecurity could have an adverse effect on our business and operations.

We rely extensively on information technology systems to conduct our business and collect, store and transmit confidential information, including personal information of customers and our employees and contractors. These systems affect, among other things, ordering and managing materials from suppliers, shipping products to customers, processing transactions, summarizing and reporting results of operations, complying with regulatory, legal or tax requirements, data security and other processes necessary to manage our business. Our information technology systems and those of our third-party service providers, vendors, strategic partners and other contractors or consultants are vulnerable to damage or interruption from computer viruses and malware (e.g. ransomware), natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, malicious code, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization.

There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our information technology systems and information. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased and evolved. We and our third-party service providers and partners may also face increased cybersecurity risks due to our reliance on internet technology and employees who work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. Our third-party service providers and partners are also subject to these heightened risks. 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 on a timely basis, we may experience interruptions in our operations, which could have an adverse effect on our business and financial condition.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur, it could lead to unauthorized access, disclosure and use of confidential information,

including personal information from our ADHERE patient registry or other patient information we create, receive, maintain or transmit, including with respect to our Inspire Cloud, SleepSync™ platform, or the Inspire Sleep app, which may be governed by HIPAA and other laws. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of personal information, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws. Any such access, disclosure, or other loss of information could result in regulatory action or investigation, legal claims or proceedings, liability under laws that protect the privacy of personal information, and damage to our reputation.

In addition, we accept payments for our sales through credit and debit card transactions, which are handled through a third-party payment processor. As a result, we are subject to a number of risks related to credit and debit card payments. As a result of these transactions, we pay interchange and other fees, which may increase over time and could require us to either increase the prices we charge for our Inspire system or experience an increase in our costs and expenses. In addition, as part of the payment processing process, we transmit our customers' credit and debit card information to our third-party payment processor. We may in the future become subject to lawsuits or other proceedings for purportedly fraudulent transactions arising out of the actual or alleged theft of our customers' credit or debit card information if the security of our third-party credit card payment processor is breached. We and our third-party credit card payment processor are also subject to payment card association operating rules, certification requirements and rules governing electronic funds transfers, which could change or be reinterpreted to make it difficult or impossible for us to comply. If we or our third-party credit card payment processor fail to comply with these rules or requirements, we may be subject to fines and higher transaction fees and lose our ability to accept credit and debit card payments from our customers, and there may be an adverse effect on our business.

Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

If our facilities are damaged or become inoperable, we may be unable to continue to research, develop, and supply our Inspire system and, as a result, there could be an adverse effect on our business until we are able to secure a new facility and rebuild our inventory.

We do not have redundant facilities. We perform substantially all of our research and development and back-office activity at two locations in Golden Valley, Minnesota. The majority of our finished goods inventory is maintained at a third-party location in Tennessee. Our facility, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. These facilities may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, tornadoes, flooding, fires and other events, including climate change-related severe weather or disasters, power outages, and public health crises, which may render it difficult or impossible for us to perform our research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it may take to rebuild our inventory of finished product, may result in the loss of customers or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

We rely on third-party distributors to effectively distribute our products in certain markets.

We depend or expect to depend in the future on qualified distributors for the marketing and selling of our products in certain markets. Currently, the markets in which we market and sell our products through distributors include Singapore and Hong Kong. If our distributors fail to effectively market and sell our Inspire system in full compliance with applicable laws, our operating results and business may suffer. Recruiting and retaining qualified third-party distributors and training them in our technology and product offering requires significant time and resources. To develop and expand our distribution, we may be required to scale and improve our processes and procedures that support our distributors. Further, if our relationship with a distributor in a given market terminates, we may be unable to replace that distributor without disruption to our business, or we may decide to transition to a direct sales force in that market. If we fail to develop or maintain positive relationships with our distributors, including in new markets, fail to manage, train or incentivize these distributors effectively, or fail to provide distributors with competitive products on attractive terms, or if these distributors are not successful in their sales

efforts, or if we are unable to successfully transition to a direct sales force in markets previously served by distributors, we may not achieve expected revenues or may have a reduction in revenue and our operating results, reputation and business would be harmed.

We are subject to anti-bribery, anti-corruption, and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could adversely affect our business, results of operations and financial condition.

As we grow our international presence and global operations, we will have increasing obligations to comply with trade and economic sanctions and other restrictions imposed by the U.S., the EU, and other governments and organizations. During the year ended December 31, 2023, approximately 3.0% of our total sales were made in EU member states and certain Asia Pacific regions. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the U.S. Foreign Corrupt Practices Act ("FCPA") and other federal statutes and regulations, including those established by the Office of Foreign Assets Control ("OFAC"). In addition, the U.K. Bribery Act of 2010 (the "Bribery Act") prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that “fails to prevent bribery” by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented “adequate procedures” to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations.

We have implemented policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti-corruption, anti-money-laundering and anti-terrorism laws and regulations. We cannot ensure, however, that our policies and procedures are or will be sufficient or that directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we ensure that our business partners have not engaged and will not engage in 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. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti-corruption, anti-money laundering and anti-terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations.

We bear the risk of warranty claims on our Inspire system.

We bear the risk of warranty claims on our Inspire system. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or that any recovery from such vendor or supplier would be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us.

We may need substantial additional funding beyond our existing cash resources and may be unable to raise capital when needed, which could force us to delay or reduce our commercialization efforts or product development programs.

Our existing cash, cash equivalents, short-term investments and revenue will be sufficient to meet our capital requirements and fund our operations for at least 12 months. However, we have based these estimates on

assumptions that may prove to be incorrect, and we could spend our available financial resources much faster than we currently expect. Any future funding requirements will depend on many factors, including:

- patient, physician and market acceptance of our Inspire therapy;
- the scope, rate of progress and cost of our current or future clinical studies;
- the cost of our research and development activities;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent or other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patents or other intellectual property rights;
- the cost and timing of additional regulatory clearances, approvals or certifications;
- the cost and timing of establishing additional sales and marketing capabilities;
- costs associated with any product recall that may occur;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in products, technologies and businesses, although we currently have no commitments or agreements relating to any of these types of transactions.

Any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds by selling additional shares of our common stock or other securities convertible into or exercisable or exchangeable for shares of our common stock, the issuance of such securities will result in dilution to our stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible into or exercisable or exchangeable for shares of our common stock, in future transactions may be higher or lower than the price per share paid by investors in previous offerings of shares of our common stock. Furthermore, investors purchasing any securities we may issue in the future may have rights superior to the rights of a holder of our common stock.

In addition, any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. If we raise additional funds through collaboration and licensing arrangements with third-parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us.

Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third-parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our business, financial condition and results of operations.

Our ability to use our net operating losses and research and development credit carryforwards to offset future taxable income may be subject to certain limitations.

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% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses ("NOLs") and its research and development credit carryforwards to offset future taxable income.

During 2023, we finalized a detailed analysis to determine whether an ownership change has occurred through December 31, 2022, and if a limitation exists. It was determined that December 11, 2018 was the only date that we experienced an ownership change. The study concluded that none of the federal net operating losses nor the federal R&D credits that were accumulated on December 11, 2018 will expire unused solely due to the limitations under Sections 382 and 383 of the Code. We are in the process of updating the analysis through December 31, 2023. Although unexpected, if we experienced an ownership change during 2023, the timing of our ability to utilize the tax attributes may be affected. As of December 31, 2023, our gross federal NOL carryforward was $226.1 million. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience a change of ownership within the definition of Section 382 of the Code, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability.

If we were deemed to be an investment company under the Investment Company Act of 1940, as amended (the "1940 Act"), applicable restrictions could make it impractical for us to continue our business as contemplated and could have a material adverse effect on our business, financial condition and results of operations.

Under Sections 3(a)(1)(A) and (C) of the 1940 Act, a company generally will be deemed to be an "investment company" for purposes of the 1940 Act if (1) it is, or holds itself out as being, engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities or (2) it engages, or proposes to engage, in the business of investing, reinvesting, owning, holding or trading in securities and it owns or proposes to acquire investment securities having a value exceeding 40% of the value of its total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis. We do not believe that we are an "investment company," as such term is defined in either of those sections of the 1940 Act.

We intend to conduct our operations so that we will not be deemed an investment company. However, if we were to be deemed an investment company, restrictions imposed by the 1940 Act, including limitations on our capital structure and our ability to transact with affiliates, could make it impractical for us to continue our business as contemplated and could have a material adverse effect on our business, financial condition and results of operations.

The increasing and evolving focus on sustainability and environmental, social, and governance initiatives from regulators and stakeholders could increase our costs, expose us to new risks, harm our reputation and adversely impact our financial results.

There has been increasing and evolving public focus by investors, customers, environmental and social activists, the media, politicians, and governmental and nongovernmental organizations and other stakeholders on a variety of environmental, social, and governance ("ESG") matters. We experience pressure to make commitments relating to ESG matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to ESG. If we are not effective in addressing ESG matters relevant to business, including meeting stakeholder expectations regarding relevant ESG goals, practices, initiatives, commitments, performance and/or public disclosures, our reputation and financial results may suffer. We may experience increased costs in order to execute upon our ESG goals, initiatives, and commitments and measure achievement of those goals, initiatives, and commitments which could have an adverse impact on our business and financial condition. Moreover, the increasing attention to corporate ESG initiatives could also result in reduced demand for products, reduced profits, and increased investigations and litigation.

In addition, organizations that provide information to investors on corporate governance and related matters have developed ratings processes for evaluating companies on ESG matters. Such ratings are used by some investors to inform their investment or voting decisions. Unfavorable ESG ratings could lead to negative investor sentiment toward us and/or our industry, which could have a negative impact on our access to and costs of capital. To the extent ESG matters negatively impact our reputation, we may also not be able to compete as effectively to recruit or retain employees.

This emphasis on ESG matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. For example, the SEC has announced proposed rules that, among other matters, would establish a framework for reporting climate-related risks. To the extent the proposed rules impose additional reporting obligations, we could face increased costs. Separately, the SEC has also announced that it is scrutinizing existing climate-change related disclosures in public filings, increasing the potential for enforcement if the SEC were to allege our existing climate disclosures are misleading or deficient.

As we continue to focus on our ESG goals, initiatives, commitments, performance, and disclosures, and as ESG-related laws, regulations, and voluntary and required disclosure standards and frameworks continue to evolve, we have expanded our public disclosures in these areas. Such disclosures may reflect goals, aspirations, commitments, and other expectations and assumptions, which are necessarily uncertain and may not be realized. If we fail to comply with new laws or regulations or accurately disclose against voluntary or required reporting standards or frameworks, our reputation and business could be adversely impacted.

Climate-related events and other events could harm our business.

Natural disasters, disease outbreaks and pandemics, power shortages, terrorism, political unrest, telecommunications failure, vandalism, geopolitical instability, war, climate-related events, and other events beyond our control could negatively impact our operations or otherwise harm our business. Such events may result in damage or loss of service to assets that our operations rely on, cause delays in product development or availability, or result in losses of critical data, any of which may adversely impact our operations.

In addition, the impacts of climate-related events on the global economy and our industry are rapidly evolving. Physical impacts of climate-related events (including but not limited to floods, droughts, more frequent and/or intense storms and wildfires), or chronic changes (such as droughts, heat waves or sea level changes) in climate patterns can adversely impact our operations, as well as the operations of our suppliers and customers. Our facilities and offices may be adversely impacted by natural disasters, including those intensified by climate change. Our locations, and those of our customers and suppliers, can be disrupted by droughts, extreme temperatures, fires, flooding and other climate change-related risks, as well as earthquakes, actions by utility providers, and other catastrophic events such as an actual or threatened public health emergency. If a catastrophic event occurs at or near any of our offices, or utility providers or public health officials take certain actions (e.g., shut off power to our facilities), our operations may be interrupted, which could adversely impact our business and results of operations. If a catastrophic event impacts a significant number of our suppliers or customers, or our ability to provide services to our customers, our business and results of operations could be adversely impacted. Longer term physical impacts may also result in changing consumer preferences, which may adversely impact demand for certain of our products. Transition impacts of climate-related events may subject us to increased regulations, reporting requirements, standards or expectations regarding the environmental impacts of our business. Failure to disclose accurate climate-related events information in a timely manner may also adversely affect our reputation, business, or financial performance.

Risks Related to Government Regulation

Our products and operations are subject to extensive government regulation and oversight both in the U.S. and abroad, and our failure to comply with applicable requirements could harm our business.

We and our products are subject to extensive regulation in the U.S. and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical studies; product safety; establishment registration and device listing; marketing, sales and distribution; pre-market clearance, approval, and certification; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export.

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. The FDA, foreign regulatory authorities, and notified bodies enforce these regulatory requirements through periodic unannounced inspections or audits. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances, approval, or certifications; withdrawals or suspensions of current approvals or certifications, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

We may not receive the necessary approvals or certifications for our future products or expanded indications, and failure to timely obtain necessary approvals or certifications for our future products or expanded indications would adversely affect our ability to grow our business and our results of operations.

An element of our strategy is to continue to upgrade our products, add new features and expand the indications and uses for our current products. In the U.S., before we can market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, we must first receive PMA from the FDA. In the process of obtaining PMA, which was required for our Inspire system, 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 study, 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.

The process of obtaining a PMA is costly and more uncertain and time consuming than the 510(k) clearance process used for lower risk devices. Despite the time, effort and cost, a device may not be approved by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business and results of operations. Furthermore, even if we are granted regulatory approval, it may include significant limitations on the indicated uses for the device, which may limit the market for the device.

The FDA and other regulatory authorities or notified bodies outside the U.S. can delay, limit or deny approval or certification of a device for many reasons, including:

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

In addition, the FDA or other regulatory authorities or notified bodies outside the U.S. may change their approval or certification policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or certification of our future products under development or impact our ability to modify our currently cleared or certified products on a timely basis. Such policy or regulatory changes could

impose additional requirements or time delays upon us that could delay our ability to obtain new approvals or certifications, increase the costs of compliance and our operating expenses, adversely impact our revenues or inventory forecasting or restrict our ability to maintain our current approval or certification.

The timing of FDA approval of a next generation product could have a significant impact on the carrying value of the inventory of our previous generation product, and therefore our results of operations.

Subject to the transitional provisions, in order to sell our products in EU member states, our products must comply with the general safety and performance requirements of the EU Medical Devices Regulation, which repeals and replaces EU Medical Devices Directive and the AIMDD. 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. 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 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. The notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. If satisfied that the relevant product conforms to the relevant general safety and performance requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to comply with applicable laws and regulations, we would be unable to affix the CE mark to our products, which would prevent us from selling them within the EU. The aforementioned EU rules are generally applicable in the EEA, and non-compliance with the above requirements would also prevent us from selling our products in these three countries.

Once devices are certified under the EU Medical Devices Regulation, we must inform the notified body that carried out the conformity assessment of the medical devices that we market or sell in the EU and the EEA of any planned substantial changes to our quality system or substantial changes to our medical devices that could affect compliance with the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the EU Medical Devices Regulation. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the general safety and performance requirements and quality system requirements laid down in the Annexes to the EU Medical Devices Regulation. The notified body may disagree with our proposed changes or take more time than anticipated to review and assess applications resulting in regulatory delays. See Part I., "Item 1A. Risk Factors — Risks Related to Government Regulation". For example, we applied for certification of silicone-based leads under the EU Medical Devices Regulation in December 2021 in order to replace the polyurethane-based leads, two components of the Inspire system currently used only in the European market. However, designated notified bodies currently have severe capacity constraints, and review times have lengthened significantly, including for our certification application. As a result of these delays, we have experienced inventory shortages and related adverse impacts on our results of operations that are expected to continue.

Modifications to our products may require us to obtain new PMAs or approvals of a PMA supplement or certification, and if we market modified products without obtaining necessary approvals or certifications, we may be required to cease marketing or recall the modified products until required approvals are obtained.

Certain modifications to a PMA-approved device may require approval of a new PMA or a PMA supplement, or alternatively a notification or other submission to the FDA. The FDA may not agree with our decisions regarding whether a new PMA or PMA supplement is necessary. We may make modifications to our approved devices in the future that we believe do not require approval of a new PMA or PMA supplement. If the FDA disagrees with our determination and requires us to submit a new PMA or PMA supplement for modifications to our previously approved products, we may be required to cease marketing or to recall the modified product until we obtain approval, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not approve

our products for the indications that are necessary or desirable for successful commercialization or could require clinical studies to support any modifications. Similar requirements may apply in foreign jurisdictions where we market our products. Any delay or failure in obtaining required approvals or certifications would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

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

Even though we have obtained approval for the Inspire system, we are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, registration, and listing of devices. For example, we must submit periodic reports to the FDA as a condition of PMA. These reports include safety and effectiveness information about the device after its approval. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation. Similar requirements may apply in foreign jurisdictions where we market our products.

In addition, the PMA for our Inspire system was subject to several conditions of approval, including a post-market long-term study. Though we believe we have complied with these conditions to date, any failure to comply with the conditions of approval could result in the withdrawal of PMA and the inability to continue to market the device. Failure to conduct the required studies in accordance with institutional review board ("IRB") and informed consent requirements, or adverse findings in these studies, could also be grounds for withdrawal of approval of the PMA.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory approval or certification to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our products;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future PMAs or foreign regulatory approvals or certifications of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of our current PMA or foreign regulatory approvals or certifications, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

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

Our products must be manufactured in accordance with foreign, federal and state regulations, and we or any of our suppliers or third-party manufacturers could be forced to recall our installed systems or terminate production if we fail to comply with these regulations.

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

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA and foreign requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals or certifications; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's or applicable foreign regulatory authority's or notified body's refusal to grant pending or future clearances, approvals or certifications for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us or our employees.

Any of these actions could significantly and negatively affect supply of our products. If any of these events occur, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs.

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

Our Inspire system has been approved by the FDA for specific indications. We train our marketing personnel and direct sales force to not promote our Inspire system for uses outside of the FDA-approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our Inspire system off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our Inspire system off-label. Furthermore, the use of our Inspire system for indications other than those approved by the FDA, approved by any foreign regulatory authority or certified by a notified body, may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory authority determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. 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.

In addition, physicians may misuse our Inspire system or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our Inspire system is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Similarly, in an effort to decrease costs, physicians may also reuse our Inspire system despite it being intended for

a single use or may purchase reprocessed Inspire systems from third-party reprocessors in lieu of purchasing a new Inspire system from us, which could result in product failure and liability. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us that may not be covered by insurance.

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

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

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

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

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA or foreign regulatory authorities. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification to the FDA or foreign regulatory authorities. If the FDA or a foreign regulatory authority disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

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

Sales of our products outside of the U.S. are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the U.S. While the regulations

of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we obtain the approval of or certification by a specified body (e.g., notified bodies in Europe). Complying with foreign regulatory requirements, including obtaining registrations, approvals or certifications, can be expensive and time-consuming, and we may not receive regulatory approvals or certifications in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations, approvals or certifications, if required by other countries, may be longer than that required for FDA approval, and requirements for such registrations, clearances, approvals or certifications may significantly differ from FDA requirements. If we modify our products, we may need to apply for additional regulatory approvals or certifications before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations or certifications that we have received. If we are unable to maintain our authorizations or certifications in a particular country, we will no longer be able to sell the applicable product in that country.

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

The FDA may modify its enforcement policies with respect to medical software products, and our software products may become subject to extensive regulatory requirements, which may increase the cost of conducting, or otherwise harm, our business.

We develop and offer certain software applications in connection with our business, including our SleepSync™ cloud-based patient management platform, which is designed to function as a medical device data system (“MDDS”). For its part, the FDA may regulate medical or health-related software, including machine learning functionality and predictive algorithms, if such software falls within the definition of a “medical device” under the FDCA. However, historically, the FDA has exercised enforcement discretion for certain low-risk software functions, and has issued several guidance documents that establish enforcement discretion policies and/or otherwise outline the FDA’s approach to the regulation of software as a medical device. For example, in September 2022 the FDA issued a guidance entitled: “Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices,” which among other things, announced the FDA’s intent not to enforce compliance with certain FDCA requirements with respect to medical device MDDS functions, including those requirements relating to registration and listing, premarket review, post-market reporting and compliance with the QSR.

In addition, the 21st Century Cures Act ("Cures Act”) amended the FDCA to exclude from the definition of “medical device” certain medical-related software, including certain software used for administrative support functions at a healthcare facility, software intended for maintaining or encouraging a healthy lifestyle, software designed to store electronic health records, certain clinical decision support software, and software for transferring, storing, or displaying medical device data or in vitro diagnostic data, including certain MDDS functionality. We believe our currently marketed applications, including the SleepSync™ platform, provide functionality that either qualifies for FDA enforcement discretion under the September 2022 policy for device MDDS, or is otherwise exempt from the FDCA’s definition of a “medical device” pursuant to the Cures Act amendments, and therefore that our products are subject to the FDA’s current enforcement discretion policy applicable to MDDS software functions or otherwise provide functions that are not currently regulated by the FDA as a medical device. However, there is a risk that the FDA could disagree with our determinations, or that the FDA could alter its enforcement discretion policies, and in either case, subject our software to more stringent medical device regulations.

If the FDA determines that any of our current or future software applications, including the SleepSync™ platform, are regulated as medical devices and not otherwise subject to enforcement discretion, we would become subject to various requirements under the FDCA and the FDA’s implementing regulations. If this occurs, we may be required to cease marketing or to recall our software products until we obtain the requisite clearances or approvals, and we may be subject to enforcement action. In addition, as we continue to update and improve our SleepSync™ platform, we are also continuing to integrate certain software functions we utilize for compliance,

quality oversight and product surveillance into the SleepSync™ platform. As such, any enforcement action with respect to our SleepSync™ software platform, or any requirements for us to obtain clearances or approvals for our software applications would also affect the speed at which we could update and modify these systems, and in any case, would entail significant cost and could harm our reputation, business, financial condition, and results of operations.

Legislative or regulatory reforms in the U.S. or the EU may make it more difficult and costly for us to obtain regulatory clearances, approvals or certification for our products or to manufacture, market or distribute our products after clearance, approval or certification is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, 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 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. For example, in February 2024, the FDA issued a final rule to amend and replace the Quality System Regulation, or QSR, which sets forth the FDA's current good manufacturing practice requirements for medical devices, to align more closely with the International Organization for Standardization standards. Specifically, this final rule, which the FDA expects to go into effect on February 2, 2026, establishes the "Quality Management System Regulation," or QMSR, which among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the QSR, and although our quality system is currently designed to comply with ISO standards in connection with our device certifications outside the United States, it is unclear the extent to which this final rule, once effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise negatively affect our business. If we are unable to comply with QMSR, once effective, or with any other changes in the laws or regulations enforced by FDA or comparable regulatory authorities, we may be subject to enforcement action, which could have an adverse effect on our business, financial condition and results of operations.

Similarly, the EU landscape concerning medical devices recently evolved. On May 25, 2017, the EU Medical Devices Regulation entered into force, which repeals and replaces the EU Medical Devices Directive and the AIMDD. See Part I, Item I, "Business – Government Regulation" for additional information on these reforms. These modifications are likely to have an effect on the way we conduct our business in the EEA. For example, as a result of the transition towards the new regime, notified body review times have lengthened, and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

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

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to: the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, the federal Civil Monetary Penalties Law, federal criminal fraud and abuse laws under HIPAA, analogous state and foreign law equivalents of each of the foregoing. See Part I, Item 1. "Business — Government Regulation."

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. Similar laws may exist in other jurisdictions where we operate, such as in the EU. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to. If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations.

We are or may be subject to U.S. federal, state, and foreign laws and regulations which impose obligations on how we collect, store and process health-related and other personal information. Our actual or perceived failure to comply with such obligations could harm our business, operations, and financial condition. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In the conduct of our business, we process health-related and other personal information. The U.S. federal government, various states, and foreign governments have adopted or proposed laws, regulations, guidelines and rules for the collection, distribution, use and storage of personal information of individuals. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder (collectively "HIPAA"), imposes privacy, security and breach notification obligations on certain healthcare providers, health plans, and healthcare 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, and their covered subcontractors. HIPAA requires covered entities and business associates to develop and maintain policies with respect to the protection of, use and disclosure of protected health information ("PHI"), including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a breach of unsecured PHI.

Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by the U.S. 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. HIPAA also authorizes state Attorneys General to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

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

it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

We may also be subject to U.S. federal rules, regulations, and guidance concerning data security for medical devices, including guidance from the FDA. State privacy and security laws which govern the privacy, processing and protection of health-related and other personal information vary from state to state and, in some cases, can impose more restrictive requirements than U.S. federal law. Where state laws are more protective, we must comply with the stricter provisions. In addition to fines and penalties that may be imposed for failure to comply with state law, some states also provide for private rights of action to individuals for certain misuses of personal information. For example, the California Consumer Privacy Act of 2018 (the "CCPA") went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act (the "CPRA") generally went into effect on January 1, 2023 and significantly amends the CCPA. 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 also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Similar laws have passed in other states, and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the U.S. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging and additional compliance investment and potential business process changes may be required.

We also expect that there will continue to be new laws, regulations and industry standards concerning privacy, data protection and information security proposed and enacted in various jurisdictions. For example, Washington State enacted a broadly applicable law to protect the privacy of personal health information known as the “My Health My Data Act,” which generally requires affirmative consent for the collection, use, or sharing of any “consumer health data.” Consumer health data is defined to include personal information that is linked or reasonably linkable to a consumer and that identifies a consumer’s past, present, or future physical or mental health status; consumer health data also includes information that is derived or extrapolated from non-health information, such as algorithms and machine learning. Other states, including Connecticut and Nevada, have also passed consumer health data laws, and given the increased focus on the use of health data by entities that are not subject to HIPAA, additional states are expected to pass consumer health privacy laws. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, in Europe, we are subject to the requirements of the GDPR (and national laws implementing the GDPR) because we are “established” in certain EU countries and we are processing personal data of individuals located in the EU and EEA in the context of these establishments, as well as offering of goods to, and/or monitoring the behavior of, individuals in the EU and EEA in connection with our clinical investigations. The GDPR, which went into effect in May 2018, imposes strict requirements for processing the personal data subject to the GDPR. If we do not comply with our obligations under the GDPR, we could be exposed to significant fines the greater of EUR 20 million or 4% of total global annual turnover for certain breaches. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease/ change our use of data, enforcement notices, as well potential civil claims including class action type litigation where individuals suffer harm.

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. Recent legal developments in Europe have created complexity and uncertainty regarding such transfers, in particular in relation to transfers to the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union (“CJEU”) states that reliance on the standard contractual clauses (SCCs) (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism) alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis.

We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contract clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, from January 1, 2021, we have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, under the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the "UK GDPR") which imposes separate but similar fines up to the greater of £17.5 million or 4% of global turnover. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the UK Government), as a UK GDPR data transfer mechanism to U.S. entities self-certified under the UK Extension to the DPF.

We are also subject to evolving EU and EEA privacy laws on cookies and e-marketing. In the EU and the UK, informed consent is required for the placement of certain cookie or similar technologies on an individual's device and for direct electronic marketing. The GDPR also imposes conditions on obtaining valid consent for cookies, such as a prohibition on pre-checked consents and a requirement to ensure separate consents are sought for each type of cookie or similar technology. Recent European court and regulator decisions and guidance are driving increased attention to cookies and tracking technologies. If the trend of increasing enforcement by regulators of the strict approach to opt-in consent for all but essential use cases, as seen in recent guidance and decisions continues, this could lead to substantial costs, require significant systems changes, limit the effectiveness of our marketing activities, divert the attention of our technology personnel, adversely affect our margins, and subject us to additional liabilities. In light of the complex and evolving nature of EU, EU Member State, and UK privacy laws on cookies and tracking technologies, there can be no assurances that we will be successful in our efforts to comply with such laws; violations of such laws could result in regulatory investigations, fines, orders to cease/ change our use of such technologies, as well as civil claims including class actions, and reputational damage.

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

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

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. In 2010, the Affordable Care Act (the "ACA") was enacted in the U.S., which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the ACA:

- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- expanded the eligibility criteria for Medicaid programs.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted, such as the Budget Control Act of 2011, the American Taxpayer Relief Act of 2012, and the Medicare Access and CHIP Reauthorization Act of 2015, among others. See Part I, Item 1. “Business — Government Regulation.” The expansion in the government’s role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payors for our Inspire system, and/or reduced medical procedure volumes, all of which may have a material adverse effect on our business, financial condition and results of operations.

We expect additional state, federal, and foreign healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our Inspire system or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our Inspire system, which in turn could impact our ability to successfully commercialize our Inspire system and could have a material adverse effect on our business, financial condition and results of operations.

Our business involves the use of hazardous materials and our third-party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how we do business.

Our third-party manufacturers’ activities may involve the controlled storage, use and disposal of hazardous materials. Our manufacturers are subject to federal, state, local, and foreign laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials. Although we believe the safety procedures of our manufacturers for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our manufacturers’ use of these materials and interrupt their business operations which could adversely affect our business. Environmental laws and regulations could change or become more stringent over time, imposing greater compliance costs, and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our business, financial condition, and results of operations.

The clinical study process required to obtain regulatory approvals or certifications is lengthy and expensive with uncertain outcomes. If clinical studies of our future products do not produce results necessary to support regulatory clearance or approval in the U.S. or foreign approval or certification, with respect to our current or future products, elsewhere, we will be unable to expand the indications for or commercialize these products and may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of those products.

We have obtained PMA for our Inspire system. In order to obtain PMA for a device, the sponsor must conduct well-controlled clinical studies designed to assess the safety and efficacy of the product candidate. Conducting clinical studies is a complex and expensive process, can take many years, and outcomes are inherently uncertain. We incur substantial expense for, and devote significant time to, clinical studies but cannot be certain that the studies will ever result in commercial revenue. We may experience significant setbacks in clinical studies, even after earlier clinical studies showed promising results, and failure can occur at any time during the clinical study process. Any of our products may malfunction or may produce undesirable adverse effects that could cause us or regulatory authorities to interrupt, delay or halt clinical studies.

We will likely need to conduct additional clinical studies in the future to support new indications for our products or for approvals, clearances or certifications of new product lines, or for the approval of the use of our products in some foreign countries. Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons. We may experience a number of events during that could adversely affect the costs, timing or successful completion of our clinical studies, including:

- we may be required to submit an IDE application or similar application to the FDA or a foreign regulatory authority, which must become effective prior to commencing human clinical studies, and the FDA or foreign regulatory authority may reject our IDE or similar application and notify us that we may not begin investigational studies;

- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical studies;

- regulators and/or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical study, or to conduct or continue a clinical study at a prospective or specific study site;

- we may not reach agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;

- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;

- the number of subjects or patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, and the number of clinical studies being conducted at any given time may be high and result in fewer available patients for any given clinical study, or patients may drop out of these clinical studies at a higher rate than we anticipate;

- our third-party contractors, including those manufacturing products or conducting clinical studies 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 studies for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;

- we may have to amend clinical study protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB or other review bodies and/or regulatory authorities for re-examination;

- regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;

- the cost of clinical studies may be greater than we anticipate;

- clinical sites may not adhere to the clinical protocol or may drop out of a clinical study;

- we may be unable to recruit a sufficient number of clinical study sites;

- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical studies may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;

- approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval or certification; and

- our current or future products may have undesirable side effects or other unexpected characteristics.

Patient enrollment in clinical studies and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the study protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical study, patient compliance, competing clinical studies and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical studies if the study protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical studies of a competitor's product candidate. In addition, patients participating in our clinical studies may drop out before completion of the study or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical study may delay commencement or completion of the clinical study, cause an increase in the costs of the clinical study and delays, or result in the failure of the clinical study.

Clinical studies must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs and other reviewing bodies at the medical institutions where the clinical studies are conducted. In addition, clinical studies must be conducted with supplies of our devices produced under current good manufacturing practice requirements and other regulations. Furthermore, we rely on CROs, and clinical study sites to ensure the proper and timely conduct of our clinical studies and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical studies in compliance with good clinical practice ("GCP") requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical studies, fail to conduct the study in accordance with GCP requirements or are delayed for a significant time in the execution of studies, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical studies that are conducted in countries outside the U.S. 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.

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. Our failure to adequately demonstrate the safety and efficacy of our system or any product we may develop in the future would prevent receipt of regulatory clearance, approval or certification and, ultimately, the commercialization of that product or indication for use. Even if our future products are cleared or approved in the U.S., commercialization of our products in foreign countries would require approval by regulatory authorities or certification by notified bodies in those countries. Approval and certification procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional preclinical studies or clinical studies. Any of these occurrences could have an adverse effect on our business, financial condition and results of operations.

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

Disruptions at the FDA and other agencies or notified bodies may also slow the time necessary for new medical devices and modifications to cleared or approved medical devices to be reviewed and/or cleared, approved or certified by necessary government agencies or notified bodies, 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. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown could prevent the timely review of our patent applications by the United States Patent and Trademark Office ("USPTO"), which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly fund our business.

In the EU, notified bodies must be officially designated to certify products and services in accordance with the EU Medical Devices Regulation. Their designation process, which is significantly stricter under the new Regulation, has experienced considerable delays in recent years. Despite a recent increase in designations, the current number of notified bodies designated under the new Regulation remains significantly lower than the number of notified bodies designated under the previous regime. The current designated notified bodies are therefore facing a backlog of requests as a consequence of which review times have lengthened. This situation may impact the way we are conducting our business in the EU and the EEA and the ability of our notified body to timely review and process our regulatory submissions and perform its audits.

Separately, in response to the global COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Any resurgence of the virus or emergence of new variants may lead to further inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA, other regulatory authorities and notified bodies from conducting their regular inspections or audits, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, other regulatory authorities or notified bodies to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Intellectual Property Matters

If we are unable to adequately protect our intellectual property rights, or if we are accused of infringing on the intellectual property rights of others, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

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

Some of our intellectual property rights depend on a licensing agreement with a third party, and our patent coverage includes protection provided by licensed patents. Many of these licensed patents are over ten years old and the standard life of a patent is 20 years from its initial filing date. If in the future we no longer have rights to one or more of these licensed patents, our patent coverage may be compromised, which in turn could affect our ability to protect our Inspire system or defend against competitors.

We own numerous issued patents and pending patent applications that relate to our system. As of December 31, 2023, we had rights to 80 issued U.S. patents, 55 issued foreign patents, 81 pending U.S. patent applications, and 79 pending foreign patent applications. Assuming all required fees are paid, issued U.S. patents owned by us will expire between 2029 and 2041.

We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our Inspire system, any additional features we develop for our Inspire system or any new products. Other parties may have developed technologies that may be related or competitive to our system, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual

questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products.

Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors could purchase our Inspire system and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our patents, or develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the U.S., and we may encounter significant problems in protecting our proprietary rights in these countries.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

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

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

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

We rely, in part, upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and consultants that obligate them to assign their inventions to us and have non-compete agreements with some, but not all, of our consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products or affect our stock price.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of others. Significant litigation regarding patent rights occurs in our industry. Our competitors in both the U.S. and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of patents issued to third parties. In addition, patent applications in the U.S. and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, competitors may claim that one or more of our products infringe their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved, and the uncertainty of litigation may increase the risk of business resources and management's attention being diverted to patent litigation. We have, and we may in the future, receive letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents.

Moreover, we may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include supplemental examination or contested post-grant proceedings such as review, reexamination, inter partes review, interference or derivation proceedings before the USPTO and challenges in U.S. District Court. Patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. We may also occasionally use these proceedings to challenge the patent rights of others. We cannot be certain that any particular challenge will be successful in limiting or eliminating the challenged patent rights of the third party.

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

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;

- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; incur significant legal expenses;

- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;

- pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;

- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and

- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products.

In addition, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. 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, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to patent protection for our issued patents and pending patent applications related to our system, we also rely upon copyright and trade secret protection for our Inspire therapy, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary

information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed.

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

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

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

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business and competitive position.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who previously worked with other companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property or personal information, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act ("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 affect patent litigation. 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, which became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention

if not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business.

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

Risks Related to Our Common Stock

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including, for example:

- the volume and timing of sales of our products;
- the introduction of new products or product enhancements by us or others in our industry;
- disputes or other developments with respect to our or others' intellectual property rights;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;
- regulatory actions with respect to our therapy or those of our competitors or companies perceived to be similar to ours;
- product liability claims or other litigation;
- changes in physician, hospital, healthcare provider practices;
- quarterly variations in our results of operations or those of others in our industry;
- media exposure of our products or of those of others in our industry;
- changes in governmental regulations
- changes in the structure of healthcare payment systems;
- changes in earnings estimates or recommendations by securities analysts; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

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

In addition, in the past, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Securities litigation brought against us following volatility in our stock price, regardless of the merit or ultimate results of such litigation, could result in substantial costs, which would hurt our financial condition and operating results and divert management's attention and resources from our business.

Provisions in our governing documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

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

- our board of directors has the exclusive right to expand the size of our board of directors and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;

- our stockholders may not act by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- a special meeting of stockholders may be called only by the chair of our board of directors, our chief executive officer or a majority of our board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;

- our amended and restated certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- our board of directors may alter certain provisions of our bylaws without obtaining stockholder approval;

- the approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors is required to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;

- stockholders must provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our Company; and

- our board of directors is authorized to issue shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding

voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, this 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, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the agreement governing our former credit facility precluded, and any future debt agreements may preclude, us from paying cash dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

General Risk Factors

Changes in U.S. and foreign tax laws could have a material adverse effect on our business, cash flow, results of operations and financial condition.

We are subject to taxation in several countries, and changes in tax laws or challenges to our tax positions could adversely affect our business, results of operations and financial condition. As such, we are subject to tax laws, regulations, and policies of the U.S. federal, state, and local governments and of comparable taxing authorities in foreign jurisdictions. Changes in tax laws in one or more jurisdictions, as well as other factors, could cause us to experience fluctuations in our tax obligations and effective tax rates in the future and otherwise adversely affect our tax positions and/or our tax liabilities. We are currently unable to predict what changes will occur and, if so, the ultimate impact on our business. To the extent that such changes have a negative impact on us or our consumers, including as a result of related uncertainty, these changes may materially and adversely impact our business, financial condition, results of operations and cash flow. There can be no assurance that our effective tax rates, tax payments or tax credits will not be adversely affected by changes in tax laws in various jurisdictions.

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

We have designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules

and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

The trading market for our common stock relies in part on the research and reports that securities or industry analysts publish about us or our business. We do not control these analysts. If any of the analysts who cover us provide inaccurate or unfavorable research or issue an adverse opinion regarding our stock price, our stock price could decline. If one or more of the analysts covering our business downgrade our stock or change their opinion of our stock, our stock price would likely decline. In addition, if one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We recognize the need to maintain the security and confidentiality of personal information, protected health information, and other confidential data that we collect and use in connection with our business, and the importance of assessing, identifying, and managing various cybersecurity risks that may impact our business. As such, we have implemented an information security program, which includes cybersecurity risk management measures intended to prevent, detect, and respond to malicious cyber activities and other security incidents that could adversely affect the confidentiality, integrity, or availability of our, or our customers' information or information systems.

Our information security program is designed based on the National Institute of Standards and Technology ("NIST") 800-53 framework. This does not imply that we meet any particular technical standards, specifications, or requirements, only that we use the NIST framework as a guide in designing and implementing our information security program.

As part of our enterprise risk management process, we assess the various cybersecurity risks that may impact our business and implement plans and initiatives that are intended to mitigate those risks.

Our information security program includes: (i) risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, software, and services; (ii) an information security team principally responsible for managing our (1) information security risk assessment processes, (2) security controls, and (3) response to cybersecurity incidents; (iii) risk assessments and security tests, conducted internally and by external security and risk audit providers, as appropriate; (iv) new-hire and annual cybersecurity awareness training of our employees; (v) a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and (vi) third-party risk assessment procedures to review material third-party vendors and applications for information security.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, see the section titled “Risk Factor—Risks Related to Our Business—Failure of a key information technology system, process or site, cyberattacks, or other deficiencies in our cybersecurity could have an adverse effect on our business and operations.”

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee oversight over our information security and technology risks, including our information security, cybersecurity and related risk management programs. The Audit Committee oversees management’s implementation of our information security program and receives periodic reports from management on our material cybersecurity risks. Additionally, management updates the Audit Committee, as necessary, regarding material cybersecurity incidents. The full Board receives quarterly updates from management on our information security program.

Our information security program is principally managed by our information security team, which is led by our Information Security Officer. Our Information Security Officer reports to our Vice President of Information Services, who has extensive experience with information technology governance, data management, and systems management, including managing information security and data privacy law compliance at large multinational companies. Our information security team includes professionals with deep professional experience and cybersecurity expertise, including our Information Security Officer. Such expertise includes applicable security and technology degrees and certifications held by information security team members, including degrees in computer science, cybersecurity, and systems engineering and management and security certifications such as COMP TIA Security+, COMP TIA Data+, and GIAC Security Essentials. We also augment our internal cybersecurity expertise by engaging security service organizations which provide 24x7 security operations centers.

Our information security team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through a variety of means, including briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the IT environment. We also augment our internal cybersecurity expertise by engaging security service organizations which provide 24x7 security operations centers.

Item 2. Properties.

Our principal offices are located in Golden Valley, Minnesota, where we lease approximately 106,000 square feet of office space. We also lease warehouse space adjacent to our principal office. We lease these spaces under non-cancelable operating lease agreements that expire May 31, 2035, with options to renew for two additional periods of five years each. We intend to add new facilities as we grow, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Item 3. Legal Proceedings.

From time to time we may be involved in claims and proceedings arising in the ordinary course of our business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain.

The information contained in “Note 11 — Commitments and Contingencies” in the Notes to the Consolidated Financial Statements is incorporated by reference into this Item 3.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock trades on the NYSE under the symbol “INSP."

Holders

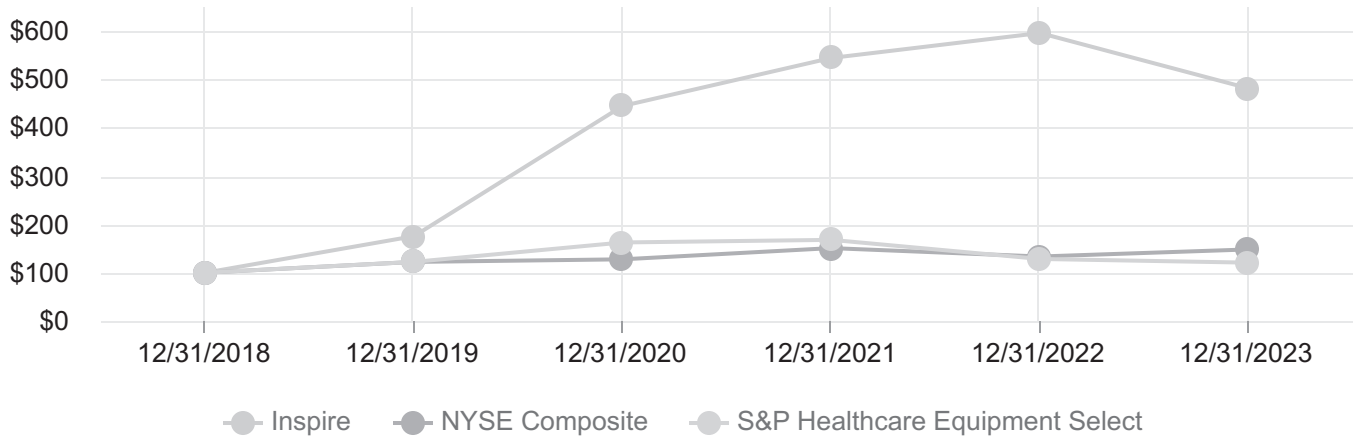
As of February 1, 2024, there were approximately 12 holders of record of our common stock. This number does not include stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Recent Sales of Unregistered Securities

None.

Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our common stock with the total return for (i) the S&P Healthcare Equipment Select Industry Index and (ii) the NYSE Composite from December 31, 2018 through December 31, 2023. The graph assumes an investment of $100 in our common stock at market close on December 31, 2018 and the reinvestment of dividends, if any. The comparisons in the table are not intended to forecast or be indicative of possible future performance of our common stock. This graph shall not be deemed “soliciting material” or be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended (the "Securities Act"), whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



		December 31,					
Stock or Index	**Ticker**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**
Inspire	INSP	$ 100.00	$ 175.64	$ 445.18	$ 544.52	$ 596.17	$ 481.49
NYSE Composite	NYA	100.00	122.32	127.70	150.90	133.50	148.17
S&P Healthcare Equipment Select	SPSIHE	100.00	122.40	162.59	167.98	128.44	120.78

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 financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Some of the numbers included herein have been rounded for the convenience of presentation. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under Part I. "Item 1A. Risk Factors'' and elsewhere in this Annual Report on Form 10-K.

Overview

We are a medical technology company focused on the development and commercialization of innovative, minimally invasive solutions for patients with OSA. Our proprietary Inspire system is the first and only FDA-approved neurostimulation technology that provides a safe and effective treatment for moderate to severe OSA. We have developed a novel, closed-loop solution that continuously monitors a patient's breathing and delivers mild hypoglossal nerve stimulation to maintain an open airway. Inspire therapy is indicated for patients with moderate to severe OSA who do not have significant central sleep apnea and do not have a complete concentric collapse of the airway at the soft palate level. In addition, patients in the U.S., Japan, Singapore, and Hong Kong must have been confirmed to fail or be unable to tolerate positive airway pressure treatments, such as CPAP, and be 18 years of age or older, though there are no similar requirements for patients in Europe.

We sell our Inspire system to hospitals and ambulatory surgery centers ("ASCs") in the U.S. and in select countries in Europe and Japan through a direct sales organization and we sell our Inspire system in Singapore and Hong Kong through distributors. Our direct sales force engages in sales efforts and promotional activities focused on ENT physicians and sleep centers. In addition, we highlight our compelling clinical data and value proposition to increase awareness and adoption amongst referring physicians. We build upon this top-down approach with strong direct-to-consumer marketing initiatives to create awareness of the benefits of our Inspire system and drive interest through patient empowerment. This outreach helps to educate thousands of patients on our Inspire therapy.

Although our sales and marketing efforts are directed at patients and physicians because they are the primary users of our technology, we consider the hospitals and ASCs where the procedure is performed to be our customers, as they are the purchasing agents of our Inspire system. Our customers are reimbursed the cost required to treat each patient through various third-party payors, such as commercial payors and government agencies. Our Inspire system is currently reimbursed primarily on a per-patient prior authorization basis for patients covered by commercial payors, under Local Coverage Determinations for patients covered by Medicare, and under U.S. government contract for patients who are treated by the Veterans Health Administration. As of February 9, 2024, we have secured positive coverage policies with many U.S. commercial payors, including virtually all large national commercial insurers, covering approximately 260 million lives in the U.S. In addition, all seven Medicare Administrative Contractors published final policies in 2020 that provide coverage of Inspire therapy when certain coverage criteria are met. Reimbursement in other countries can often be established through a combination of private (commercial insurance) and public funding sources, or at the hospital level through innovation budgets.

The procedures performed to implant, revise, or explant our device are described for billing purposes in the U.S. with Category I Current Procedural Terminology ("CPT") codes (64582, 64583, and 64584, respectively). A Category I code (42975) is also used for Drug-Induced Sleep Endoscopy ("DISE") to evaluate sleep disordered breathing, which may be a necessary procedure to determine which patients are appropriate for Inspire therapy. The Medicare national average 2024 payment to implant our device in a hospital outpatient site of service is $29,586, an increase of 1% from the 2023 rate. The 2024 Medicare national average ASC reimbursement is $24,847, a decrease of 1% from the 2023 rate. The 2024 Medicare national average physician reimbursement is $823 for implantation of a hypoglossal nerve stimulator, a 6% decrease over the 2023 payment. The reimbursement for the DISE procedure in the hospital setting is $1,617, an 803% increase over the prior year amount. In the ASC setting, the reimbursement for the DISE procedure is $757, a 714% increase from the 2023

amount. The 2024 Medicare national average physician reimbursement for the DISE procedure is $95, a 2% decrease over the prior year amount.

Reimbursement in other countries can often be established through a combination of private (commercial insurance) and public funding sources, or at the hospital level through innovation budgets.

For the year ended December 31, 2023, 97.0% of our revenue was derived in the U.S. and 3.0% was derived outside of the U.S. No single customer accounted for more than 10% of our revenue.

We rely on third-party suppliers to manufacture our Inspire system and its components. Many of these suppliers are currently single source suppliers. We have experienced and continue to experience supply disruptions that began during the COVID-19 pandemic, but to date we have managed to avoid major delays in implant procedures due to those issues. During the third quarter of 2023, we also began experiencing an inventory supply issue related to our polyurethane-based stimulation leads, one component of the Inspire system currently used only in the European market. In 2022, the FDA approved our silicone-based stimulation and sensing leads in the U.S., which replaced the polyurethane versions of the leads, and we stopped manufacturing polyurethane leads. We applied for European Union ("EU") Medical Devices Regulation ("MDR") approval in December 2021, which we expect to obtain in the second quarter of 2024, following delays in the process. In the interim, we received derogation approval from the Dutch, German, Swiss, and Belgian national competent authorities allowing us to place the silicone-based leads on the market in those countries until various dates in 2024 or until we receive certification under the EU MDR, whichever occurs first. We are also pursuing derogation in other European states, however, we cannot be certain that other national competent authorities will grant a derogation similar to the above-mentioned authorities. Until we obtain certification under the EU MDR, silicone leads may only be sold in the EU members states that have granted derogation. Polyurethane-based leads are the only leads that may be sold in the EU members states that have not granted derogation, and the polyurethane stimulation lead is in low supply. During the fourth quarter of 2023 and extending into early 2024, the delay in certification and the shortage of polyurethane-based stimulation leads caused delays to implant procedures which adversely affected our business in the EU, including a reduction in our European revenue, and thereby our consolidated revenue. We estimate the impact on our revenue during the fourth quarter of 2023 was approximately $4 million. We continue to expect delays to implant procedures, and therefore reductions to our revenue, however, to a lesser extent than in prior year periods as a result of the derogations received thus far, and we believe would be further improved if we receive certification under the EU MDR.

We typically seek to maintain higher levels of inventory to protect ourselves from supply interruptions, and, as a result, we are subject to the risk of inventory obsolescence and expiration, which could lead to inventory impairment charges. For example, during 2022, we recorded a charge of $2.8 million for obsolete inventory and component parts related to product introductions, including the new silicone leads and the Bluetooth®-enabled patient remote.

In the U.S., our products are shipped directly to our U.S. customers and to our Singapore and Hong Kong distributors on a purchase order basis, primarily by a third-party vendor with a facility in Tennessee, although we do ship some products from our facility in Minnesota. Warehousing and shipping operations for our European customers are handled by a third-party vendor with a facility located in the Netherlands, and warehousing and shipping operations for our Japanese customers are handled by a third-party with a facility in Japan. Customers do not have the right to return a non-defective product, nor do we place product on consignment. Our sales representatives do not maintain trunk stock.

Since our inception in 2007, we have financed our operations primarily through sales of our Inspire system, private placements of our convertible preferred securities, amounts borrowed under our former credit facility, and equity offerings of our common stock. We have devoted significant resources to research and development activities related to our Inspire system, including clinical and regulatory initiatives to obtain marketing approval, and sales and marketing activities. For the year ended December 31, 2023, we generated revenue of $624.8 million with a gross margin of 84.5% and a net loss of $21.2 million, compared to revenue of $407.9 million with a gross margin of 83.8% and a net loss of $44.9 million for the year ended December 31, 2022, and revenue of $233.4 million with a gross margin of 85.7% and a net loss of $42.0 million for the year ended December 31, 2021. Our accumulated deficit as of December 31, 2023 was $345.4 million.

We have invested heavily in product development. Our research and development activities have been centered on driving continuous improvements to our Inspire therapy. We have also made significant investments in clinical studies to demonstrate the safety and efficacy of our Inspire therapy and to support regulatory submissions. We continue to make investments in research and development efforts to develop our next generation Inspire systems and support our future regulatory submissions for expanded indications and for new markets such as additional European countries and the Asia Pacific region. For example, in June 2023, we submitted a premarket approval ("PMA") supplement to the FDA for our next generation Inspire system. Also in June 2023, we received approval from the FDA on an expanded indication which includes an increase on the upper limit of the Apnea Hypopnea Index to 100 events per hour from 65, and raises the Body Mass Index ("BMI") warning in the labeling to 40 from 32, and we also received FDA approval of our new physician programmer, called the SleepSync™ programmer, which we expect to formally launch in the U.S. in early 2024. In March 2023, we received FDA approval to offer Inspire therapy to certain pediatric patients with Down syndrome, and in 2022, we received FDA approval for additional magnetic resonance imaging ("MRI") scan conditions for use with Inspire therapy. This full-body MRI approval expands the Inspire use labeling that previously allowed only head, neck, and extremity MRI scans. Also in 2022, the FDA approved silicone-based stimulation and sensing leads, which provides improved manufacturability, easier system implantation, increased long-term performance, and enhanced reliability.

Our direct-to-consumer marketing includes the use of social media platforms such as Facebook, Google ad placements, and radio and television commercials. In January 2022, we purchased our first national television advertising spots and began airing new TV commercials, and in March 2023, we began airing additional new television commercials. The objective of this outreach is to bring patients to our website, where they can find educational materials and videos on sleep apnea and the use and benefits of our Inspire therapy, contact information for physicians and clinical sites, and information regarding community awareness events. Further, our team leverages the Inspire Sleep app for patient education. We plan to continue to refine our approach to direct-to-consumer outreach, including increasing attention to digital advertising directed towards qualified patients. We expect to maintain our level of direct-to-consumer activities.

We have a call center which we refer to as the Inspire Advisor Care Program ("ACP"). The primary purpose of this program is to assist patients with making a connection with a qualified healthcare provider based on their specific needs. In 2022, we initiated a digital scheduling pilot program to facilitate and streamline patient access to care. We plan to continue to enhance this scheduling capability during 2024.

We also continue to make significant investments to build our sales and marketing organization by increasing the number of U.S. and European sales representatives and continuing our direct-to-consumer marketing efforts in existing and new markets throughout the U.S. and in Europe. During 2023, we activated 280 U.S. centers bringing the total to 1,180 U.S. medical centers implanting Inspire therapy as of December 31, 2023. Additionally, we created 62 new U.S. sales territories during 2023, bringing the total to 287 U.S. territories as of December 31, 2023.

During 2023, glucagon-like peptide 1 ("GLP-1s"), a class of drug indicated for diabetes and obesity, continued to gain popularity as a weight-loss drug. OSA is a multifactorial disease with many independent factors including age, gender, weight, and neck circumference. Inspire is designed to address anteroposterior airway collapse, also known as tongue-based collapse. Additionally, patients with a higher BMI are subject to a larger neck circumference and present predominantly with lateral-wall collapse. A combination of tongue-based collapse and lateral-wall collapse is identified as a complete concentric collapse of the upper airway. Inspire is contraindicated for complete concentric collapse. While weight loss may help reduce a patient’s Apnea-Hypopnea Index and other OSA symptoms, we have seen from numerous studies that weight loss alone will not resolve OSA for the vast majority of patients. We expect GLP-1s may help patients address their lateral wall collapse, making them a potential candidate for Inspire therapy to the extent they also have tongue-based collapse. Based on our ongoing ADHERE patient registry, the average BMI of patients treated with Inspire therapy is 29 and the American Academy of Sleep Medicine guidelines recommend weight loss prior to surgery for patients with BMI over 35 and nonsurgical solutions for patients with BMI over 40. Therefore, we do not believe there is not a significant overlap between the Inspire patient population and the patient population being treated with GLP-1s today. While we cannot quantify the impact, we believe that there could be a benefit to our business as a result of GLP-1s, although there can be no assurance of such benefit. If GLP-1s are successful in treating OSA in an indication for which Inspire therapy is approved, demand for our Inspire system could be reduced.

Macroeconomic Environment

The global economy continues to experience increased inflationary pressures which we anticipate will continue. Higher interest rates and capital costs, higher shipping costs, increased costs of labor, international conflicts and terrorism, and weakening foreign currency exchange rates are creating additional economic challenges. These conditions may cause our customers to decrease or delay orders for our products.

Our inventory on-hand has been constrained by the continuing supply chain challenges and component shortages, although the supply chain constraints eased somewhat throughout 2023. As mentioned above, not having received EU MDR approval of our silicone-based leads which resulted in shortages of polyurethane-based leads, we have experienced and may continue experience to cause delays to implant procedures and a reduction in our European revenue.

Components of Our Results of Operations

Revenue

We derive primarily all of our revenue from the sale of our Inspire system to hospitals and ASCs in the U.S., select countries in Europe, Japan, Singapore, and Hong Kong. We recognize revenues from sales of our Inspire system when the customer obtains control of the product, which occurs at a point in time, either upon shipment of the product or receipt of the product, depending on shipment terms.

Our revenue has fluctuated, and may continue to fluctuate, from quarter to quarter due to a variety of factors. For example, we have historically experienced seasonality in our first and fourth quarters and have experienced adverse impacts on our revenue due to the COVID-19 pandemic and foreign currency exchange rates. In addition, in the three months ended September 30, 2023, we believe our revenue growth was adversely impacted by certain changes to the assistance that we provide to patients in connection with their seeking prior authorization approval prior to treatment, as well as lack of ENT surgeon capacity. While we believe the impact caused by the changes to the assistance that we provide in connection with prior authorizations has improved, ENT surgeon capacity challenges remain. If such impacts continue, our revenue growth may be further adversely impacted.

Our business has grown rapidly in recent years, resulting in substantially increased revenues, and we expect that our business will continue to grow. However, our revenue growth rate has generally declined in recent periods, and it may continue to do so as a result of the difficulty of maintaining growth rates as our revenues increase to higher levels.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of acquisition costs for the components of the Inspire system, overhead costs, scrap, and inventory obsolescence, warranty replacement costs, as well as distribution-related expenses such as logistics and shipping costs, net of shipping costs charged to customers. The overhead costs include the cost of material procurement, depreciation expense for production equipment, and operations supervision and management personnel, including employee compensation, stock-based compensation, supplies, and travel. We expect cost of goods sold to increase or decrease in absolute dollars primarily as, and to the extent, our revenue grows or declines, respectively.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and we expect it will continue to be affected by a variety of factors, including manufacturing costs, the average selling price of our Inspire system, the implementation of cost-reduction strategies, inventory obsolescence costs, which generally occur when new generations of our Inspire system are introduced, and to a lesser extent the sales mix between the U.S. and countries outside of the U.S., as our average selling price in the U.S. tends to be higher than in other countries. Our gross margin may increase slightly to the extent our production volumes increase and we receive discounts on the costs charged by our contract manufacturers, thereby reducing our per unit costs, and when we

implement price increases on our products, thereby increasing our revenue. On the other hand, our gross margin may decrease slightly to the extent our yields decrease, or materials and labor prices increase due to supply chain issues and inflation, thereby increasing our per unit costs. However, our gross margin may also fluctuate from quarter to quarter due to seasonality and foreign currency exchange rates.

Our gross margin in the second half of 2022 was lower than in previous periods primarily due to inventory obsolescence charges associated with product introductions, additional costs associated with the transition of manufacturing lines to produce our new silicone-based leads, and higher costs of certain component parts which were impacted by supply chain issues. In 2024, we expect gross margins to be in the range of 83% to 85%.

Research and Development Expenses

Research and development expenses consist primarily of product development, engineering, clinical studies to develop and support our products, regulatory expenses, quality assurance, testing, consulting services, prelaunch inventory, and other costs associated with the next generation versions of the Inspire system and SleepSync™, a cloud-based patient management system. These expenses include employee compensation, including stock-based compensation, supplies, materials, consulting, and travel expenses related to research and development programs. Additionally, these expenses include clinical study management, payments to clinical investigators, data management and travel expenses for our various clinical studies.

We expense prelaunch inventory as research and development expense in the period incurred unless objective and persuasive evidence exists that regulatory approval and subsequent commercialization of a product candidate is probable and we also expect future economic benefit from the sales of the product candidate to be realized.

We expect research and development expenses to increase in the future as we develop next generation versions of our Inspire system and SleepSync™ and continue to expand our clinical studies to further expand positive coverage policies from private commercial payors in the U.S. and enter into new markets including additional European countries and the Asia Pacific region. We expect research and development expenses as a percentage of revenue to vary over time depending on the level and timing of initiating new product development efforts and new clinical development activities.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses consist primarily of compensation for personnel, including base salaries, stock-based compensation expense and commissions related to our sales organization, finance, information technology, human resource, and legal functions, as well as spending related to marketing, sales operations, and training and reimbursement personnel. Other SG&A expenses include training physicians, travel expenses, advertising, direct-to-consumer promotional programs, conferences, trade shows and consulting services, professional services fees, audit fees, insurance costs and general corporate expenses, including facilities-related expenses.

We expect SG&A expenses to continue to increase as we expand our commercial infrastructure to both drive and support our planned growth in revenue and as we increase our headcount and expand administrative personnel to support our growth and operations as a public company including finance, legal, and human resources personnel and information technology services. Additionally, we anticipate an increase in our stock-based compensation expense with grants of stock options, restricted stock units, performance stock units, and shares of our common stock purchased pursuant to our employee stock purchase plan.

Other (Income) Expense, Net

Other (income) expense consists primarily of interest and dividend income, interest expense under our former credit facility, the impacts of foreign currency transactions and remeasurements, and gains and losses on investments.

Results of Operations

Year Ended December 31, 2023 Compared to Year Ended December 31, 2022

	Year Ended December 31,		Change	
	2023	2022	$	%
	(in thousands, except percentages)			
Revenue	$ 624,799	$407,856	$ 216,943	53.2 %
Cost of goods sold	96,576	66,115	30,461	46.1 %
Gross profit	528,223	341,741	186,482	54.6 %
Gross margin	*84.5 %*	*83.8 %*		
Operating expenses:				
Research and development	116,536	68,645	47,891	69.8 %
Selling, general and administrative	451,958	320,688	131,270	40.9 %
Total operating expenses	568,494	389,333	179,161	46.0 %
Operating loss	(40,271)	(47,592)	7,321	(15.4)%
Other income, net	(20,365)	(3,324)	(17,041)	512.7 %
Loss before income taxes	(19,906)	(44,268)	24,362	(55.0)%
Income taxes	1,247	613	634	103.4 %
Net loss	$ (21,153)	$ (44,881)	$ 23,728	(52.9)%

Revenue

Revenue increased $216.9 million, or 53.2%, to $624.8 million for the year ended December 31, 2023 compared to the year ended December 31, 2022. These results reflect an increase in sales of our Inspire system of $211.3 million in the U.S. and an increase of $5.6 million outside of the U.S. Overall revenue growth was primarily due to increased market penetration in existing territories, expansion into new territories, and, we believe, increased physician and patient awareness of our Inspire system, and to a lesser extent, a list price increase that began to impact some customers in May 2022, partially offset by ENT surgeon capacity constraints and reduced procedures as a result of the polyurethane-based lead shortage in Europe and the factors described under "Components of our Results of Operations - Revenue" above.

Revenue information by region is summarized as follows:

	Year Ended December 31,					
	2023		2022		Change	
	Amount	% of Revenue	Amount	% of Revenue	$	%
	(in thousands, except percentages)					
United States	$ 606,178	97.0 %	$ 394,833	96.8 %	$ 211,345	53.5 %
All other countries	18,621	3.0 %	13,023	3.2 %	5,598	43.0 %
Total revenue	$ 624,799	100.0 %	$ 407,856	100.0 %	$ 216,943	53.2 %

Revenue generated in the U.S. was $606.2 million for the year ended December 31, 2023, an increase of $211.3 million, or 53.5%, over the year ended December 31, 2022. Revenue growth in the U.S. was primarily due to increased market penetration in existing territories, the expansion into new territories, and, we believe, increased physician and patient awareness of our Inspire system and, to a lesser extent, a list price increase that began to impact some U.S. customers in May 2022.

Revenue generated outside of the U.S. was $18.6 million in the year ended December 31, 2023, an increase of $5.6 million, or 43.0%, over the year ended December 31, 2022. Revenue growth was primarily due to increased market penetration in existing territories, the expansion of our European sales representatives into new territories,

increased sales in the Asia Pacific region, and, we believe, increased physician and patient awareness of our Inspire system. As noted above, during the fourth quarter of 2023, not having received EU MDR certification of our silicone-based stimulation lead and the resulting shortage of polyurethane-based stimulation leads had an estimated adverse impact on European revenue of approximately $4 million.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased $30.5 million, or 46.1%, to $96.6 million for the year ended December 31, 2023 compared to $66.1 million for the year ended December 31, 2022. The increase was primarily due to product costs associated with higher sales volume of our Inspire system, additional manufacturing costs of sensors and lower yields prior to process enhancements, additional costs associated with an isolated production issue at a supplier, and higher costs of certain component parts.

Gross margin was 84.5% for the year ended December 31, 2023 compared to 83.8% for the year ended December 31, 2022. Gross margin for the year ended December 31, 2023 was higher than the previous year primarily due to $2.8 million of inventory obsolescence charges taken during 2022 associated with new product introductions, which lowered the gross margin during that period. Gross margin for the year ended December 31, 2023 was negatively impacted by additional manufacturing costs of sensors and lower yields prior to process enhancements, additional costs associated with an isolated production issue at a supplier, and higher costs of certain component parts, partially offset by the price increase that began taking effect for some U.S. customers in May 2022.

Research and Development Expenses

Research and development expenses increased $47.9 million, or 69.8%, to $116.5 million for the year ended December 31, 2023 compared to $68.6 million for the year ended December 31, 2022. This change was primarily due to an increase of $21.7 million of compensation and employee-related expenses, mainly as a result of increased headcount and stock-based compensation expense and $20.8 million of incremental ongoing research and development costs, including ongoing development of the SleepSync™ platform and the next generation Inspire neurostimulator and physician programmer. The change also includes an increase of $5.2 million of prelaunch inventory expense related to our next generation Inspire neurostimulator, and an increase of $0.2 million in clinical studies expenses and quality compliance audit fees.

Selling, General and Administrative Expenses

SG&A expenses increased $131.3 million, or 40.9%, to $452.0 million for the year ended December 31, 2023 compared to $320.7 million for the year ended December 31, 2022. The primary driver of this change was an increase of $75.7 million in compensation, including salaries, commissions, stock-based compensation, and other employee-related expenses, mainly as a result of increased headcount. In addition, marketing expenses increased $36.3 million, primarily consisting of direct-to-consumer initiatives, including new national TV advertisements, which began airing in March 2023, and the expansion of our Advisor Care Program call center. Other drivers of the change to SG&A expenses included an increase in travel expenses of $7.8 million and an increase in general corporate costs of $11.5 million primarily due to consulting fees, computer equipment and software, legal fees, bank fees, bad debt expense, and office rent expense.

Other (Income) Expense, Net

Other (income) expense, net changed by $17.1 million, or 512.7%, to $20.4 million of income for the year ended December 31, 2023 compared to $3.3 million of income for the year ended December 31, 2022. This change was due to an increase of $15.5 million in interest and dividend income due to higher interest rates on our higher cash, cash equivalents, and investment balances, and a decrease of $1.7 million in interest expense due to the early termination of our credit facility, partially offset by a $0.1 million change in foreign currency translation and remeasurement gains due to exchange rates.

Income Taxes

We recorded a provision for income taxes of $1.2 million and $0.6 million for the years ended December 31, 2023 and 2022, respectively. This change was primarily due to an increase of $0.3 million in state and local taxes, as well as $0.3 million in foreign taxes.

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

For a discussion of our results of operations for the year ended December 31, 2022, including a year-to-year comparison between 2022 and 2021, refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2022.

Liquidity and Capital Resources

As of December 31, 2023, we had cash, cash equivalents and available-for-sale debt securities of $469.5 million, an increase of $18.1 million from $451.4 million as of December 31, 2022. Working capital totaled $515.6 million as of December 31, 2023, an increase of $46.8 million from December 31, 2022. We define working capital as current assets less current liabilities. The increase in working capital was primarily due to the following factors:

- an increase of $9.0 million in cash and cash equivalents and short-term available for sale investments due primarily to sales of the Inspire system, proceeds from the exercise of stock options, and interest and dividend income;
- an increase of $28.7 million in accounts receivable due to higher sales which occurred during the fourth quarter of 2023;
- an increase of $22.0 million in inventory balances which increased as supply chain issues ease; and
- an increase of $4.1 million in prepaid expense and other current assets which increased primarily due to miscellaneous prepaid expenses and interest income receivable.

The increase in working capital was offset by the following factors:

- an increase of $12.0 million in accounts payable, generally due to our business volume and headcount growth from the prior year; and
- an increase of $4.9 million in accrued expenses which increased primarily due to compensation and personnel-related costs.

We proactively manage our access to capital to support liquidity and continued growth. Our sources of capital have included sales of our Inspire system and registered offerings of our common stock. In August 2022, we completed a follow-on offering that included our offer and sale of 1,150,000 shares of common stock at a public offering price of $215.00 per share. We received net proceeds of approximately $243.8 million after deducting underwriting discounts, commissions, and offering expenses. During the quarter ended September 30, 2022, we repaid all amounts outstanding under our former credit facility. See Note 4 to our audited financial statements for additional information on our previous credit facility.

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk or decreasing availability. To achieve these objectives, our investment policy allows us to maintain a portfolio of certain types of debt securities issued by the U.S. government and its agencies, corporations with investment-grade credit ratings, or commercial paper and money market funds issued by the highest quality financial and non-financial companies. At December 31, 2023, we had $146.2 million in money market funds, $243.6 million in U.S. government securities, and $40.4 million in corporate debt securities, certificates of deposit, commercial paper, and asset-asset-backed securities. See Note 2 to our audited financial statements for additional information on our investments.

In 2023, our R&D and SG&A expenditures increased significantly over the prior year levels, and we anticipate further increases during 2024. Our SG&A expenditures, primarily for increasing headcount and advertising, may

exceed any associated increases in revenues, and therefore would reduce our cash flow from operations. We also anticipate R&D expenses will continue to be significant in 2024, primarily related to the ongoing development of the SleepSync™ platform and next generation products.

We spent $23.6 million on purchases of property and equipment in 2023, mainly on testing systems and production equipment for our next generation Inspire system, our SleepSync™ platform, computer hardware and software, and leasehold improvements. We anticipate further capital expenditures in 2024, primarily for additional production equipment and our SleepSync™ platform, computer hardware and software, and leasehold improvements on our corporate office buildings.

We believe that our existing cash and cash equivalents and available for sale investments, which totaled $469.5 million as of December 31, 2023, together with cash flows from operations, will provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures for at least the next 12 months. There can be no assurance, however, that our business will continue to generate cash flows at the same levels achieved in prior periods.

Beyond the next 12 months, our cash requirements will depend extensively on the timing of market introduction, and extent of market acceptance of, our Inspire system. Our long-term cash requirements also will be significantly impacted by the level of our investment in commercialization, entry and expansion into new markets such as Hong Kong and Australia, whether we make strategic acquisitions, and competition. We cannot accurately predict our long-term cash requirements at this time. An extended period of global supply chain and economic disruption could materially affect our business, results of operations, access to sources of liquidity, and financial condition. We may seek additional sources of liquidity and capital resources through equity or debt financings, such as additional securities offerings or through borrowings under a new credit facility. There can be no assurance that such transactions will be available to us on favorable terms, if at all.

Below is a summary of short-term and long-term anticipated cash requirements under contractual obligations existing as of December 31, 2023.

	As of December 31, 2023		
($ in thousands)	**Total**	**Fiscal 2024**	**After Fiscal 2024**
Recorded contractual obligations:			
Operating leases[(1)]	$ 35,089	$ (3,582)	$ 38,671
Unrecorded contractual obligations:			
Purchase obligations[(2)]	91,375	91,375	—
Total	$ 126,464	$ 87,793	$ 38,671

[(1)] See Note 3 to our audited consolidated financial statements.

[(2)] Primarily purchase obligations to suppliers for inventory.

As of December 31, 2023, we did not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Cash Flows

The following table presents a summary of our cash flow for the periods indicated:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ 24,653	$ 11,569
Investing activities	(294,822)	(19,596)
Financing activities	13,950	235,077
Effect of exchange rate on cash	164	75
(Decrease) increase in cash and cash equivalents	$ (256,055)	$ 227,125

Operating Activities

Net cash provided by operating activities was $24.7 million for 2023 and consisted of a net loss of $21.2 million, non-cash charges of $86.6 million, and a decrease in net operating assets of $40.8 million. The non-cash charges consisted primarily of stock-based compensation, which increased mainly as a result of granting more stock options, restricted stock units, and performance stock units to a greater number of employees at a higher fair market value. The remainder of the non-cash charges included depreciation and amortization expense which increased with additional purchases of property and equipment, accretion of investment discount due to higher investment balances, non-cash lease expense, stock issued for services rendered, and other, net. Operating assets include inventories, which increased as supply chain constraints eased, and accounts receivable, which increased due to higher sales volume. Operating assets also include prepaid expenses and other current assets, which increased primarily due to various prepaid expenses and interest income receivable. Operating liabilities include accounts payable, which increased generally due to our increased business volume year-over-year and the costs to support the growth of our operations, and accrued expenses, which increased primarily due to compensation and personnel-related costs.

Net cash provided by operating activities was $11.6 million for 2022 and consisted of a net loss of $44.9 million, non-cash charges of $54.6 million, and a decrease in net operating assets of $1.8 million. The non-cash charges consisted primarily of stock-based compensation, which increased mainly as a result of granting more stock options and restricted stock units to more employees at a higher fair market value, as well as the introduction of performance stock unit grants. The remainder of the non-cash charges included depreciation and amortization, non-cash lease expense, stock issued for services rendered, and other, net. Operating assets includes accounts receivable which increased due to higher sales, and to a lesser extent prepaid expenses and other current assets. Operating assets also includes inventories, which decreased primarily due to increased sales demand and supply chain constraints. Operating liabilities includes accounts payable, which increased generally due to our increased business volume year-over-year and the costs to support the growth of our operations, and accrued expenses, which increased primarily due to compensation and personnel-related costs.

Investing Activities

Net cash used in investing activities for 2023 was $294.8 million and consisted primarily of the purchase of investments of $281.2 million, partially offset by $10.2 million of proceeds from sales or maturities of investments. Investing activities also included purchases of property and equipment of $23.6 million, mainly for testing systems and production equipment for our next generation Inspire system, our SleepSync™ platform, computer hardware and software, and leasehold improvements, as well as the purchase of strategic investments of $0.3 million.

Net cash used in investing activities for 2022 was $19.6 million and consisted of the purchase of strategic investments of $10.5 million and the purchases of property and equipment, net of $9.1 million, mainly for testing systems, production equipment, and leasehold improvements on our corporate office.

Financing Activities

Net cash provided by financing activities was $14.0 million for 2023 and consisted primarily of proceeds from the exercise of stock options of $25.8 million and proceeds from the issuance of common stock from our employee stock purchase plan of $5.3 million, partially offset by $17.2 million of taxes paid on net share settlement of equity awards.

Net cash provided by financing activities was $235.1 million for 2022 and consisted primarily of proceeds from the offering of common stock of $243.8 million, as well as proceeds from the exercise of stock options of $12.1 million, and proceeds from the issuance of common stock from our employee stock purchase plan of $3.7 million, partially offset by $24.5 million in payments on our long-term debt obligation, which we prepaid in August 2022, and less than $0.1 million of taxes paid on net share settlement of equity awards.

Critical Accounting Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the amounts reported in the audited financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. We believe that such estimates have been based on reasonable and supportable assumptions and the resulting estimates are reasonable for use in the preparation of the audited financial statements. Actual results could differ from these estimates.

The following areas require management estimates, assumptions, and judgments:

Inventories

Inventories are valued at the lower of cost or net realizable value, computed on a first-in, first out basis. We estimate the recoverability of our inventory by reference to internal estimates of future demands, introduction of new products, and product life cycles, including expiration of inventory prior to sale. We regularly review inventory quantities on-hand for excess and obsolete inventory and, when circumstances indicate, incur charges to write down inventories to their net realizable value. The determination of a reserve for excess and obsolete inventory involves management exercising judgment to determine the required reserve, considering future demand, product life cycles, introduction of new products, and current market conditions. Although we make every effort to ensure the accuracy of our forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of our inventories and reported operating results. Likewise, the timing of FDA approval of a next generation product, if granted, could have a significant impact on the carrying value of the inventory of our previous generation product, and therefore our reported operating results. During 2022, we recorded a $1.8 million inventory reserve related to product introductions, including the new silicone leads and the Bluetooth®-enabled patient remote. The net inventory balance was $33.9 million and $11.9 million as of December 31, 2023 and 2022, respectively. The reserve for excess and obsolete inventory was $2.4 million and $2.7 million as of December 31, 2023 and 2022, respectively.

Stock-Based Compensation

We maintain an equity incentive plan to provide long-term incentives for eligible employees, consultants, and members of the board of directors. The plan allows for the issuance of performance stock units ("PSUs"), and during 2022 and 2023, we granted PSUs to officers and key employees. The number of PSUs that will ultimately be earned is based on our performance relative to pre-established goals for the three-year periods ending December 31, 2024 and 2025, respectively. Management expectations related to the achievement of the performance goals associated with PSU grants is assessed each reporting period, which determines the amount of stock-based compensation expense recorded during the period. The number of shares earned at the end of the three-year periods will vary based on actual performance, from 0% to 200% of the number of PSUs granted. If the performance goals are not met, no shares will be earned. If 200% of the PSUs outstanding as of December 31, 2023 are ultimately earned, the total stock-based compensation expense recognized over the three-year period ending December 31, 2024 will be $83.9 million. If the performance conditions are not met or not expected to be

met, any compensation expense previously recognized associated with the grant will be reversed which will impact our operating results.

Recent Accounting Pronouncements

A discussion of recent accounting pronouncements is included in Note 2 to our financial statements contained in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents which are carried at quoted market prices and our short-term investments. We do not currently use or plan to use financial derivatives in our investment portfolio. A hypothetical 1% change in interest rates would have impacted interest and dividend income on our consolidated financial statements by approximately $3.1 million and $2.4 million for the years ended December 31, 2023 and 2022, respectively.

Credit Risk

As of December 31, 2023 and 2022, our cash, cash equivalents, and investments were maintained with financial institutions which we believe have sufficient assets and liquidity to conduct their operations in the ordinary course of business with little or no credit risk to us, however our cash balances were in excess of insured limits. Market conditions can impact the viability of institutions where our cash is held. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we will be able to access uninsured funds in a timely manner or at all.

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk or decreasing availability. To achieve these objectives, our investment policy allows us to maintain a portfolio of certain types of debt securities issued by the U.S. government and its agencies, corporations with investment-grade credit ratings, or commercial paper and money market funds issued by the highest quality financial and non-financial companies. We place restrictions on maturities and concentration by type and issuer. We are exposed to credit risk in the event of a default by the issuers of these securities to the extent recorded on the consolidated balance sheets. See Note 2 to our financial statements contained in this Annual Report on Form 10-K for additional information on our cash equivalents and available-for-sale marketable securities.

Our accounts receivable primarily relate to revenue from the sale of our Inspire system to hospitals and ASCs in the U.S. and Europe, primarily in Germany. We believe that the credit risk in our accounts receivable is mitigated by our credit evaluation process, relatively short collection terms, and dispersion of our customer base. We generally do not require collateral, and losses on accounts receivable have historically not been significant. No single customer represented more than 10% of our accounts receivable as of December 31, 2023 or 2022.

Foreign Currency Risk

The majority of our business is currently conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows.

Inflation Risk

Inflationary factors, such as increases in our cost of goods sold and selling and operating expenses, may adversely affect our operating results. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, a high rate of inflation in the future may have an adverse effect on our ability to maintain and increase our gross margin and selling and marketing and operating expenses as a percentage of our revenue if the selling prices of our products do not increase as much as or more than these increased costs.

Item 8. Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Inspire Medical Systems, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Inspire Medical Systems, 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 three 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 three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 9, 2024 expressed an unqualified opinion thereon.

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 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. 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Inventory valuation reserves

Description of the Matter

At December 31, 2023, the Company's net inventory balance was $33.9 million. As explained in Note 2 to the financial statements, the determination of a reserve for excess and obsolete inventory involves management exercising judgment to determine the required reserve, considering future demand, product life cycles, introduction of new products, and current market conditions.

Auditing management's estimate for excess and obsolete inventory involved subjective auditor judgment because of the assumptions and judgments used to calculate the inventory valuation reserve, including consideration of the timing of the introduction of new products and current market conditions. In particular, the excess and obsolete inventory calculations are sensitive to significant assumptions, including forecasted customer demand, technological and/or market obsolescence, introduction of new products, and possible alternative uses.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls over the Company's process to determine the amount of the Company's reserve for excess and obsolete inventory. This included controls over the Company's review of the significant assumptions underlying the reserve estimate.

To test the adequacy of the Company's inventory valuation reserve, we performed audit procedures that included, among others, testing the accuracy and completeness of the underlying data used in the estimation calculations and evaluating significant assumptions, specifically forecasted customer demand, technological and/or market obsolescence, introduction of new products and possible alternative uses. We evaluated management's ability to accurately estimate the amount of excess and obsolete inventory by comparing actual inventory write-off activity in recent years to management's prior year estimates of the inventory valuation reserve. We also audited management's calculation of the inventory valuation reserve by testing the mathematical accuracy of the Company's reserve calculation.

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

/s/Ernst & Young LLP

Minneapolis, Minnesota
February 9, 2024

Inspire Medical Systems, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 185,537	$ 441,592
Investments, short-term	274,838	9,821
Accounts receivable, net of allowance for credit losses of $1,648 and $36, respectively	89,884	61,228
Inventories, net	33,885	11,886
Prepaid expenses and other current assets	9,595	5,505
Total current assets	593,739	530,032
Investments, long-term	9,143	—
Property and equipment, net	39,984	17,249
Operating lease right-of-use assets	22,667	6,880
Other non-current assets	11,278	10,715
Total assets	$ 676,811	$ 564,876
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 38,839	$ 26,847
Accrued expenses	39,266	34,339
Total current liabilities	78,105	61,186
Operating lease liabilities, non-current portion	24,846	7,536
Other non-current liabilities	1,346	146
Total liabilities	104,297	68,868
Stockholders' equity		
Preferred Stock, $0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common Stock, $0.001 par value, 200,000,000 shares authorized; 29,560,464 and 29,008,368 shares issued and outstanding at December 31, 2023 and 2022, respectively	30	29
Additional paid-in capital	917,107	820,335
Accumulated other comprehensive income (loss)	800	(86)
Accumulated deficit	(345,423)	(324,270)
Total stockholders' equity	572,514	496,008
Total liabilities and stockholders' equity	$ 676,811	$ 564,876

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

Inspire Medical Systems, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2023	**2022**	**2021**
Revenue	$ 624,799	$ 407,856	$ 233,394
Cost of goods sold	96,576	66,115	33,279
Gross profit	528,223	341,741	200,115
Operating expenses:			
Research and development	116,536	68,645	37,350
Selling, general and administrative	451,958	320,688	202,615
Total operating expenses	568,494	389,333	239,965
Operating loss	(40,271)	(47,592)	(39,850)
Other expense (income):			
Interest and dividend income	(20,560)	(5,050)	(125)
Interest expense	—	1,677	2,128
Other expense, net	195	49	117
Total other (income) expense	(20,365)	(3,324)	2,120
Loss before income taxes	(19,906)	(44,268)	(41,970)
Income taxes	1,247	613	72
Net loss	(21,153)	(44,881)	(42,042)
Other comprehensive loss:			
Foreign currency translation gain	140	89	—
Unrealized gain (loss) on investments	746	(120)	(84)
Total comprehensive loss	$ (20,267)	$ (44,912)	$ (42,126)
Net loss per share, basic and diluted	$ (0.72)	$ (1.60)	$ (1.54)
Weighted average common shares used to compute net loss per share, basic and diluted	29,302,154	28,071,748	27,262,979

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

Inspire Medical Systems, Inc.

STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share amounts)

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2020	27,069,276	27	467,038	29	(237,347)	229,747
Stock options exercised	323,860	—	11,476	—	—	11,476
Issuance of common stock	1,463	—	301	—	—	301
Issuance of common stock for employee stock purchase plan	21,507	—	3,472	—	—	3,472
Stock-based compensation expense	—	—	26,178	—	—	26,178
Other comprehensive loss	—	—	—	(84)	—	(84)
Net loss	—	—	—	—	(42,042)	(42,042)
Balance at December 31, 2021	27,416,106	27	508,465	(55)	(279,389)	229,048
Stock options exercised	416,602	1	12,080	—	—	12,081
Vesting of restricted stock units	569	—	—	—	—	—
Shares held for tax withholdings	(205)	—	(43)	—	—	(43)
Issuance of common stock	1,587	—	325	—	—	325
Sale of common stock from follow-on public offering, net of offering expenses	1,150,000	1	243,800	—	—	243,801
Issuance of common stock for employee stock purchase plan	23,709	—	3,738	—	—	3,738
Stock-based compensation expense	—	—	51,970	—	—	51,970
Other comprehensive loss	—	—	—	(31)	—	(31)
Net loss	—	—	—	—	(44,881)	(44,881)
Balance at December 31, 2022	29,008,368	$ 29	$ 820,335	$ (86)	$ (324,270)	$ 496,008
Stock options exercised	595,188	1	25,808	—	—	25,809
Vesting of restricted stock units	40,915	—	—	—	—	—
Shares held for tax withholdings	(113,062)	—	(17,158)	—	—	(17,158)
Issuance of common stock	1,575	—	353	—	—	353
Issuance of common stock for employee stock purchase plan	27,480	—	5,299	—	—	5,299
Stock-based compensation expense	—	—	82,470	—	—	82,470
Other comprehensive income	—	—	—	886	—	886
Net loss	—	—	—	—	(21,153)	(21,153)
Balance at December 31, 2023	29,560,464	$ 30	$ 917,107	$ 800	$ (345,423)	$ 572,514

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

Inspire Medical Systems, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,		
	2023	2022	2021
Operating activities			
Net loss	$ (21,153)	$ (44,881)	$ (42,042)
Adjustments to reconcile net loss:			
Depreciation and amortization	2,846	1,858	1,218
(Accretion) amortization of investment (discount) premium	(2,469)	(4)	14
Non-cash lease expense	1,400	1,040	771
Stock-based compensation expense	82,470	51,970	26,178
Non-cash stock issuance for services rendered	353	325	301
Other, net	1,987	(549)	296
Changes in operating assets and liabilities:			
Accounts receivable	(30,218)	(27,017)	(9,244)
Inventories	(21,999)	5,345	(8,752)
Prepaid expenses and other assets	(4,758)	(2,815)	(696)
Accounts payable	9,296	14,355	4,779
Accrued expenses and other liabilities	6,898	11,942	7,058
Net cash provided by (used in) operating activities	24,653	11,569	(20,119)
Investing activities			
Purchases of property and equipment	(23,629)	(9,096)	(4,668)
Purchases of investments	(281,189)	—	(9,993)
Proceeds from sales or maturities of investments	10,246	—	43,800
Purchases of strategic investments	(250)	(10,500)	—
Net cash (used in) provided by investing activities	(294,822)	(19,596)	29,139
Financing activities			
Payments on long-term debt obligation	—	(24,500)	—
Proceeds from the exercise of stock options	25,809	12,081	11,476
Proceeds from sale of common stock	—	243,801	—
Payment of taxes on net share settlement of equity awards	(17,158)	(43)	—
Proceeds from the issuance of common stock from employee stock purchase plan	5,299	3,738	3,472
Net cash provided by financing activities	13,950	235,077	14,948
Effect of exchange rate on cash	164	75	(19)
(Decrease) increase in cash and cash equivalents	(256,055)	227,125	23,949
Cash and cash equivalents at beginning of year	441,592	214,467	190,518
Cash and cash equivalents at end of year	$ 185,537	$ 441,592	$ 214,467
Supplemental cash flow information			
Cash paid for interest	$ —	$ 2,321	$ 1,888
Property and equipment included in accounts payable and accrued expenses	4,018	2,067	274

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

1. Organization

Description of Business

Inspire Medical Systems, Inc. is a medical technology company focused on the development and commercialization of innovative, minimally invasive solutions for patients with obstructive sleep apnea ("OSA"). Our proprietary Inspire system is the first and only United States ("U.S.") Food and Drug Administration ("FDA") approved neurostimulation technology that provides a safe and effective treatment for moderate to severe OSA. Inspire therapy received premarket approval ("PMA") from the FDA in 2014 and has been commercially available in certain European markets since 2011 and certain Asia Pacific markets since 2021.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC").

In the opinion of management, all adjustments, consisting of only normal recurring adjustments that are necessary to present fairly the financial position, results of operations, and cash flows have been made. The results of operations for the year ended December 31, 2023 are not necessarily indicative of the operating results for any future periods.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the consolidated financial statements. We use significant judgment when making estimates related to the inventory reserves and stock-based awards. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Follow-On Public Offering

In August 2022, we completed a follow-on offering that included our offer and sale of 1,150,000 shares of common stock at a public offering price of $215.00 per share. We received net proceeds of $243.8 million after deducting underwriting discounts, commissions, and offering expenses.

Cash and Cash Equivalents

We consider all highly liquid securities, readily convertible to cash, that have original maturities of 90 days or less from the date of purchase to be cash equivalents. Cash is carried at cost, which approximates fair value, and cash equivalents, which consist of money market funds and corporate debt securities, are stated at fair value.

Foreign Currency

Our functional and reporting currency is the U.S. dollar. Our subsidiaries have functional currency in Euro and Yen. The consolidated financial statements are translated to U.S. dollars. Non-monetary assets and liabilities denominated in foreign currencies are translated at rates of exchange in effect at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are translated using the exchange rate prevailing

(Table amounts in thousands, except share and per share amounts)

at the balance sheet date. Sales and expenses denominated in foreign currencies are translated at exchange rates in effect on the date of the transaction. Foreign currency transaction gains and losses and the impacts of foreign currency remeasurement are recognized in other expense, net in the consolidated statements of operations and comprehensive loss. For the years ended December 31, 2023 and 2022, we recognized a total of $0.2 million and $0.1 million of losses, net, respectively. Any unrealized gains and losses due to translation adjustments are included in accumulated other comprehensive loss within stockholders' equity in the consolidated balance sheets. We had $0.2 million and $0.1 million of unrecognized gain in our accumulated other comprehensive loss balance as of December 31, 2023 and 2022, respectively.

Investments

Our investments are classified as available-for-sale and consist of the following:

	December 31, 2023			
	Amortized Cost	Unrealized Gross Gains	Unrealized Gross Losses	Aggregate Fair Value
Short-Term:				
Commercial paper	$ 2,950	$ 1	$ —	$ 2,951
Corporate debt securities	30,154	61	—	30,215
Certificates of deposit	2,953	15	—	2,968
U.S. treasury debt securities	238,237	467	—	238,704
Short-term investments	$ 274,294	$ 544	$ —	$ 274,838
Long-Term:				
Corporate debt securities	$ 3,109	$ 13	$ —	$ 3,122
Asset-backed securities	1,170	1	—	1,171
U.S. treasury debt securities	4,838	12	—	4,850
Long-term investments	$ 9,117	$ 26	$ —	$ 9,143

	December 31, 2022			
	Amortized Cost	Unrealized Gross Gains	Unrealized Gross Losses	Aggregate Fair Value
Short-Term:				
U.S. treasury debt securities	$ 9,998	$ —	$ (177)	$ 9,821
Short-term investments	$ 9,998	$ —	$ (177)	$ 9,821

Investments are classified as available-for-sale and are reported at their estimated fair market values which are based on quoted, active or inactive market prices when available. Any unrealized gains and losses due to interest rate fluctuations and other external factors are reported as a separate component of accumulated other comprehensive income (loss) within stockholders' equity. We had $0.6 million of unrecognized gain and $0.2 million of unrecognized loss in our accumulated other comprehensive income (loss) balance at December 31, 2023 and 2022, respectively. Any realized gains and losses are calculated on the specific identification method and reported net in other expense, net in the consolidated statements of operations and comprehensive loss. For both of the years ended December 31, 2023 and 2022, we recognized $0 of gains, net.

As of December 31, 2023, we had no investments with a contractual maturity of greater than three years. Currently, we do not intend to sell the investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost bases, which may be maturity. We do not consider those investments to be other-than-temporarily impaired as of December 31, 2023. Each reporting period, we evaluate

whether declines in fair value below carrying value are due to expected credit losses, as well as our ability and intent to hold the investment until a forecasted recovery occurs. Expected credit losses, not to exceed the amount of the unrealized loss, are recorded as an allowance through other expense, net in the consolidated statements of operations and comprehensive loss. The total allowance for credit losses was $0 at both December 31, 2023 and 2022.

Fair Value of Financial Instruments

We measure certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents and investments. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

Level 1: Observable inputs, such as quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2: Inputs include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, and inputs (other than quoted prices) that are observable for the asset or liability, either directly or indirectly.

Level 3: Unobservable inputs that are supported by little or no market activities, which would require us to develop our own assumptions.

We classify instruments within Level 1 if quoted prices are available in active markets for identical assets, which include our money market funds and U.S. treasury securities. We classify instruments in Level 2 if the instruments are valued using observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or an income approach, such as a discounted cash flow pricing model that calculates values from observable inputs such as quoted interest rates, yield curves and other observable market information. These instruments include our commercial paper, certificates of deposit, corporate debt securities and asset-backed securities. The available-for-sale securities are held by a custodian who obtains investment prices from a third-party pricing provider that uses standard inputs (observable in the market) to models which vary by asset class.

The following tables sets forth by level within the fair value hierarchy our assets that are measured on a recurring basis and reported at fair value as of December 31, 2023 and 2022. Assets are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

(Table amounts in thousands, except share and per share amounts)

	Fair Value Measurements as of December 31, 2023			
	Estimated Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 146,217	$ 146,217	$ —	$ —
Total cash equivalents	146,217	146,217	—	—
Investments:				
Commercial paper	$ 2,951	$ —	$ 2,951	$ —
Corporate debt securities	33,337	—	33,337	—
Certificates of deposit	2,968	—	2,968	—
Asset-backed securities	1,171	—	1,171	—
U.S. government securities	243,554	243,554	—	—
Total investments	283,981	243,554	40,427	—
Total cash equivalents and investments	$ 430,198	$ 389,771	$ 40,427	$ —

	Fair Value Measurements as of December 31, 2022			
	Estimated Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$ 390,846	$ 390,846	$ —	$ —
Total cash equivalents	390,846	390,846	—	—
Investments:				
U.S. government securities	9,821	9,821	—	—
Total investments	9,821	9,821	—	—
Total cash equivalents and investments	$ 400,667	$ 400,667	$ —	$ —

There were no transfers between levels during the years ended December 31, 2023 and 2022.

Concentration of Credit Risk

Financial instruments, which potentially subject us to concentrations of credit risk, consist principally of cash equivalents, investments, and accounts receivable. We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we will be able to access uninsured funds in a timely manner or at all.

Our investment policy limits investments to certain types of debt securities issued by the U.S. government and its agencies, corporations with investment-grade credit ratings, or commercial paper and money market funds issued by the highest quality financial and non-financial companies. We place restrictions on maturities and concentration by type and issuer. We are exposed to credit risk in the event of a default by the issuers of these securities to the extent recorded on the consolidated balance sheets. However, as of December 31, 2023 and 2022, we limited our credit risk associated with cash equivalents by placing investments with banks we believe are highly creditworthy.

We believe that the credit risk in our accounts receivable is mitigated by our credit evaluation process, relatively short collection terms, and dispersion of our customer base. We generally do not require collateral, and losses on accounts receivable have historically not been significant.

(Table amounts in thousands, except share and per share amounts)

Accounts Receivable and Allowance for Expected Credit Losses

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. Customer credit terms are established prior to shipment with the general standard being net 30 days. Collateral or any other security to support payment of these receivables generally is not required.

Each reporting period, we estimate the credit loss related to accounts receivable based on a migration analysis of accounts grouped by individual receivables delinquency status and apply our historic loss rate adjusted for management's assumption of future market conditions. Any change in the allowance from new receivables acquired or changes due to credit deterioration on previously existing receivables is recorded in selling, general and administrative expenses. Write-offs of receivables considered uncollectible are deducted from the allowance. Specific accounts receivable are written-off once a determination is made that the amount is uncollectible. The write-off is recorded in the period in which the account receivable is deemed uncollectible. Recoveries are recognized when received and as a direct credit to earnings or as a reduction to the allowance for credit losses (which would indirectly reduce the loss by decreasing bad debt expense).

The following table presents the changes in the allowance for credit losses related to accounts receivable:

	Year Ended December 31,		
	2023	2022	2021
Balance at beginning of period	$ 36	$ 99	$ 42
Charges (credits) to the allowance, net	1,622	(13)	57
Accounts written off, net of recoveries	(10)	(50)	—
Balance at the end of the period	$ 1,648	$ 36	$ 99

The increase in charges to the allowance during the year ended December 31, 2023 relate primarily to accounts receivable with two healthcare systems.

Inventories

Inventories are valued at the lower of cost or net realizable value, computed on a first-in, first-out basis, and consisted of the following:

	December 31,	
	2023	2022
Raw materials	$ 6,115	$ 5,645
Finished goods	27,770	6,241
Total inventories, net of reserves	$ 33,885	$ 11,886

We expense prelaunch inventory as research and development expense in the period incurred unless objective and persuasive evidence exists that regulatory approval and subsequent commercialization of a product candidate is probable and where we also expect the future economic benefit from the sales of the product candidate to be realized.

We regularly review inventory quantities on-hand for excess and obsolete inventory and, when circumstances indicate, incur charges to write down inventories to their net realizable value. The determination of a reserve for excess and obsolete inventory involves management exercising judgment to determine the required reserve, considering future demand, product life cycles, introduction of new products, and current market conditions. During the year ended December 31, 2022, we recorded a $1.8 million inventory reserve related to product introductions, including the new silicone-based leads and the Bluetooth®-enabled patient remote. The reserve for excess and obsolete inventory was $2.4 million and $2.7 million as of December 31, 2023 and 2022, respectively.

(Table amounts in thousands, except share and per share amounts)

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization and consisted of the following:

	December 31,	
	2023	2022
Computer equipment and software	$ 2,601	$ 1,729
Manufacturing equipment	7,245	5,974
Other equipment	1,842	535
Leasehold improvements	2,356	2,064
Construction in process	33,211	11,857
Property and equipment, cost	47,255	22,159
Less: accumulated depreciation and amortization	(7,271)	(4,910)
Property and equipment, net	$ 39,984	$ 17,249

Construction in process is comprised primarily of production equipment. Depreciation is determined using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the term of the lease. Depreciation and amortization expense was $2.8 million, $1.9 million, and $1.2 million during the years ended December 31, 2023, 2022, and 2021, respectively.

Strategic Investments

For equity securities without readily determinable fair values, we have elected the measurement alternative under which we measure these investments at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. These securities are presented within other non-current assets on the consolidated balance sheets. The balance of equity securities without readily determinable fair values was $10.4 million and $10.5 million as of December 31, 2023 and 2022, respectively. We recognized an impairment charge of $0.4 million during the year ended December 31, 2023 due to a deterioration in the performance and quality of one of the equity securities that had an original carrying amount of $0.8 million. There was no adjustment to the carrying amounts during the year ended December 31, 2022.

Impairment of Long-lived Assets

Long-lived assets consist primarily of property and equipment, operating lease right-of-use assets, and strategic investments are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require that an asset be tested for possible impairment, we compare the undiscounted cash flows expected to be generated by the asset to the carrying amount of the asset. If the carrying amount of the asset is not recoverable on an undiscounted cash flow basis, we determine the fair value of the asset and recognize an impairment loss to the extent the carrying amount of the asset exceeds its fair value. We determine fair value using the income approach based on the present value of expected future cash flows or other appropriate measures of estimated fair value. Our cash flow assumptions consider historical and forecasted revenue and operating costs and other relevant factors. We did not record any impairment charges on long-lived assets, other than the $0.4 million discussed above in the *Strategic Investments* section, during the years ended December 31, 2023, 2022, or 2021.

(Table amounts in thousands, except share and per share amounts)

Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2023	2022
Payroll related	$ 33,875	$ 30,398
Product warranty liability	1,100	920
Operating lease liabilities, current portion	—	1,336
Other accrued expenses	4,291	1,685
Total accrued expenses	$ 39,266	$ 34,339

The following table shows the changes in our estimated product warranty liability accrual, included in accrued liabilities:

	Year Ended December 31,		
	2023	2022	2021
Balance at beginning of period	$ 920	$ 468	$ 159
Provisions for warranty	912	798	576
Settlements of warranty claims	(732)	(346)	(267)
Balance at the end of the period	$ 1,100	$ 920	$ 468

Revenue Recognition

We derive our revenue from sales of our products in the U.S. and internationally. Customers are primarily comprised of hospitals and ambulatory surgery centers, with distributors being used in certain international locations where we do not have a direct commercial presence.

Revenues from product sales are recognized when the customer obtains control of the product, which occurs at a point in time, either upon shipment of the product or receipt of the product, depending on shipment terms. Our standard shipping terms are free on board shipping point, unless the customer requests that control and title to the inventory transfer upon delivery. In those cases where shipping and handling costs are billed to customers, we classify the amounts billed as a component of cost of goods sold.

Revenue is measured as the amount of consideration we expect to receive, adjusted for any applicable estimates of variable consideration and other factors affecting the transaction price, which is based on the invoiced price, in exchange for transferring products. All revenue is recognized when we satisfy our performance obligations under the contract. The majority of our contracts have a single performance obligation and are short term in nature.

Sales taxes and value added taxes in foreign jurisdictions that are collected from customers and remitted to governmental authorities are accounted for on a net basis and therefore are excluded from net sales. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of goods sold.

Variable consideration related to certain customer sales incentives is estimated based on the amounts expected to be paid based on the agreement with the customer using probability assessments.

We offer customers a limited right of return for our product in case of non-conformity or performance issues. We estimate the amount of our product sales that may be returned by our customers based on historical sales and returns. As our historical product returns to date have been immaterial, we have not recorded a reduction in revenue related to variable consideration for product returns.

See Note 8 for disaggregated revenue by geographic area.

Cost of Goods Sold

Cost of goods sold consists primarily of acquisition costs for the components of the Inspire system, overhead costs, scrap and inventory obsolescence, warranty replacement costs, as well as distribution-related expenses such as logistics and shipping costs, net of shipping costs charged to customers. The overhead costs include the cost of material procurement, depreciation expense for production equipment, and operations supervision and management personnel, including employee compensation, stock-based compensation, supplies, and travel.

Research and Development

Research and development expenses consist primarily of product development, clinical and regulatory affairs, quality assurance, consulting services, and other costs associated with products and technologies in development. These expenses include employee compensation, including stock-based compensation, supplies, materials, prelaunch inventory, consulting, and travel expenses related to research and development programs. Clinical expenses include clinical study design, clinical site reimbursement, data management, travel expenses, and the cost of manufacturing products for clinical studies.

We expense prelaunch inventory as research and development expense in the period incurred unless objective and persuasive evidence exists that regulatory approval and subsequent commercialization of a product candidate is probable and where we also expect the future economic benefit from the sales of the product candidate to be realized. Prelaunch inventory expenses were $5.2 million and $0 during the years ended December 31, 2023 and 2022, respectively.

Stock-Based Compensation

We maintain an equity incentive plan to provide long-term incentives for eligible employees, consultants, and members of the board of directors. The plan allows for the issuance of restricted stock units ("RSUs"), performance stock units ("PSUs"), and non-statutory and incentive stock options to employees, and RSUs, PSUs, and non-statutory stock options to consultants and directors. We also offer an employee stock purchase plan ("ESPP") which allows participating employees to purchase shares of our common stock at a discount through payroll deductions.

We recognize equity-based compensation expense for awards of equity instruments based on the grant date fair value of those awards as expense in the consolidated statements of operations and comprehensive loss. We estimate the fair value of stock options using the Black-Scholes option pricing model and the fair value of RSUs and PSUs is equal to the closing price of our common stock on the grant date. The fair value of each purchase under the employee stock purchase plan is estimated at the beginning of the offering period using the Black-Scholes option pricing model.

Stock-based compensation expense is recognized on a straight-line basis over the vesting term for stock options and RSUs, and over the vesting and performance period based on the probability of achieving the performance objectives for PSUs. We account for award forfeitures as they occur.

Advertising Expenses

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses were $100.3 million, $74.3 million, and $47.8 million during the years ended December 31, 2023, 2022, and 2021, respectively.

Leases

Operating leases are included in operating lease right-of-use ("ROU") assets, accrued expenses, and operating lease liabilities – non-current portion in our consolidated balance sheets. ROU assets represent our right to use an

underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, we use our incremental borrowing rate based on the information available at the lease commencement date as the rate implicit in the lease is not readily determinable. The determination of our incremental borrowing rate requires management judgment based on information available at lease commencement. The operating lease ROU assets also include adjustments for prepayments, accrued lease payments, and exclude lease incentives. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise such options. Operating lease cost is recognized on a straight-line basis over the expected lease term. Lease agreements that include lease and non-lease components are accounted for as a single lease component. Lease agreements with a noncancelable term of less than 12 months are not recorded on our consolidated balance sheets.

Income Taxes

We account for income taxes using the liability method. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. Valuation allowances against deferred tax assets are established, when necessary, to reduce deferred tax assets to the amounts expected to be realized. As we have historically incurred operating losses, we have recorded a full valuation allowance against our net deferred tax assets, and there is no provision for income taxes other than minimal state and foreign taxes, which includes a foreign tax provision relating to uncertain tax positions. Our policy is to record interest and penalties expense related to uncertain tax positions as other expense in the consolidated statements of operations and comprehensive loss.

Comprehensive Loss

Comprehensive loss consists of net loss and changes in unrealized gains and losses due to interest rate fluctuations and other external factors on investments classified as available-for-sale, and foreign currency translation adjustments. Accumulated other comprehensive income (loss) is presented in the accompanying consolidated balance sheets as a component of stockholders' equity.

Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Because we have reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share as all potentially dilutive shares consisting of outstanding stock options, unvested RSUs and PSUs, and shares issuable under our employee stock purchase plan were antidilutive in those periods.

Purchase Commitments

As of December 31, 2023, we had purchase commitments to suppliers for purchases totaling $91.4 million.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* (“ASU 2023-07”). The standard requires disclosure of significant segment expenses that are regularly provided to the chief operating decision maker (“CODM”) and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items to reconcile to segment profit or loss, and the title and position of the entity’s CODM. The amendments in this update also expand the interim segment disclosure requirements. This authoritative guidance will be effective for us in fiscal

(Table amounts in thousands, except share and per share amounts)

2025 for annual periods and in the first quarter of fiscal 2026 for interim periods, with early adoption permitted. We are currently evaluating the effect of this new guidance on our consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Improvements to Income Tax Disclosures* ("ASU 2023-09"). The guidance is intended to improve income tax disclosure requirements by requiring (i) consistent categories and greater disaggregation of information in the rate reconciliation and (ii) the disaggregation of income taxes paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements. The amendments in ASU 2023-09 are effective for us in fiscal 2025, with early adoption permitted, and is required to be applied prospectively with the option of retrospective application. We are evaluating the impact of the standard on our income tax disclosures.

We have reviewed and considered all other recent accounting pronouncements that have not yet been adopted and believe there are none that could potentially have a material impact on our business practices, financial condition, results of operations, or disclosures.

3. Leases

We lease office space for our corporate headquarters under a non-cancelable operating lease. The corporate office leases were amended in May 2023 to increase the total space leased to approximately 106,000 square feet and to extend the noncancellable lease term through May 31, 2035, resulting in a non-cash increase in the associated right-of-use asset and lease liability of $15.1 million. We entered into an additional warehouse and office space lease for our corporate headquarters under a non-cancelable operating lease in August 2023. This space includes approximately 22,000 square feet and a noncancellable lease term through May 31, 2035, resulting in an associated right-of-use asset and lease liability of $2.3 million. Each lease includes options to renew for up to two additional period of five years each at the then-prevailing market rates. The exercises of the lease renewal options are at our sole discretion and were not included in the lease term for the calculation of the ROU assets and lease liabilities as of the lease modification date as they were not reasonably certain of exercise.

In addition to base rent in these leases, we also pay our proportionate share of the operating expenses, as defined in the leases. These payments are made monthly and adjusted annually to reflect actual charges incurred for operating expenses, such as common area maintenance, taxes, and insurance.

The following table presents the lease balances within the consolidated balance sheets:

	December 31,	
	2023	2022
Right-of-use assets:		
Operating lease right-of-use assets	$ 22,667	$ 6,880
Operating lease liabilities:		
Accrued liabilities	—	1,336
Operating lease liabilities, non-current portion	24,846	7,536
Total operating lease liabilities	$ 24,846	$ 8,872

(Table amounts in thousands, except share and per share amounts)

The cost components of our operating leases were as follows:

	Year Ended December 31,		
	2023	2022	2021
Operating lease cost	$ 2,166	$ 1,529	$ 1,125
Short-term lease cost	250	—	—
Variable lease cost	1,667	1,366	1,001
Total lease cost	$ 4,083	$ 2,895	$ 2,126

Variable lease costs consist primarily of taxes, insurance, and common area maintenance costs.

Maturities of our lease liability for our operating lease are as follows as of December 31, 2023:

2024	$ (3,582)
2025	3,056
2026	3,313
2027	3,416
2028	3,523
Thereafter	25,363
Total undiscounted lease payments	35,089
Less: imputed interest	(10,243)
Present value of lease liability	$ 24,846

As of December 31, 2023, the remaining lease terms were 11.4 years and the weighted average discount rate was 4.9%. The operating cash outflows from our operating leases were $2.2 million, $0.7 million, and $0.1 million for the years ended December 31, 2023, 2022, and 2021, respectively.

4. Long-Term Debt

In March 2019, we amended our $24.5 million loan and security agreement, which we refer to as our former credit facility. The debt was interest only until April 1, 2022 and was scheduled to mature on March 1, 2024. The basic interest rate was the 30-day U.S. LIBOR rate, subject to a floor of 7.60%. In addition to the principal and interest payments, we were required to pay a final payment fee of 3.50% on all amounts outstanding, which was being accreted using the effective interest rate method over the term of the credit facility and was to be due at the earlier of maturity or prepayment. Borrowings were prepayable in whole at our option, subject to a prepayment fee of 1.00%.

In August 2022, we prepaid the outstanding principal balance of $19.4 million, the final payment fee of $0.9 million, and the prepayment fee of $0.2 million. As of December 31, 2023, we had no remaining amounts outstanding under our former credit facility.

5. Employee Retirement Plan

We sponsor a defined contribution employee retirement plan covering all of our full-time employees. The plan allows for eligible employees to defer a portion of their eligible compensation up to the maximum allowed by IRS Regulations. Beginning January 1, 2022, we elected to begin making voluntary matching contributions to the plan. We match 50% of the first 6% of each participating employee's contribution, up to 3% of eligible earnings. Our

(Table amounts in thousands, except share and per share amounts)

match contributions are made to funds designated by the participant, none of which are based on Inspire common stock. Discretionary contributions to the plan totaled $3.7 million and $2.4 million for the years ended December 31, 2023 and 2022, respectively.

6. Stock-Based Compensation

As of December 31, 2023, there were 4,233,020 shares reserved for issuance under our equity incentive plan, of which 1,510,522 shares were available for issuance.

Stock-based compensation expense is recognized on a straight-line basis over the vesting term for stock options and RSUs, and over the performance period based on the probability of achieving the performance objectives for PSUs, and is reduced by actual forfeitures as they occur. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase, or cancel any remaining unearned stock compensation expense. Future stock-based compensation expense and unearned stock-based compensation will increase to the extent that we grant additional stock-based awards.

Stock Options

Options are granted at the exercise price, which is equal to the closing price of our stock on the date of grant. The stock options granted to employees include a four-year service period and 25% vest after the first year of service and the remainder vest in equal monthly installments over the next 36 months of service. The stock options granted to the board of directors vest in one or three equal annual installments, in each case subject to the director's continuous services through the applicable vesting date. The stock options have a contractual life of ten years.

The fair value per share of options is estimated on the date of grant using the Black-Scholes option pricing model.

Option Value and Assumptions

	Year Ended December 31,		
	2023	2022	2021
Weighted average fair value	$149.70	$121.43	$113.71
Assumptions:			
Expected term (years)	6.25	5.50 - 6.25	5.50 - 6.25
Expected volatility	56.4% - 58.2%	56.2% - 57.0%	54.9% - 55.9%
Risk-free interest rate	3.49% - 4.89%	1.75% - 4.18%	0.79% - 1.44%
Expected dividend yield	—%	—%	—%

Expected Term — Due to our limited amount of historical exercise, forfeiture, and expiration activity, we have opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting terms and the original contractual term of the option. We will continue to analyze our expected term assumption as more historical data becomes available.

Expected Volatility — Due to our limited company specific historical and implied volatility data, we have incorporated our historical stock trading volatility with those of a group of similar companies that are publicly traded for the calculation of volatility. When selecting this peer group of public companies on which we have based our expected stock price volatility, we generally selected companies with comparable characteristics, including enterprise value, stages of clinical development, risk profiles, position within the industry, and those with historical share price information sufficient to meet the expected life of the stock-based awards. We will continue to analyze the historical stock price volatility assumption as more historical data for our common stock becomes available.

Risk-Free Interest Rate — The risk-free rate assumption is based on the U.S. government Treasury instruments with maturities similar to the expected term of our stock options.

Expected Dividend Yield — The expected dividend assumption is based on our history of not paying dividends and our expectation that we will not declare dividends for the foreseeable future.

Stock Option Activity

	Options	Weighted Average Exercise Price	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2020	2,857,564	$ 66.09	7.9	$ 351,626
Granted	228,302	$215.34		
Exercised	(323,860)	$ 35.44		$ 58,360
Forfeited/expired	(115,771)	$118.85		
Outstanding at December 31, 2021	2,646,235	$ 80.41	7.1	$ 397,015
Granted	500,148	$217.85		
Exercised	(416,602)	$ 29.00		$ 73,036
Forfeited/expired	(69,047)	$161.48		
Outstanding at December 31, 2022	2,660,734	$112.19	6.9	$ 372,068
Granted	441,394	$257.22		
Exercised	(595,188)	$ 45.09		$ 105,952
Forfeited/expired	(59,799)	$214.61		
Outstanding at December 31, 2023	2,447,141	$152.17	7.0	$ 160,691
Exercisable at December 31, 2023	1,573,566	$107.96	6.1	$ 155,377

The aggregate intrinsic value of options exercised is the difference between the estimated fair market value of our common stock at the date of exercise and the exercise price for those options. The aggregate intrinsic value of outstanding options is the difference between the closing price as of the date outstanding and the exercise price of the underlying stock options. The total grant date fair value of options vested during the year was $45.7 million, $30.6 million and $23.9 million for the years ended December 31, 2023, 2022, and 2021, respectively. As of December 31, 2023, the amount of unearned stock-based compensation currently estimated to be expensed from now through the year 2027 related to unvested stock options is $99.6 million which we expect to recognize over a weighted average period of 2.5 years.

Restricted Stock Units

RSUs are share awards that entitle the holder to receive freely tradable shares of our common stock upon vesting. The RSUs cannot be transferred and the awards are subject to forfeiture if the holder's service terminates prior to the release of the vesting restrictions. The RSUs granted to employees include three- or four-year service periods and vest in equal installments on each anniversary of the date of grant. The RSUs granted to the board of directors include one- or three-year service periods and vest in equal installments on each anniversary of the date of grant. The fair value of the RSUs is equal to the closing price of our common stock on the grant date. A summary of RSUs and related information is as follows:

	Restricted Stock Units	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value (in thousands)
Unvested at December 31, 2020	—	$ —	$ —
Granted	2,275	$ 201.51	
Unvested at December 31, 2021	2,275	$ 201.51	$ 524
Granted	130,463	$ 214.16	
Vested	(569)	$ 201.51	$ 118
Forfeited	(7,489)	$ 214.40	
Unvested at December 31, 2022	124,680	$ 213.97	$ 31,404
Granted	128,661	$ 249.58	
Vested	(40,915)	$ 214.06	$ 10,190
Forfeited	(11,356)	$ 236.30	
Unvested at December 31, 2023	201,070	$ 235.47	$ 40,904

There were no RSUs granted prior to 2021. The aggregate intrinsic value of unvested RSUs was based on our closing stock price on the last trading day of the period. The aggregate intrinsic value of vested RSUs was based on our closing stock price on the date of vest. As of December 31, 2023, the amount of unearned stock-based compensation currently estimated to be expensed from now through the year 2026 related to unvested RSUs is $34.4 million which we expect to recognize over a weighted average period of 1.9 years.

Performance Stock Units

During 2022 and 2023, we granted PSUs to officers and key employees. The number of PSUs that will ultimately be earned is based on our performance relative to pre-established goals for the three-year periods ending December 31, 2024 and December 31, 2025, respectively. The expense is recorded on a straight-line basis over the requisite service periods based on an estimate of the number of PSUs expected to vest. Management expectations related to the achievement of the performance goals associated with PSU grants are assessed each reporting period. The number of shares earned at the end of each of the three-year periods will vary based on actual performance, from 0% to 200% of the number of PSUs granted. If the performance conditions are not met or not expected to be met, any compensation expense recognized associated with the grant will be reversed.

A summary of PSUs and related information is as follows:

	Performance Stock Units	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value (in thousands)
Unvested at December 31, 2021	—	$ —	$ —
Granted	78,351	$ 227.53	
Forfeited	(879)	$ 227.53	
Unvested at December 31, 2022	77,472	$ 227.53	$ 19,514
Granted	95,994	$ 264.59	
Forfeited	(4,497)	$ 242.27	
Unvested at December 31, 2023	168,969	$ 248.19	$ 34,373

There were no PSUs granted prior to 2022. The fair value of the PSUs is equal to the closing price of our common stock on the grant date. The aggregate intrinsic value of unvested PSUs was based on our closing stock price on the last trading day of the period. As of December 31, 2023, there was $27.6 million of unrecognized stock-based

(Table amounts in thousands, except share and per share amounts)

compensation expense related to outstanding PSUs that is expected to be recognized over a weighted average period of 1.8 years.

Employee Stock Purchase Plan

Employees may participate in our ESPP provided they meet certain eligibility requirements. The purchase price for our common stock under the terms of the ESPP is defined as 85% of the lower of the closing market price per share of our common stock on the first or last trading day of a purchase period. We issued 27,480 shares under the ESPP during 2023 and there were 1,063,223 shares available for future issuance under the ESPP as of December 31, 2023.

7. Income Taxes

Due to our cumulative net loss position, a valuation allowance is required for all deferred tax assets as of December 31, 2023, 2022, and 2021.

The components of our provision for income taxes are as follows:

	December 31,		
	2023	2022	2021
Current			
United States	$ 644	$ 342	$ 23
Foreign	603	271	49
Total current	1,247	613	72
Total provision for income taxes	$ 1,247	$ 613	$ 72

The reconciliation of taxes at the federal statutory rate to our provision for income taxes are as follows:

	Year Ended December 31,		
	2023	2022	2021
Tax at federal statutory rate	21.0 %	21.0 %	21.0 %
State, net of federal benefit	4.0	3.4	4.0
Stock-based compensation	33.6	9.1	18.1
Research and development ("R&D") tax credit	20.6	6.4	3.3
Other	(4.6)	(0.7)	0.4
Executive compensation	(16.3)	(0.1)	—
Change in valuation allowance	(64.6)	(40.5)	(47.0)
Total	(6.3)%	(1.4)%	(0.2)%

(Table amounts in thousands, except share and per share amounts)

Significant components of net deferred tax assets and liabilities were as follows:

	Year Ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating losses	$ 57,276	$ 64,321
R&D tax credits	14,110	9,626
R&D expenditures, capitalized for tax	22,533	14,230
Accruals and other	3,587	2,305
Depreciation	79	—
Lease liability	6,138	2,223
Inventory	2,561	997
Stock-based compensation	16,824	12,439
Other comprehensive loss	—	44
Total deferred tax assets	123,108	106,185
Deferred tax liabilities:		
Depreciation	—	(9)
Lease asset	(5,600)	(1,724)
Other comprehensive income	(141)	—
Total deferred tax liabilities	(5,741)	(1,733)
Net deferred tax assets	117,367	104,452
Valuation allowance	(117,367)	(104,452)
	$ —	$ —

Deferred income taxes reflect the tax effects of net operating loss and tax credit carryforwards and the net temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

As of December 31, 2023, our gross federal net operating loss carryforwards of $226.1 million will expire at various dates beginning in 2034. In addition, net operating loss carryforwards for state income tax purposes of $173.5 million will begin to expire in 2024. We also have gross R&D credit carryforwards of $14.7 million as of December 31, 2023 which will expire at various dates beginning in 2033.

Under the Tax Cuts and Jobs Act of 2017, R&D costs are no longer fully deductible and are required to be capitalized and amortized for U.S. tax purposes effective January 1, 2022. The mandatory capitalization requirement increased our deferred tax assets, which were fully offset by a decrease in our net operating loss carry forwards and an increase in the valuation allowance.

Utilization of the net operating loss carryforwards and R&D credit carryforwards may be subject to an annual limitation due to the ownership change limitations provided by Section 382 and Section 383 of the Code and similar state provisions. During 2023, we finalized a detailed analysis to determine whether an ownership change has occurred through December 31, 2022, and if a limitation exists. It was determined that December 11, 2018 was the only date that we experienced an ownership change. The study concluded that none of the $126.5 million of federal net operating losses nor the $1.7 million of federal R&D credits that were accumulated on December 11, 2018 will expire unused solely due to the limitations under Sections 382 and 383 of the Code. We are in the process of updating the analysis through December 31, 2023. Although unexpected, if we experienced an ownership change during 2023, the timing of our ability to utilize the tax attributes may be affected.

(Table amounts in thousands, except share and per share amounts)

Realization of the deferred tax assets is dependent upon the generation of future taxable income, if any, the amount and timing of which are uncertain. Based on available objective evidence and cumulative losses, we believe it is more likely than not that the deferred tax assets are not recognizable and will not be recognizable until we have sufficient book income. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $12.9 million and $17.5 million during the years ended December 31, 2023 and 2022, respectively.

The changes to our gross unrecognized tax benefits were as follows:

	Year Ended December 31,		
	2023	2022	2021
Balance beginning of the year	$ 146	$ 134	$ 85
Increase in balances related to current year tax positions	—	12	49
Increase in balances related to prior year tax positions	—	—	—
Balance end of the year	$ 146	$ 146	$ 134

We file income tax returns in the applicable jurisdictions. The 2020 to 2022 tax years remain open to examination by the major taxing authorities to which we are subject. We do not expect a significant change to our unrecognized tax benefits over the next 12 months.

Our policy is to record interest related to uncertain tax positions as interest expense and any penalties as other expense in our consolidated statements of operations and comprehensive loss. There were no interest or penalties accrued as of December 31, 2023 and 2022.

8. Segment Reporting and Revenue Disaggregation

We operate our business as one operating segment. An operating segment is defined as a component of an enterprise for which separate discrete financial information is available and evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance.

We sell our Inspire system to hospitals and ambulatory surgery centers in the U.S. and in select countries in Europe and Japan through a direct sales organization, and in Singapore and Hong Kong through distributors. Revenue by geographic region is as follows:

	Year Ended December 31,		
	2023	2022	2021
United States	$ 606,178	$ 394,833	$ 220,976
All other countries	18,621	13,023	12,418
Total revenue	$ 624,799	$ 407,856	$ 233,394

Long-lived tangible assets by geographic location were as follows:

	December 31,	
	2023	2022
United States	$ 39,916	$ 17,249
All other countries	68	—
Total long-lived tangible assets	$ 39,984	$ 17,249

(Table amounts in thousands, except share and per share amounts)

9. Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Because we have reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share as all of the following potentially dilutive shares were antidilutive in those periods.

The following common stock-based awards were excluded from the computation of diluted net loss per common share for the periods presented because including them would have been anti-dilutive:

	Year Ended December 31,		
	2023	2022	2021
Common stock options outstanding	2,447,141	2,660,734	2,646,235
Unvested restricted stock units	201,070	124,680	2,275
Total	2,648,211	2,785,414	2,648,510

10. Related Party Transaction

In December 2023, we entered into an agreement with an entity controlled by our CEO (the "Entity"), pursuant to which we agreed to share the costs of a corporate suite at a sports and entertainment venue (the "Venue") (the “Suite”) (the “Cost Sharing Agreement”). In August 2023, the Entity entered into an agreement with the Venue, pursuant to which the Entity acquired certain rights to use the Suite for specified sporting and other events at the Venue through August 2026. Pursuant to this agreement, the Entity agreed to pay $0.2 million per year, with each year beginning September 1 and ending August 31, and the fee increasing by 5% for each succeeding year. Under the Cost Sharing Agreement, we will reimburse the Entity 50% of the cost of the Suite in exchange for the right to use the Suite for 50% of the specified events at the Venue through August 2026.

11. Commitments and Contingencies

On December 22, 2023, plaintiff City of Hollywood Firefighters’ Pension Fund, on behalf of itself and similarly situated investors, filed a putative class action lawsuit in the United States District Court for the District of Minnesota against the Company and certain of its executive officers, captioned *City of Hollywood Firefighters’ Pension Fund v. Inspire Medical Systems, Inc., et. al.*, 0:23-cv-03884 (D. Minn). The complaint generally alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, by making allegedly materially false and misleading statements between May 3, 2023 and November 7, 2023 regarding the effectiveness of the Company’s Acceleration Program, a program designed to facilitate customers’ receiving prior authorizations from doctors with the goal of increasing demand for the Company’s Inspire therapy. The Complaint alleges that when subsequent disclosures were made regarding issues with the Acceleration Program and the Company announced its third quarter 2023 financial results, the Company’s stock price fell, causing significant losses and damages. The plaintiffs are seeking, among other things, unquantified compensatory damages, attorneys' fees and costs. The defendants believe the allegations are without merit and intend to vigorously defend against these claims.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in the Company's internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, that occurred during the quarter ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management 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 Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, a company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's 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 U.S. generally accepted accounting principles. It includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. 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
- 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2023, based on the criteria set forth in “Internal Control-Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

Ernst & Young LLP, our independent registered public accounting firm that audited the consolidated financial statements included in this Annual Report on Form 10-K, has issued an attestation report on our internal control over financial reporting. See Report of Independent Registered Public Accounting Firm below.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Inspire Medical Systems, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Inspire Medical Systems, Inc.'s internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Inspire Medical Systems, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of Inspire Medical Systems, Inc. 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 three years in the period ended December 31, 2023, and the related notes and our report dated February 9, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/Ernst & Young LLP

Minneapolis, Minnesota

February 9, 2024

Item 9B. Other Information.

(b) Adoption or Termination of Trading Arrangements by Directors and Executive Officers

Name	Title	Action	Rule 10b5-1 Adoption/ Termination Date	Aggregate Number of Shares of Common Stock to be Sold	Expiration Date
John C. Rondoni	Chief Technology Officer	Terminate	November 23, 2023	12,992	June 28, 2024
John C. Rondoni	Chief Technology Officer	Adopt	November 30, 2023	12,992	November 29, 2024
Jerry Griffin, M.D.	Director	Terminate	November 30, 2023	17,296	November 30, 2023
Jerry Griffin, M.D.	Director	Adopt	November 30, 2023	4,296	May 30, 2024

There were no other Rule 10b5-1 trading arrangements or non-Rule 10b5-1 trading arrangements adopted, modified or terminated by the Company's directors and executive officers during the quarter ended December 31, 2023.

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

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2024 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2024 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

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

The following table provides information as of December 31, 2023 regarding our common stock that may be issued under the Inspire Medical Systems, Inc. 2007 Incentive Award Plan, as amended (the "2007 Plan"), the Inspire Medical Systems, Inc. 2017 Incentive Award Plan, as amended (the "2017 Plan"), the Inspire Medical Systems, Inc. 2018 Incentive Award Plan (the "2018 Plan") and the Inspire Medical Systems, Inc. 2018 Employee Stock Purchase Plan (the "2018 ESPP").

Plan category:	Number of Securities to be Issued Upon Exercise of Outstanding Options, Restricted Stock Units, and Performance Stock Units (a)	Weighted-Average Exercise Price of Outstanding Options, Restricted Stock Units, and Performance Stock Units (b)	Number of Securities Available for Future Issuance Under Equity Compensation Plans (excludes securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders			
2007 Plan (1)	78,560	$ 1.15	—
2017 Plan (1)	16,122	$ 7.65	—
2018 Plan (2)	2,722,498	$ 136.70	1,510,522
2018 ESPP (3)	—	$ —	1,063,223
Equity compensation plans not approved by stockholders	—	$ —	—
Total	2,817,180	$ 132.18	2,573,745

(1) The 2007 Plan terminated in accordance with its terms on November 28, 2017; however, outstanding stock options may continue to be exercised in accordance with their terms. In connection with our IPO, we adopted the 2018 Plan and do not make grants or awards under the 2017 Plan.

(2) Pursuant to the terms of the 2018 Plan, the number of shares of common stock available for issuance under the 2018 Plan automatically increases on each January 1, until and including January 1, 2028, by an amount equal to the lesser of (a) 739,631 shares, (b) 4% of the number of shares of common stock outstanding (on an as-converted basis) on the last day of the immediately preceding fiscal year, and (c) such smaller number of shares as is determined by our board of directors. The weighted average exercise price is calculated without taking into account restricted stock that will become issuable, without any cash consideration or other payment, as vesting requirements are achieved.

(3) Pursuant to the terms of the 2018 ESPP Plan, the number of shares reserved under the 2018 ESPP Plan will automatically be supplemented each January 1, until and including January 1, 2028, by an amount of shares equal to the lesser of a) 184,908 shares, b) 1% of the shares outstanding on the final day of the immediately preceding calendar year, and c) such smaller number of shares as the board of directors may determine.

Other

The remaining information required by this Item is incorporated by reference to our definitive proxy statement for our 2024 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

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

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2024 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

Item 14. Principal Accounting Fees and Services.

Our independent registered public accounting firm is Ernst & Young LLP, Minneapolis, MN, Auditor Firm ID: 42.

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2024 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

(1) Financial Statements

The consolidated financial statements included in Part II, Item 8 of this document are filed as part of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

All schedules are omitted because they are not applicable or the amounts are immaterial or the required information is presented in the consolidated financial statements and notes thereto in Part II, Item 8 above.

(3) Exhibits

The following documents are filed as exhibits to this Annual Report on Form 10-K.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
3.1	Seventh Amended and Restated Certificate of Incorporation of Inspire Medical Systems, Inc.	8-K	001-38468	3.1	5/7/2018	
3.2	Amended and Restated Bylaws of Inspire Medical Systems, Inc.	8-K	001-38468	3.2	5/7/2018	
4.1	Form of Certificate of Common Stock	S-1	333-224176	4.1	4/23/2018	
4.2	Fifth Amended and Restated Investor Rights Agreement, dated October 25, 2016, among Inspire Medical Systems, Inc. and the Investors party thereto	S-1	333-224176	4.2	4/6/2018	
4.3	Amendment No. 1 to Fifth Amended and Restated Investor Rights Agreement, dated April 20, 2018, among Inspire Medical Systems, Inc. and the Investors party thereto	S-1	333-224176	4.3	4/23/2018	
4.6	Description of Capital Stock	10-K	001-38468	4.6	2/25/2020	
10.1	Assignment and License Agreement, dated as of November 28, 2007, by and between Inspire Medical Systems, Inc. and Medtronic, Inc.	S-1	333-224176	10.1	4/6/2018	
10.2	First Amendment to Assignment and License Agreement, dated as of February 4, 2010, by and between Inspire Medical Systems, Inc. and Medtronic, Inc.	S-1	333-224176	10.2	4/6/2018	
10.3†	2007 Stock Incentive Plan, as amended	S-1	333-224176	10.6	4/6/2018	
10.4†	Form of Incentive Stock Option Agreement pursuant to 2007 Stock Incentive Plan	S-1	333-224176	10.7	4/6/2018	
10.5†	2017 Stock Incentive Plan, as amended	S-1	333-224176	10.8	4/6/2018	
10.6†	Form of Incentive Stock Option Agreement pursuant to 2017 Stock Incentive Plan	S-1	333-224176	10.9	4/6/2018	
10.7†	Form of Non-Statutory Stock Option Agreement pursuant to 2017 Stock Incentive Plan	S-1	333-224176	10.10	4/6/2018	
10.8†	Inspire Medical Systems, Inc. 2018 Incentive Award Plan	S-1	333-224176	10.11	4/23/2018	
10.9†	Form of Stock Option Award Agreement under Inspire Medical Systems, Inc. 2018 Incentive Award Plan	S-1	333-224176	10.12	4/23/2018	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.10†	Amended Form of Stock Option Award Agreement under Inspire Medical Systems, Inc. 2018 Incentive Award Plan for awards granted on or after January 31, 2023	10-K	001-38468	10.10	2/10/2023	
10.11†	Form of Restricted Stock Unit Award Agreement under Inspire Medical Systems, Inc. 2018 Incentive Award Plan	10-K	001-38468	10.13	2/24/2021	
10.12†	Form of Performance Stock Unit Award Agreement under Inspire Medical Systems, Inc. 2018 Incentive Award Plan	10-K	001-38468	10.14	2/15/2022	
10.13†	Inspire Medical Systems, Inc. 2018 Employee Stock Purchase Plan	S-1	333-224176	10.13	4/23/2018	
10.14†	Amended and Restated Employment Agreement, by and between Inspire Medical Systems, Inc. and Timothy Herbert	S-1	333-224176	10.15	4/23/2018	
10.15†	Amended and Restated Employment Agreement, by and between Inspire Medical Systems, Inc. and Randy Ban	S-1	333-224176	10.17	4/23/2018	
10.16†	Amended and Restated Employment Agreement, by and between Inspire Medical Systems, Inc. and Richard Buchholz	S-1	333-224176	10.19	4/23/2018	
10.17†	Amended and Restated Employment Agreement, by and between Inspire Medical Systems, Inc. and Steven Jandrich	S-1	333-224176	10.21	4/23/2018	
10.18†	Employment Agreement between the Company and Philip Ebeling	8-K	001-38468	10.1	6/8/2020	
10.19†	Employment Agreement between the Company and Bryan Phillips	10-K	001-38468	10.20	2/24/2021	
10.20†	Employment Agreement between the Company and Carlton Weatherby	10-Q	001-38468	10.2	8/1/2023	
10.21†	Employment Agreement between the Company and Charisse Sparks	10-Q	001-38468	10.1	11/7/2023	
10.22†	Form of Indemnification Agreement between Inspire Medical Systems, Inc. and its directors and officers	S-1	333-224176	10.23	4/6/2018	
10.23†	Inspire Medical Systems, Inc. Non-Employee Director Compensation Policy	10-Q	001-38468	10.1	8/1/2023	
21.1	Subsidiaries of Inspire Medical Systems, Inc.					*
23.1	Consent of Ernst & Young LLP					*
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					*
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
97.1	Inspire Medical Systems, Inc. Recovery of Erroneously Awarded Compensation Policy					**

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

* Filed herewith.

** Furnished herewith.

† Denotes a management contract or compensation plan or arrangement.

Certain agreements filed as exhibits to this Annual Report on Form 10-K contain representations and warranties that the parties thereto made to each other. These representations and warranties have been made solely for the benefit of the other parties to such agreements and may have been qualified by certain information that has been disclosed to the other parties to such agreements and that may not be reflected in such agreements. In addition, these representations and warranties may be intended as a way of allocating risks among parties if the statements contained therein prove to be incorrect, rather than as actual statements of fact. Accordingly, there can be no reliance on any such representations and warranties as characterizations of the actual state of facts. Moreover, information concerning the subject matter of any such representations and warranties may have changed since the date of such agreements.

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, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Inspire Medical Systems, Inc.

Date: February 9, 2024

By: /s/ TIMOTHY P. HERBERT
Timothy P. Herbert
President and Chief Executive Officer
(principal executive officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on February 9, 2024.

Signature	Title
/s/ TIMOTHY P. HERBERT Timothy P. Herbert	Chief Executive Officer (principal executive officer), President and Director
/s/ RICHARD BUCHHOLZ Richard Buchholz	Chief Financial Officer (principal financial and accounting officer)
/s/ MARILYN CARLSON NELSON Marilyn Carlson Nelson	Chair of the Board of Directors
/s/ SHELLEY G. BROADER Shelley G. Broader	Director
/s/ CYNTHIA B. BURKS Cynthia B. Burks	Director
/s/ MYRIAM J. CURET, M.D. Myriam J. Curet, M.D.	Director
/s/ GARY L. ELLIS Gary L. Ellis	Director
/s/ JERRY C. GRIFFIN, M.D. Jerry C. Griffin, M.D.	Director
/s/ SHAWN T MCCORMICK Shawn T McCormick	Director
/s/ DANA G. MEAD, JR. Dana G. Mead, Jr.	Director
/s/ GEORGIA MELENIKIOTOU Georgia Melenikiotou	Director
/s/ CASEY M. TANSEY Casey M. Tansey	Director

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Board of Directors

Marilyn Carlson Nelson
Chair of the Board, Former Co-Chair & Co-Chief Executive Officer, Carlson Holdings, Inc.

Timothy P. Herbert
President and Chief Executive Officer, Inspire Medical Systems, Inc.

Shelley G. Broader
Former Chief Executive Officer, Chico's FAS

Cynthia B. Burks
Former Chief Human Resources Officer, Genetech, Inc.

Myriam J. Curet, M.D.
Executive Vice President and Chief Medical Officer, Intuitive Surgical, Inc.

Gary L. Ellis
Former Chief Financial Officer, Medtronic, Inc.

Georgia Garinois-Melenikiotou
Former Executive Vice President, The Estée Lauder Companies

Jerry C. Griffin, M.D.
President, Griffin & Schwartz, Scientific Services, Inc.

Shawn T McCormick
Former Chief Financial Officer, Aldevron, LLC & Tornier N.V.

Dana G. Mead, Jr.
Former Chief Executive Officer, HeartFlow, Inc.

Casey M. Tansey
General Partner, U.S. Venture Partners

Senior Leadership

Timothy P. Herbert
President and Chief Executive Officer

Richard J. Buchholz
Chief Financial Officer

Randall A. Ban
Chief Commercial Officer

Philip J. Ebeling
Chief Operating Officer

Bryan K. Phillips
Chief Compliance Officer, General Counsel, and Secretary

John C. Rondoni
Chief Technology Officer

Charisse Y. Sparks, M.D.
Chief Medical Officer

Carlton Weatherby
Chief Strategy Officer

Steven L. Jandrich
Vice President, Human Resources

Andreas Henke
Executive Vice President, Managing Director Europe

Ivan Lubogo
Senior Vice President, U.S. Sales

Kathy L. Sherwood
Senior Vice President, Global Market Access

Ezgi Yagci
Vice President, Investor Relations

Corporate Information

Annual Meeting of Stockholders
Our annual meeting will be a completely virtual meeting of stockholders.

May 2, 2024 at 8:00 AM CT
www.virtualshareholdermeeting.com/INSP2024

Stock Exchange
New York Stock Exchange
Symbol: **INSP**

Independent Registered Public Accounting Firm
Ernst & Young LLP
Minneapolis, Minnesota

Outside Counsel
Stinson LLP
Minneapolis, Minnesota

Latham & Watkins LLP
New York, New York

Investor Inquiries
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Transfer Agent & Registrar
Equiniti Trust Company, LLC

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New York, New York 10005
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Safe Harbor Statement

Statements in this document regarding future events and expectations, such as forecasts, plans, trends and projections relating to the Company's business and financial performance, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements speak only as of the date such statements are made and are subject to risks and uncertainties that could cause the Company's results to differ materially from these statements. These risks and uncertainties are described in the Company's Annual Report on Form 10-K, and Inspire undertakes no obligation to update them unless otherwise required by law.

No mask.
No hose.
Just sleep.™

Inspire®

Corporate Headquarters

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