FORM S-1 · REGISTRATION STATEMENT

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INSPIRE MEDICAL SYSTEMS, INC. INDEX TO FINANCIAL STATEMENTS

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON DECEMBER 4, 2018

REGISTRATION NO. 333-

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

FORM S-1 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Inspire Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

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Delaware	**3841**	**26-1377674**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

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9700 63rd Ave. N., Suite 200

Maple Grove, MN 55369 (844) 672-4357

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices) **Timothy P. Herbert**

Chief Executive Officer 9700 63rd Ave. N., Suite 200 Maple Grove, MN 55369 (844) 672-4357 (Name, address, including zip code, and telephone number, including area code, of agent for service)

User-specified TAGGED TABLE

Copies to:	
B. Shayne Kennedy **Nathan Ajiashvili Latham & Watkins LLP 650 Town Center Drive, 20th Floor** **Costa Mesa, CA 92626 (714) 540-1235**	**Ilir Mujalovic** **Shearman & Sterling LLP 599 Lexington Avenue New** **York, NY 10022 (212) 848-4000**

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Approximate date of commencement of proposed sale to the public:

As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o 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.

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Large accelerated filer o	Accelerated filer o	Non-accelerated filer ý	Smaller reporting company ý Emerging growth company ý

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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 7(a)(2)(B) of the Securities Act. o

CALCULATION OF REGISTRATION FEE

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Title of Each Class of Securities To Be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common Stock, $0.001 par value per share	$137,683,750	$16,688

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(1)
Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes 375,000 shares of common stock that the underwriters have an option to purchase.

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

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

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

Subject to Completion
Preliminary Prospectus dated December 4, 2018 PROSPECTUS 2,500,000 Shares Inspire Medical Systems, Inc.

Common Stock

We are selling 1,500,000 shares of our common stock and the selling stockholders named in this prospectus are selling 1,000,000 shares of our common stock. We will not receive any proceeds from the sale of shares of our common stock to be offered by the selling stockholders.

Our common stock is listed on the New York Stock Exchange under the symbol "INSP." On December 3, 2018, the last reported sale price of our common stock as reported on the New York Stock Exchange was $47.89 per share.

We are an "emerging growth company" under the federal securities laws and are subject to reduced public company disclosure standards. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

Investing in the common stock involves risks that are described in the "Risk Factors" section beginning on page 12 of this prospectus.

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	PER SHARE	TOTAL
Public offering price		$ $
Underwriting discount(1)		$ $
Proceeds, before expenses, to us		$ $
Proceeds, before expenses, to the selling stockholders		$ $

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(1)
We refer you to "Underwriting" beginning on page 164 for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional 375,000 shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

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

The shares will be ready for delivery on or about , 2018.

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BofA Merrill Lynch	Leerink Partners	Wells Fargo Securities

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Guggenheim Securities	Stifel

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The date of this prospectus is , 2018

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We have not, the selling stockholders have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We, the selling stockholders and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

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

TRADEMARKS

This prospectus includes our trademarks and trade names, including, without limitation, Inspire®, Inspire Medical Systems, Inc.™, Inspire Cloud™, Inspire Upper Airway Stimulation™ and our logo, which are our property and are protected under applicable intellectual property laws. This prospectus also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this prospectus may appear without the ®, ™ or ^{SM} symbols, but such references are not intended to indicate, in any way, that we or the applicable owner will not assert, to the fullest extent permitted under applicable law, our or its rights or the right of any applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

MARKET AND INDUSTRY DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management's estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. We believe that the information from these third-party publications, research, surveys and studies included in this prospectus is reliable. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

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Prospectus Summary

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the "Risk Factors" section beginning on page 12 and our financial statements and the related notes appearing at the end of this prospectus, before making an investment decision.

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

Overview

We are a medical technology company focused on the development and commercialization of innovative and minimally invasive solutions for patients with obstructive sleep apnea. Our proprietary Inspire system is the first and only FDA-approved neurostimulation technology that provides a safe and effective treatment for moderate to severe obstructive sleep apnea. 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. The safety and efficacy of our Inspire therapy is supported by a significant body of clinical data, which includes a publication in the *New England Journal of Medicine* and more than 70 peer-reviewed publications. Inspire therapy received premarket approval, or PMA, from the U.S. Food and Drug Administration, or FDA, in April 2014 and has been commercially available in certain European markets since November 2011.

Inspire therapy is indicated for patients with moderate to severe obstructive sleep apnea 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 must have been confirmed to fail or be unable to tolerate positive airway pressure treatments, such as CPAP, and be 22

years of age or older, though there are no similar requirements for patients in Europe. Physicians have treated more than 4,000 patients with Inspire therapy at over 220 medical centers across the United States and Europe.

Sleep apnea is a serious and chronic disease that negatively impacts a patient's sleep, health and quality of life. According to the World Health Organization, sleep apnea affects more than 100 million people worldwide. Obstructive sleep apnea, or 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, or AHI. Moderate OSA patients have an AHI of 15 to 30 events per hour, while severe OSA patients have an AHI of 30 or 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.

Continuous positive airway pressure, or 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. The effectiveness of CPAP has been limited by low patient compliance, as many patients find the mask or treatment cumbersome, uncomfortable and loud. According to published literature, only approximately 35% to 65% of patients prescribed a CPAP device are compliant with the therapy. When CPAP fails or cannot be tolerated, patients' remaining treatment options are limited and consist primarily of invasive surgical procedures. We believe that there is both an urgent clinical need and a strong market opportunity for an alternative to CPAP that is safe, effective and minimally invasive.

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. Our Inspire system consists of a remote control and three implantable components, which include a pressure sensing lead, a neurostimulator and a stimulation lead. Once implanted, the Inspire system uses a proprietary algorithm to continuously monitor a patient's breathing and delivers electrical stimulation that causes a slight forward movement of the back of the tongue. This forward movement helps to maintain an open airway, enabling the patient to inhale freely and without interruption.

The results from multiple clinical trials, which include four sponsored and 12 independent clinical studies, together with patient-reported outcomes, 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 clinical trial, the Stimulation Therapy for Apnea Reduction, or STAR, trial, was designed to demonstrate longitudinal therapy efficacy and included a randomized controlled therapy withdrawal study. Patients in the longitudinal study experienced 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. Ongoing 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 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 Inspire therapy experienced sustained therapeutic benefits.

We sell our Inspire system to hospitals and ambulatory surgery centers, or ASCs, in the United States and in select countries in Europe through a direct sales organization. We have 40 sales representatives in the United States and six in Europe. Our direct sales force engages in sales efforts and promotional activities focused on ear, nose and throat, or 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-patient marketing initiatives to create awareness of the benefits of our Inspire system and drive demand through patient empowerment. This outreach has helped to educate thousands of patients on our Inspire therapy and frequently results in patient leads.

Our customers are reimbursed the cost required to treat each patient through various third-party payors, such as commercial payors and government agencies. We are in active discussions with commercial payors to establish positive national coverage policies to support reimbursement of Inspire therapy. In July 2018, Aetna Inc., one of the leading health plans in the United States, began providing coverage for our Inspire therapy, bringing the number of our secured positive coverage policies to nine U.S. commercial payors. In parallel, our 15-person reimbursement team, which we refer to as our market access team, is focused on assisting patients and physicians in obtaining appropriate prior authorization approvals from commercial payors on a case-by-

case basis in advance of treatment with our Inspire therapy. We have been successful in obtaining prior authorization approvals from approximately 300 commercial payors. In addition, Medicare may cover our procedure on a medical necessity basis. We also have a U.S. government contract for patients who are treated by the Veterans Health Administration.

We generated revenue of $28.6 million, with a gross margin of 78.9% and a net loss of $17.5 million, for the year ended December 31, 2017, compared to revenue of $16.4 million, with a gross margin of 76.2% and a net loss of $18.5 million, for the year ended December 31, 2016, and revenue of $8.0 million, with a gross margin of 64.9% and a net loss of $21.3 million for the year ended December 31, 2015. For the nine months ended September 30, 2018, we generated revenue of $34.0 million with a gross margin of 79.8% and a net loss of $17.1 million compared to revenue of $18.6 million with a gross margin of 77.8% and a net loss of $13.3 million for the nine months ended September 30, 2017. Our accumulated deficit as of September 30, 2018 was $142.1 million.

Our Market Opportunity

The market for OSA treatment is large and growing. We believe there is a significant population in the United States with moderate to severe OSA who are unable to use or get consistent benefit from CPAP and who are eligible for our Inspire therapy. Currently, there are approximately 17 million individuals in the United States with moderate to severe OSA. Based on industry sources, we estimate that approximately 2 million patients are prescribed a CPAP device annually in the United States. Further, based on published literature, we estimate that at least 35% of patients prescribed a CPAP device are not compliant with the therapy and approximately 70% of those non-compliant patients have an airway anatomy that would allow for effective treatment with Inspire therapy. As a result, we believe the annual total addressable market for our Inspire therapy in the United States to be approximately 500,000 patients, which, based on our average selling price per implantation, represents an estimated annual market opportunity of approximately $10 billion. We also believe there is a substantial market opportunity outside the United States.

Current Treatments for OSA and their Limitations

There are several treatment options for OSA patients depending on the level of severity of the disease, ranging from lifestyle changes to surgery. Some patients are prescribed an oral device designed to prevent the airway from collapsing by shifting the position of the jaw forward; however, these devices are not always effective and are used primarily in mild to slightly moderate cases. CPAP is the leading therapy for patients with moderate to severe OSA but faces significant limitations as a therapeutic option, primarily due to low patient compliance. Commonly cited reasons patients fail to use the CPAP device on a regular basis include mask discomfort, mask leakage, pressure intolerance, skin irritation, nasal congestion, nasal drying, nosebleeds, claustrophobia and lack of intimacy. Low patient compliance persists despite the development of various CPAP devices designed to improve patient comfort and treatment through a variety of methods. In cases of moderate to severe OSA where CPAP has failed or patients have discontinued treatment, surgery may be an alternate therapy. Two of the primary surgical procedures for treating OSA are uvulopalatopharyngoplasty, or UPPP, and maxillomandibular advancement, or MMA. Both of these are invasive in-patient procedures that irreversibly alter the patient's anatomy, require extended recovery periods which are often painful, and have limited or unpredictable clinical benefit.

Our Solution for OSA

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, which is the nerve that controls forward movement of the tongue. To receive the Inspire system, patients undergo a short, minimally invasive outpatient surgical procedure, typically lasting two hours, during which the neurostimulator, sensing lead and stimulation lead are implanted in a series of three small incisions. Patients typically recover quickly and are able to resume normal activities in just a few days. Once the Inspire system has been activated, patients are able to turn it 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.

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** 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 provides electrical stimulation during the inspiratory phase.
- **Comfortable and convenient therapy resulting in high patient satisfaction** that was reported to be 94% at an average of 12 months from initial treatment in the first 508 patients in our ongoing global patient registry.
- **Strong patient compliance**, with 80% of patients reporting continued nightly use through five years from initial treatment in our pivotal 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.

`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. Unlike CPAP, our Inspire therapy has shown high patient compliance. We believe our high patient compliance rate is due to our innovative, closed-loop, minimally invasive solution that is designed to provide comfort and convenience. We believe we have a significant first mover advantage and momentum over future competitors, as physicians have treated more than 4,000 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 four sponsored and 12 independent clinical studies that evaluated approximately 980 patients, including more than 280 patients evaluated in independent clinical studies, and have been highlighted in more than 70 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 that centers on active engagement with patients, physicians and sleep centers. 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. In addition, we are highlighting 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-patient marketing initiatives which helps to educate thousands of patients on our Inspire therapy and frequently results in patient leads. We are confident that our 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 highly efficient approach to advance patients, once identified, to placement of the Inspire system. Our dedicated market access team helps patients and providers work with payors to secure the appropriate prior authorization approvals in advance of initial treatment. This highly leverageable team has been successful in securing reimbursement from approximately 300 commercial payors. In addition, this team continues to work with payors to establish positive coverage policies by

highlighting the compelling clinical data and the economic benefits of our Inspire therapy, and has successfully secured positive coverage policies from nine U.S. commercial payors to date, including Aetna, Inc.

- ***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 the United States, we launched in July 2017 the fourth generation of our Inspire system, which has several benefits including a significantly smaller size with an approximate 11-year battery life and allowing patients to undergo an MRI scan of the head or extremities. We launched our fourth generation Inspire system in Europe in the second quarter of 2018. We have a comprehensive patent portfolio to protect our intellectual property and technology, with rights as of September 30, 2018 to 20 issued U.S. patents, 22 issued foreign patents, 25 pending U.S. patent applications and 39 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:

- ***Promote awareness among patients, ENT physicians, sleep centers and referring physicians.*** We believe that many patients and physicians are unaware of our Inspire therapy. We intend to continue to promote awareness of our therapy through training and educating ENT physicians, sleep centers, referring physicians, key opinion leaders and various medical societies. We also plan to continue building patient awareness through our direct-to-patient marketing initiatives, which include paid search, radio, social media and online videos.
- ***Expand our U.S. sales and marketing organization to drive adoption of our Inspire therapy.*** We plan to expand our sales and marketing organization and seek to recruit and train exceptionally talented sales representatives in existing and new markets in the United States to help us broaden adoption of our Inspire therapy and drive revenue growth.
- ***Leverage our prior authorization model while we work with payors to broaden coverage.*** Our dedicated in-house market access team will continue to assist patients and physicians in obtaining prior authorization approvals from commercial payors for treatment with our Inspire therapy. In parallel, we plan to continue our active discussions with commercial payors to establish positive national coverage policies.
- ***Invest in research and development to drive innovation and expand indications.*** We are committed to ongoing research and development and intend to invest in our business to further improve our products and clinical outcomes, increase patient acceptance and comfort and broaden the patient population that can benefit from our Inspire therapy. For example, we are currently evaluating the use of Inspire therapy in pediatric patients with Down syndrome.
- ***Further penetrate and expand into existing and new international markets.*** We plan to establish and strengthen our presence in existing international markets in Europe, including Germany and the Netherlands, and expand our reach to new international markets, such as Japan.

Risks Associated with Our Business

Our business is subject to a number of risks that you should be aware of before making an investment decision. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth under "Risk Factors" in deciding whether to invest in our common stock. Among these important risks are the following:

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

- Our revenue is primarily generated from sales of our Inspire system and we are therefore highly dependent on it for our success.
- If we are unable to increase patient and physician awareness of our Inspire therapy, our ability to increase our revenue and grow our business will be impaired.
- 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.
- 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.
- 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 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.
- Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.
- 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.

Corporate Information

We were incorporated in Delaware in November 2007 when our predecessor, Inspire Medical Systems, LLC, a Minnesota limited liability company, was spun-off from Medtronic Inc. (now Medtronic Public Limited Company), or Medtronic. Inspire Medical Systems, LLC merged with us in November 2007, and we continued as the surviving entity. Our offices are located at 9700 63rd Avenue North, Suite 200, Maple Grove, Minnesota 55369. Our telephone number is (844) 672-4357. Our corporate website is *www.inspiresleep.com*. The information contained on or that can be accessed through our website is not incorporated by reference into this prospectus, and you should not consider information on our website to be part of this prospectus or in deciding to purchase our common stock.

Implications of Being an Emerging Growth Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we may take advantage of certain exemptions from various reporting requirements that are applicable to other publicly-traded entities that are not emerging growth companies. These exemptions include:

- the option to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);

- not being required to submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay," "say-on-frequency," and "say-on-golden parachutes;" and
- not being required to disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

As a result, we do not know if some investors will find our common stock less attractive. The result may be a less active trading market for our common stock, and the price of our common stock may become more volatile.

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 13(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, as a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable.

We will remain an emerging growth company until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion; (ii) the last day of 2023; (iii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common equity held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during any three-year period.

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The Offering

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Common stock offered by us	1,500,000 shares.
Common stock offered by the selling stockholders	1,000,000 shares.
Common stock to be outstanding after this offering	22,891,590 shares (or 23,266,590 if the underwriters exercise in full their option to purchase additional shares of common stock).
Option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to 375,000 additional shares of our common stock at the public offering price less the underwriting discounts and commissions.
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $66.8 million (or approximately $83.7 million if the underwriters exercise in full their option to purchase additional shares of common stock), based on an assumed public offering price of $47.89 per share, the last reported sale price of our common stock on the New York Stock Exchange, or NYSE, on December 3, 2018, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to hire additional sales and marketing personnel and expand marketing programs in the United States, Europe and Japan, to fund product development and research and development activities and the remainder for working capital and general corporate purposes.
	We will not receive any proceeds from the sale of any shares of our common stock by the selling stockholders in this offering. See "Use of Proceeds."
Risk factors	Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 12 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
NYSE symbol	"INSP."

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The number of shares of our common stock to be outstanding after this offering is based on 21,391,590 shares of our common stock outstanding as of September 30, 2018, and excludes:

- 2,198,130 shares of our common stock issuable upon the exercise of options outstanding as of September 30, 2018, at a weighted average exercise price of $3.80 per share;
- 1,209,585 additional shares of our common stock reserved for future issuance under our 2018 Incentive Award Plan, or 2018 Plan, as of September 30, 2018, as well as shares of our common stock that may be issued pursuant to provisions of our 2018 Plan that automatically increase the common stock reserve under our 2018 Plan;
- 80,884 shares of our common stock issuable upon the exercise of warrants to purchase shares of our common stock outstanding as of September 30, 2018 at a weighted average exercise price of $9.61 per share, 31,270 of which were issued pursuant to the net exercise of certain warrants subsequent to September 30, 2018; and
- 277,362 shares of our common stock reserved for future issuance under our 2018 Employee Stock Purchase Plan, or ESPP, as of September 30, 2018 as well as shares of our common stock that may be issued pursuant to provisions in our ESPP that automatically increase the common stock reserve under the ESPP.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- no exercise of the outstanding options and warrants referred to above; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock from the selling stockholders.

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Summary Historical Financial Data

The following tables set forth, for the periods and as of the dates indicated, our summary historical financial data. The statements of operations data for the years ended December 31, 2015, 2016 and 2017 are derived from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the nine months ended September 30, 2017 and 2018 and the balance sheet data as of September 30, 2018 are derived from our unaudited interim condensed financial statements included elsewhere in this prospectus. In our opinion, these unaudited interim condensed financial statements have been prepared on a basis consistent with our audited financial statements and contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such financial data. Our historical results are not necessarily indicative of the results that may be expected in the future and our operating results for the nine month period ended September 30, 2018 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2018 or any other interim periods or any future year or period. You should read the following information together with the more detailed information contained in "Selected Historical Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus.

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	Year ended December 31,			Nine Months Ended September 30,	
	2015	2016	2017	2017	2018
				(unaudited)	
	(in thousands, except share and per share data)				
Statement of Operations Data:					
Revenue	$8,012	$16,427	$28,567	$18,610	$34,034

Cost of goods sold	2,809	3,905	6,018	4,137	6,863
Gross profit	5,203	12,522	22,549	14,473	27,171
Operating expenses:					
Selling and marketing	15,291	20,019	28,552	19,566	31,913
Research and development	7,079	7,091	6,194	4,512	5,236
General and administrative	2,631	2,665	3,806	2,552	5,503
Total operating expenses	25,001	29,775	38,552	26,630	42,652
Operating loss	(19,798)	(17,253)	(16,003)	(12,157)	(15,481)
Other expense (income):					
Interest income	(66)	(57)	(203)	(119)	(1,049)
Interest expense	1,564	1,303	1,753	1,224	2,615
Other expense (income), net	41	29	(42)	(2)	3
Loss before income taxes	(21,337)	(18,528)	(17,511)	(13,260)	(17,050)
Income taxes	—	—	—	—	—
Net loss	(21,337)	(18,528)	(17,511)	(13,260)	(17,050)
Net loss per share, basic and diluted(1)	$(20.74)	$(16.90)	$(14.88)	$(11.45)	$(1.40)
Weighted average shares of common stock outstanding used to compute net loss per share, basic and diluted(1)	1,027,925	1,096,013	1,176,650	1,158,548	12,137,512

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See note 12 to our audited financial statements included elsewhere in this prospectus and note 13 to our unaudited interim condensed financial statements included elsewhere in this

prospectus for an explanation of the method used to calculate our basic and diluted net loss per share.

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	As of September 30, 2018	
	Actual	As Adjusted(1)
	(unaudited)	
	(in thousands)	

Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$120,426	$187,251
Working capital(2)	122,360	189,185
Total assets	130,720	197,545
Total liabilities	32,409	32,409
Total stockholders' equity	98,311	165,136

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(1)

The as adjusted balance sheet data give effect to our issuance and sale of 1,500,000 shares of common stock in this offering at an assumed public offering price of $47.89 per share, which is the last reported sale price of our common stock on the NYSE on December 3, 2018, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(2)

We define working capital as current assets less current liabilities.

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Risk Factors

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 all of the other information in this prospectus, including our financial statements and related notes, before investing in our common stock. The realization of any of these risks could have a significant adverse effect on our reputation, business, financial condition, results of operations and growth, and our ability to accomplish our strategic objectives. In that event, the trading price of our common stock could decline, and you may lose part or all of your investment.

Risks Related to Our Business

We have incurred significant operating losses since inception, we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability. We have limited history operating as a commercial company.

We have incurred net losses since our inception in 2007. For the years ended December 31, 2015, 2016 and 2017, we had net losses of $21.3 million, $18.5 million and $17.5 million, respectively, and for the nine months ended September 30, 2017 and 2018, we had net losses of $13.3 million and $17.1 million, respectively. As of September 30, 2018, we had an accumulated deficit of $142.1 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 and the initial public offering of our common stock, or IPO, which closed in May 2018. 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.

We first commercialized our Inspire system in certain European markets in 2011 and in the United States in 2014 and therefore do not have a long history operating as a commercial company. 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, our Inspire system has limited product and brand recognition. 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, develop, enhance and commercialize new products and incur additional operational costs associated with being a public company. As a result, we expect to 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 and 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 and in 2014 in the United States. Sales of our Inspire system accounted for primarily all of our revenue for the years ended December 31, 2015, 2016 and 2017 and for the nine months ended September 30, 2018. 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. Some physicians may have prior history with or a preference for other treatment options, such as positive airway pressure devices, surgical treatments or oral appliances, or may be reluctant to alter their practice patterns and undergo the training required to enable them to treat patients with our Inspire therapy. Patients may not 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 for our Inspire therapy.

We cannot assure you that our Inspire therapy will achieve 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 in recent years, 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:

- 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;
- 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.

We focus our sales, marketing and training efforts primarily on ENT physicians and sleep physicians. However, physicians from other disciplines, including cardiologists, pulmonologists, electrophysiologists and primary care physicians, as well as other medical professionals, such as dentists, nurse practitioners and physician assistants, are often the initial point of contact for patients with OSA.

These 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 get consistent benefit from CPAP. We believe that educating physicians in these 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 primarily 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. Many third-party payors do not currently cover our products and the related procedures because they have determined that our products and the related procedures are experimental or investigational. When our products and the related procedures are reimbursed, they are reimbursed primarily on a per-patient prior authorization basis for patients covered by commercial insurers, on a medical necessity basis for most patients covered by Medicare and under U.S. government contract for patients who are treated by the Veterans Health Administration. Customers that 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. 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.

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 United States and in international markets. Third-party coverage and reimbursement for procedures using our products or any of our products in development for which we may receive regulatory approval may not be

available or adequate in either the United States 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.

Third-party payors and physicians who do not cover or use our Inspire system may require additional clinical data prior to adopting or maintaining coverage of our Inspire system.

Our success depends on physician and third-party payor acceptance of our Inspire therapy as an effective treatment option for patients with moderate to severe OSA. If physicians or payors do not find our body of published clinical evidence and data compelling or wish to wait for additional studies, they may choose not to use or provide coverage and reimbursement for our products. Currently, there are a number of large third-party payors that have determined upper airway neurostimulation to be experimental or investigational and therefore do not cover it at this time.

In addition, the long-term effects of upper airway neurostimulation with our Inspire system beyond five years are not yet known. Certain physicians, hospitals, ASCs and payors may prefer to see longer-term safety and efficacy data than we have produced. We cannot provide assurance that any data that we or others may generate in the future will be consistent with that observed in our existing clinical studies.

The training required for physicians to use our Inspire system could reduce the market acceptance of our products.

As with any new method or technique, physicians must undergo a thorough training program before they are qualified to perform the surgery to implant our Inspire system. Physicians could experience difficulty with the technique necessary to successfully insert the device and may not achieve the technical competency necessary to complete the training program. Even after successfully completing the training program, physicians could still experience difficulty implanting our Inspire system and, as a result, limit its use significantly in their practice or cease utilizing it altogether.

In addition, we may experience difficulty growing the number of physicians who complete our training program if patient demand is low, if the length of time necessary to train each physician is longer than expected, if the capacity of our sales representatives to train physicians is less than expected or if we are unable to sufficiently grow our sales organization. All of these events would lead to fewer trained physicians qualified to implant our Inspire system, which could negatively affect 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 United States by the FDA, we currently compete outside the United States with ImThera (now a part of LivaNova), which produces an open-loop neurostimulation device, and are aware that it is currently conducting clinical trials of its device in the United States. We also 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 United States, 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 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, 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.

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

- 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.

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 trials;

- obtain the necessary regulatory clearances or approvals for expanded indications, new products or product modifications;
- be fully FDA-compliant with marketing of 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 may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. One such factor includes seasonal variations in our sales. 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. In the first quarter of each year in Europe, we have experienced and may in the future experience reduced demand for our Inspire therapy as Neue Untersuchungs-und Behandlungsmethoden, or NUB, coverage status is being determined in Germany and as hospitals are establishing their budgets pertaining to allocation of funds to purchase our Inspire therapy.

Other factors that may cause fluctuations in our quarterly and annual results include:

- patient and physician adoption of our Inspire therapy;
- changes in coverage policies by third-party payors that affect the reimbursement of procedures using our products;
- 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 or approval for any products in development or for our current products for additional indications or in additional countries outside the United States;
- results of clinical research and trials on our existing products and products in development;
- delays in receipt of anticipated purchase orders;
- delays in, or failure of, component and raw material deliveries by our suppliers; 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 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, including Integer and Cirtec, 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, either because of acts of nature, the nature of our agreements with those manufacturers or our relative importance to them as a customer, and our manufacturers may decide in the future 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.

While we believe replacement suppliers and manufacturers exist for all materials, components and services necessary to manufacture our Inspire system, 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 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 loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our Inspire system and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our 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.

We have limited experience marketing and selling our Inspire system, and 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 began selling our Inspire system in certain European markets in 2011, and in the United States in 2014. As a result, we have limited experience marketing and selling our Inspire system. We currently sell our Inspire system through a direct sales force that targets ENT physicians and sleep centers in the United States and Europe, and also utilize various direct-to-patient marketing initiatives, including paid search, radio, social media and online videos. As of September 30, 2018, our direct sales and marketing organization, including reimbursement personnel, consisted of 117 employees, having increased from 40 employees as of December 31, 2015. 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 and obtain reimbursement for it, our revenue may be adversely affected.

In order to generate future revenue growth, we plan 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 assure you 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 United States, we must address many international business risks with which we have limited experience.

Sales in markets outside of the United States accounted for approximately 16.1% and 15.0% of our revenue for the years ended December 31, 2016 and 2017, respectively, and approximately 13.1% of our revenue for the nine months ended September 30, 2018. Our strategy is to increase our international presence in Europe, including Germany and the Netherlands, as well as other international markets, such as Japan, which may increase our revenue from markets outside the United States. International sales are 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;
- 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 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 rely on our own direct sales force, which as of September 30, 2018, consisted of 40 representatives in the United States and six representatives in Europe, 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 may subject us to higher fixed costs than those of companies that market competing products through independent third parties, due to the costs that we will 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 may be unable to manage our growth effectively.

Our past growth has provided, and our future growth may create, challenges for our organization. From December 31, 2015 to September 30, 2018, the number of our employees increased from 66 to 150. In the future, we expect to hire and train new personnel as we continue to grow and expand our operations. This growth may place significant strain on us. Successful growth is also dependent upon our ability to implement appropriate financial and management controls and systems and procedures. If we fail to manage these challenges effectively, there may be an adverse effect on our business, financial condition and results of operations.

Our ability to maintain our competitive position depends on our ability to attract and retain senior management and other highly qualified personnel.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and other personnel. We are highly dependent upon our management team, particularly our Chief Executive Officer and President and the rest of our senior management, and other key personnel. Although we have entered into employment letter agreements with all of our executive officers, each of them may terminate their employment with us at any time. The replacement of any of our key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives and could therefore have an adverse effect on our business. In addition, we do not carry any "key person" insurance policies that could offset potential loss of service under applicable circumstances.

Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees.

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 or approved for commercial sale by the FDA and manufactured in facilities licensed and 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 merely appears 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 trial participants;
- substantial monetary awards to patients or other claimants; or
- loss of sales.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. 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 that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. 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. Although we have established internal procedures designed to minimize risks that may arise from quality issues, there can be no assurance that we will be able to eliminate or mitigate occurrences of these 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, although we have no current commitments with respect to any acquisition or investment, 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. The global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including weakened demand for our Inspire system, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also 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 could have an adverse effect on our business.

We rely extensively on information technology systems to conduct our business. 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. 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. Furthermore, any breach in our IT systems could lead to the unauthorized access, disclosure and use of non-public information, including information from our ADHERE patient registry or other patient information, which is protected by HIPAA and other laws. Any such access, disclosure, or other loss of information could result in 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 many of 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.

THIS IS THE END OF A COMPOSITION COMPONENT

If our facilities are damaged or become inoperable, we will be unable to continue to research, develop and supply our Inspire system and, as a result, there will 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 and maintain all our finished goods inventory in a single location in Maple Grove, Minnesota. Our facility, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, tornadoes, flooding, fire and power outages, 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 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 United States, the European Union and other governments and organizations. 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, or the FCPA, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control, or OFAC. In addition, the U.K. Bribery Act of 2010, or the Bribery Act, prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that "fails to prevent bribery" by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented "adequate procedures" to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. 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 assure you, 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 assure you 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.

Our indebtedness may limit our flexibility in operating our business and adversely affect our financial health and competitive position.

As of September 30, 2018, we had $24.5 million of indebtedness outstanding under our credit facility with Oxford Finance LLC, or Oxford Finance. In order to service this indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This will place us at a competitive disadvantage compared to our competitors that have less indebtedness.

In addition, the agreement governing the credit facility contains, and any agreements evidencing or governing other future indebtedness may contain, certain covenants that limit our ability to engage in certain transactions that may be in our long-term best interests. Subject to certain limited exceptions, these covenants limit our ability to, among other things:

- convey, sell, lease, transfer, assign, dispose of or otherwise make cash payments consisting of all or any part of our business or property;
- effect certain changes in our business, management, ownership or business locations;
- merge or consolidate with, or acquire all or substantially all of the capital stock or assets of, any other company;
- create, incur, assume or be liable for any additional indebtedness, or create, incur, allow or permit to exist any additional liens;

- pay cash dividends on, make any other distributions in respect of, or redeem, retire or repurchase, any shares of our capital stock;
- make certain investments; and
- enter into transactions with our affiliates.

While we have not previously breached and are not currently in breach of these or any of the other covenants contained in our credit agreement, there can be no guarantee that we will not breach these covenants in the future. Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, our lender may choose to declare an event of default and require that we immediately repay all amounts outstanding, terminate any commitment to extend further credit and foreclose on the collateral granted to it to collateralize such indebtedness. The occurrence of any of these events 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 the proceeds from this offering and may be unable to raise capital when needed, which could force us to delay or reduce our commercialization efforts or product development programs.

We believe that the net proceeds from this offering, together with 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 or approvals;
- 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;
-

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; and

- the costs of operating as a public company.

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 after this offering (including through the exercise by the underwriters of their option to purchase additional 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 this offering. Furthermore, investors purchasing any securities we may issue in the future may have rights superior to your rights as 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, or 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, or NOLs, and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. 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 control, 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.

Risks Related to Government Regulation

Our products and operations are subject to extensive government regulation and oversight both in the United States 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 United States 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 trials; product safety; establishment registration and device listing; marketing, sales and distribution; pre-market clearance and approval; 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 enforces these regulatory requirements through periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. 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 or approvals; withdrawals or suspensions of current approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

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

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 United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, or approval of a pre-market approval application, or PMA, from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, 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 trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

In the United States, we have obtained approval of our Inspire system through the PMA pathway. Any modification to the Inspire system that has not been previously approved may require us to submit a new PMA or PMA supplement and obtain FDA approval prior to implementing the change. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials or the interpretation of data from pre-clinical studies or clinical trials;
-

serious and unexpected adverse device effects experienced by participants in our clinical trials;

- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new approvals, increase the costs of compliance or restrict our ability to maintain our current approval. For example, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance and approval. Some of these proposals and reforms could impose additional regulatory requirements upon us that could delay our ability to obtain new approvals, increase the costs of compliance or restrict our ability to maintain our current approval.

In order to sell our products in member countries of the EEA our products must comply with the essential requirements of the European Union Medical Devices Directive (Council Directive 93/42/EEC) and the Active Implantable Medical Devices Directive (Council Directive 90/385/EEC). Compliance with these requirements is a prerequisite to be able to affix the Conformité Européene, or CE, mark to our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the European Union Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a member state of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, 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. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EEA.

Modifications to our products may require us to obtain new PMA approvals or approvals of a PMA supplement, and if we market modified products without obtaining necessary approvals, 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 trials to support any modifications. Any delay or failure in obtaining required approvals 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 approval. 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.

In addition, the PMA approval for our Inspire system was subject to several conditions of approval, including a post-market long-term study and extended follow-up of the pre-market study cohort. 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 approval and the inability to continue to market the device. Failure to conduct the required studies in accordance with institutional review board, or 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 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 PMA approvals or foreign regulatory approvals of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of our current PMA or foreign regulatory approvals, 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 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, or 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 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; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals 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 occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs.

If treatment guidelines for OSA change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for one or more of our products.

If treatment guidelines for OSA changes or the standard of care for this condition evolves, we may need to redesign the applicable product and seek new approvals from the FDA. Our PMA approvals from the FDA are based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable, the clinical utility of one or more of our products could be diminished and our business could be adversely affected.

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

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

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new 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 warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. 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 or approvals for our products, we will be unable to market and sell our products outside of the United States.

Sales of our products outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. 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 a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or approvals, can be expensive and time-consuming, and we may not receive regulatory approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA approval, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our products, we may need to

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

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

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

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the 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.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i.e., without the need for adoption of EEA member state laws implementing them, in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation will, however, only become applicable three years after publication (in 2020). Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU;
- strengthened rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an effect on the way we conduct our business in the EEA.

We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security 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. We may also be subject to privacy and security regulation related to patient, customer, employee and other third-party information by both the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. These laws can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,181 to $22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to

  have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Physician Sunshine Act under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, which require certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, or CHIP, to report annually to the DHHS Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, certain other healthcare providers, and teaching hospitals, and applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Applicable manufacturers are required to submit annual reports to CMS. Failure to

submit required information may result in civil monetary penalties of $11,052 per failure up to an aggregate of $165,786 per year (or up to an aggregate of $1.105 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH Act, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $55,910 per violation, not to exceed $1.68 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the EU General Data Protection Regulation, or GDPR, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. 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.

THIS IS THE END OF A COMPOSITION COMPONENT

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 may be subject to, or may in the future become subject to, U.S. federal, state, and foreign laws and regulations imposing obligations on how we collect, store and process personal information. Our actual or perceived failure to comply with such obligations could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In the conduct of our business, we may at times process personal data, including health-related personal data. The U.S. federal government and various states have adopted or proposed laws, regulations, guidelines and rules for the collection, distribution, use and storage of personal information of individuals. We may also be subject to U.S. federal rules, regulations and guidance concerning data security for medical devices, including guidance from the FDA. State privacy and security laws 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 misuse of personal information.

The EU also has laws and regulations dealing with the collection, use and processing of personal data obtained from individuals in the EU, which are often more restrictive than those in the United States and which restrict transfers of personal data to the United States unless certain requirements are met. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. In addition, these rules are constantly under scrutiny. For example, following a decision of the Court of Justice of the European Union in October 2015, transferring personal data to U.S. companies that had certified as members of the U.S. Safe Harbor Scheme was declared invalid. In July 2016 the European Commission adopted the U.S.-EU Privacy Shield Framework which replaces the Safe Harbor Scheme. However, this Framework is under review and there is currently litigation challenging other EU mechanisms for adequate data transfers (i.e., the standard contractual clauses). It is uncertain whether the Privacy Shield Framework and/or the standard contractual clauses will be similarly invalidated by the European courts. We rely on a mixture of mechanisms to transfer personal data from our EU business to the United States, and could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators under the GDPR, as well as current challenges to these mechanisms in the European courts.

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

From May 25, 2018 onwards, we have been subject to the requirements of the GDPR because we are processing personal data in the EU and/or offering goods to, or monitor the behavior of, individuals in the EU. The GDPR implements more stringent administrative requirements for controllers and processors of personal data, including, for example, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data, additional obligations when we contract with service providers, more robust rights for individuals over their personal data. The GDPR provides that EU member states may make their own further laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs could increase, and harm our business and financial condition. If we do not comply with our obligations under the GDPR, we could be exposed to significant fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher.

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 United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the Affordable Care Act was enacted in the United States, 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 Affordable Care Act:

- imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions (described in more detail below), although the effective rate paid may be lower. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020;
-

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.

We do not yet know the full impact that the Affordable Care Act will have on our business. The taxes imposed by the Affordable Care Act and 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. The Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the Tax Cuts and Jobs Act of 2017 was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. Additionally, all or a portion of the Affordable Care Act and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our 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.

The clinical trial process required to obtain regulatory approvals 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 United States or, 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 approval for our Inspire system. In order to obtain PMA approval for a device, the sponsor must conduct well-controlled clinical trials designed to assess the safety and efficacy of the product candidate. Conducting clinical trials 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 trials but cannot be certain that the trials will ever result in commercial revenue. We may experience significant setbacks in clinical trials, even after earlier clinical trials showed promising results, and failure can occur at any time during the clinical trial 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 trials. We, the FDA, or another regulatory authority may suspend or terminate clinical trials at any time to avoid exposing trial participants to unacceptable health risks.

Successful results of pre-clinical studies are not necessarily indicative of future clinical trial results, and predecessor clinical trial results may not be replicated in subsequent clinical trials. Additionally, the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the clearance or approval of our products. The data we collect from our pre-clinical studies and clinical trials may not be sufficient to support FDA clearance or approval, and if we are unable to demonstrate the safety and efficacy of our future products in our clinical trials, we will be unable to obtain regulatory clearance or approval to market our products.

In addition, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which are often referred to as milestones. These milestones could include the obtainment of the right to affix the CE mark in the European Union; the submission to the FDA of an investigational device exemption, or IDE, application to commence a pivotal clinical trial for a new product candidate; the enrollment of patients in clinical trials; the release of data from clinical trials; and other clinical and regulatory events. The actual timing of these milestones could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot assure you that we will meet our projected milestones and if we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

Clinical trials are necessary to support PMA applications and may be necessary to support PMA supplements for modified versions of our marketed device products. This would require the enrollment of large numbers of suitable subjects, which may be difficult to identify, recruit and maintain as participants in the clinical trial. The clinical trials supporting the PMA application for our Inspire system involved 126 randomized patients. Adverse outcomes in the post-approval studies could also result in restrictions or withdrawal of approval of the PMA. We will likely need to conduct additional clinical studies in the future to support new indications for our products or for approvals or clearances 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 trials, including:

- we may be required to submit an IDE application to FDA, which must become effective prior to commencing human clinical trials, and FDA may reject our IDE application and notify us that we may not begin investigational trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB 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 trials may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials 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; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

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

Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under current good manufacturing practice, or cGMP, requirements and other regulations. Furthermore, we rely on CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements

governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

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 or approval and, ultimately, the commercialization of that product or indication for use. Even if our future products are cleared or approved in the United States, commercialization of our products in foreign countries would require approval by regulatory authorities in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. Any of these occurrences could have an adverse effect on our business, financial condition and results of operations.

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 will depend in part on our success in obtaining and maintaining issued patents, trademarks and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we 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 September 30, 2018, we had rights to 20 issued U.S. patents, 22 issued foreign patents, 25 pending U.S. patent applications and 39 pending foreign patent applications. Assuming all required fees are paid, issued U.S. patents owned by us will expire between 2019 and 2035.

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 United States, 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 United States 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 United States 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, we expect 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 U.S. Patent and Trademark Office 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.

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

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may

affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

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 data, 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, or 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 U.S. Patent and Trademark Office 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, or 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 and this Offering

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 If you purchase shares of common stock in this offering, you may not be able to resell those shares at or above the public offering price. The trading price of our common stock has fluctuated, and is likely to continue to be subject to substantial fluctuations in the future. The trading price of our common stock depends on a number of factors, including those described below and elsewhere in this "Risk Factors" section, many of which are beyond our control and are not related to our operating performance. In addition, although our common stock is listed on the NYSE, we cannot assure you that a trading market for our common stock will be maintained.

Since the shares were sold in our initial public offering in May 2018 at a price of $16.00 per share, the price per share of our common stock has ranged as low as $22.50 and as high as $57.87 through December 3, 2018. The market price of our common stock may be influenced by many factors, including:

- 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;
- product liability claims or other litigation;
- 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 or in reimbursement;
- 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. These fluctuations may be even more pronounced in the trading market for our common stock shortly following this offering. If the market price for shares of our common stock after this offering does not ever exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

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.

We are an "emerging growth company" and the reduced disclosure requirements applicable to "emerging growth companies" may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." In particular, while we are an "emerging growth company" (1) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, (2) we will be exempt from any rules that could be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor's report on financial statements, (3) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and (4) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

We may remain an "emerging growth company" until as late as December 31, 2023, the fiscal year-end following the fifth anniversary of the completion of our IPO, though we may cease to be an "emerging growth company" earlier under certain circumstances, including if (1) we have more than $1.07 billion in annual revenue in any fiscal year, (2) the market value of our

common stock that is held by non-affiliates exceeds $700 million as of any June 30 and we are deemed to be a "large accelerated filer" as defined under the Exchange Act or (3) we issue more than $1.0 billion of non-convertible debt over a three-year period.

The exact implications of the JOBS Act are still subject to interpretations and guidance by the SEC and other regulatory agencies, and we cannot assure you that we will be able to take advantage of all of the benefits of the JOBS Act. In addition, investors may find our common stock less attractive to the extent we rely on the exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or become more volatile.

Because we have opted to take advantage of the JOBS Act provision which allows us to delay implementing new accounting standards, our financial statements may not be directly comparable to other public companies.

Pursuant to the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. Because we have elected to take advantage of this provision of the JOBS Act, our financial statements and the reported results of operations contained therein may not be directly comparable to those of other public companies.

If you purchase shares of our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

Investors purchasing shares of our common stock in this offering will pay a price per share that substantially exceeds the as adjusted net tangible book value per share of our common stock. As a result, investors purchasing common stock in this offering will incur immediate dilution of $40.68 per share, representing the difference between our assumed public offering price of $47.89 per share, which is the last reported sale price of our common stock on the NYSE on December 3, 2018, and our as adjusted net tangible book value per share as of September 30, 2018. To the extent outstanding warrants or options to purchase shares of our common stock are exercised, new investors may incur further dilution. For more information on the dilution you may experience as a result of investing in this offering, see the section of this prospectus entitled "Dilution."

A significant portion of our total outstanding shares are eligible to be sold into the market. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Subject to the restrictions set forth in the 90-day lock-up agreements to be entered into by each of our directors and officers and certain of our stockholders in connection with this offering as described elsewhere in this prospectus under the heading "Underwriting" (which restrictions may be waived, with or without notice, by Merrill Lynch, Pierce, Fenner & Smith Incorporated), outstanding shares of our common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act, or to the extent that such shares have already been registered under the Securities Act and are held by non-affiliates of ours. Moreover, holders of a substantial number of shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also have registered all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

After this offering, our officers, directors and principal stockholders each holding more than 5% of our common stock, collectively, will control approximately 32.1% of our outstanding common stock. As a result, these stockholders, if they act together, may be able to control the management and affairs of our Company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a

change in control of the Company, even if such change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the Company or our assets, and might affect the prevailing market price of our common stock due to investors' perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in the best interests of our other stockholders.

We will have broad discretion in the use of proceeds of this offering designated for working capital and general corporate purposes.

We intend to use the net proceeds from this offering to hire additional sales and marketing personnel and expand marketing programs primarily in the United States, to fund product development and research and development activities and the remainder for working capital and general corporate purposes. Within those categories, we have not determined the specific allocation of the net proceeds of this offering. Our management will have broad discretion over the use and investment of the net proceeds of this offering within those categories. Accordingly, investors in this offering have only limited information concerning management's specific intentions and will need to rely upon the judgment of our management with respect to the use of proceeds.

We have incurred and expect to continue to incur significant additional costs as a result of being a public company, which may adversely affect our business, financial condition and results of operations.

We have incurred and expect to continue to incur costs associated with corporate governance requirements that are applicable to us as a public company, including rules and regulations of the SEC, under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the Exchange Act, as well as the rules of the NYSE. These rules and regulations significantly increase our accounting, legal and financial compliance costs and make some activities more time-consuming. We also expect these rules and regulations to make it more expensive for us to maintain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers. Accordingly, increases in costs incurred as a result of being a publicly traded company may adversely affect our business, financial condition and results of operations.

As a result of becoming a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our Company and, as a result, the value of our common stock.

To comply with the requirements of being a public company, we will need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act, is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls when we become subject to this requirement could negatively affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we may be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may be unable to remain listed on the NYSE.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of our second annual report or the first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company," as defined in the JOBS Act, depending on whether we choose to rely on certain exemptions set forth in the JOBS Act.

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

Upon the closing of our IPO, we became subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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

Provisions in our corporate charter documents and under Delaware law could make an acquisition of 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 credit facility precludes, 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.

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 one or more of the analysts covering our business downgrade our stock or change their opinion of our stock, our share 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.

The impact of the Tax Reform Bill could have a negative effect on us or our stockholders.

On December 20, 2017, the U.S. Congress passed the Tax Cuts and Jobs Act of 2017 (H.R. 1), or the Tax Reform Bill, and on December 22, 2017, President Trump signed the Tax Reform Bill into law. The Tax Reform Bill makes significant changes to the U.S. federal income tax rules applicable to both individuals and entities, including corporations. There still remains some uncertainty as a result of the Tax Reform Bill, and we are continuing to evaluate the impact that it will have on our business and on any investment in our common stock. You should consult with your tax advisor with respect to the status of U.S. tax reform and its potential effect on your investment in our common stock.

Special Note Regarding Forward-Looking Statements

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- estimates regarding the annual total addressable market for our Inspire therapy in the United States and our market opportunity outside the United States, future results of operations, financial position, research and development costs, capital requirements and our needs for additional financing;
- 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;
- our ability to enhance our Inspire system, expand our indications and develop and commercialize additional products;
- our business model and strategic plans for our products, technologies and business, including our implementation thereof;
- our ability to accurately forecast customer demand for our Inspire system and manage our inventory;
- 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 hire and retain our senior management and other highly qualified personnel;
- our ability to obtain additional financing in this or future offerings;
- our ability to commercialize or obtain regulatory approvals for our Inspire therapy and system, or the effect of delays in commercializing or obtaining regulatory approvals;
- FDA or other U.S. or foreign regulatory actions affecting us or the healthcare industry generally, including healthcare reform measures in the United States and international markets;
- the timing or likelihood of regulatory filings and approvals;
- our ability to establish and maintain intellectual property protection for our Inspire therapy and system or avoid claims of infringement;
- the volatility of the trading price of our common stock;
- our expectations regarding the use of proceeds from this offering; and
-

our expectations about market trends.

The forward-looking statements in this prospectus 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 prospectus and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this prospectus entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. 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.

Use of Proceeds

USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately $66.8 million, based on an assumed public offering price of $47.89 per share, which is the last reported sale price of our common stock on the NYSE on December 3, 2018, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' option to purchase additional shares from us is exercised in full, we estimate that our net proceeds will be approximately $83.7 million. Each $1.00 increase (decrease) in the assumed public offering price of $47.89 per share would increase (decrease) the net proceeds to us from this offering by approximately $1.4 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering to hire additional sales and marketing personnel and expand marketing programs in the United States, Europe and Japan, to fund product development and research and development activities and for working capital and other general corporate purposes.

We may also use a portion of the net proceeds from this offering to acquire, in-license or invest in products, technologies or businesses that are complementary to our business. However, we currently have no agreements or commitments to complete any such transaction.

As of the date of this prospectus, we cannot estimate with certainty the amount of net proceeds to be used for the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds. Pending the uses described above, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments or other securities.

We will not receive any proceeds from the sale of our common stock by the selling stockholders in this offering.

Dividend Policy

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors our board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. In addition, our ability to pay cash dividends is currently restricted by the terms of the agreement governing our credit facility. Our ability to pay cash dividends on

our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any additional indebtedness we may incur.

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Capitalization

CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term investments and capitalization as of September 30, 2018, as follows:

- on an actual basis; and
- on an as adjusted basis to give effect to our issuance and sale of 1,500,000 shares of common stock in this offering at an assumed public offering price of $47.89 per share, which is the last reported sale price of our common stock on the NYSE on December 3, 2018, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the closing of this offering will be adjusted based on the actual offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and the related notes appearing at the end of this prospectus, the information set forth under the headings "Use of Proceeds," "Selected Historical Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the other financial information contained in this prospectus.

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	As of September 30, 2018	
	Actual	As Adjusted(1)
	(unaudited)	
	(in thousands, except share and per share data)	
Cash, cash equivalents and short-term investments	$120,426	$187,251
Notes payable(2)	$24,814	$24,814
Stockholders' equity:		
Common stock, par value $0.001 per share; 200,000,000 shares authorized, 21,391,590 shares issued and outstanding, actual; 200,000,000 shares authorized, 22,891,590 shares issued and outstanding, as adjusted	21	23
Preferred stock, par value $0.001 per share; 10,000,000 shares authorized, no shares issued and outstanding, actual and as adjusted	—	—
Additional paid-in capital	240,451	307,274
Accumulated other comprehensive loss	(26)	(26)
Accumulated deficit	(142,135)	(142,135)
Total stockholders' equity	98,311	165,136
Total capitalization	$123,125	$189,950

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(1) Each $1.00 increase (decrease) in the assumed public offering price of $47.89 per share, which is the last reported sale price of our common stock on the NYSE on December 3, 2018, would increase (decrease) the as adjusted amount of each of cash, cash equivalents and short-term investments, additional paid-in capital, total stockholders' equity and total capitalization by approximately $1.4 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(2) Represents borrowings outstanding under our credit facility. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Indebtedness."

The number of shares in the table above does not include:

- 2,198,130 shares of our common stock issuable upon the exercise of options outstanding as of September 30, 2018, at a weighted average exercise price of $3.80 per share;
- 1,209,585 additional shares of our common stock reserved for future issuance under our 2018 Plan as of September 30, 2018, as well as shares of our common stock that may be issued pursuant to provisions of our 2018 Plan that automatically increase the common stock reserve under our 2018 Plan;
- 80,884 shares of our common stock issuable upon the exercise of warrants to purchase shares of our common stock outstanding as of September 30, 2018 at a weighted average exercise price of $9.61 per share, 31,270 of which were issued pursuant to the net exercise of certain warrants subsequent to September 30, 2018; and
- 277,362 shares of our common stock reserved for future issuance under our ESPP as of September 30, 2018 as well as shares of our common stock that may be issued pursuant to provisions in our ESPP that automatically increase the common stock reserve under the ESPP.

Dilution

DILUTION

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

As of September 30, 2018, our historical net tangible book value was $98.3 million, or $4.60 per share of our common stock. Net tangible book value per share represents the book value of our total tangible assets less the book value of our total liabilities, divided by the number of shares of our common stock outstanding as of September 30, 2018.

After giving effect to our sale of 1,500,000 shares of our common stock in this offering at an assumed public offering price of $47.89 per share, which is the last reported sale price of our common stock on the NYSE on December 3, 2018, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2018 would have been approximately $165.1 million, or approximately $7.21 per share. This amount represents an immediate increase in net tangible book value of $2.61 per share to our existing stockholders and an immediate dilution in net tangible book value of approximately $40.68 per share to new investors purchasing shares of

our common stock in this offering. We determine dilution by subtracting our as adjusted net tangible book value per share after this offering from the amount of cash per share of common stock paid by new investors in this offering. The following table illustrates this dilution:

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Assumed public offering price per share		$47.89
Historical net tangible book value per share as of September 30, 2018	$4.60	
Increase in net tangible book value per share attributable to new investors participating in this offering	2.61	
As adjusted net tangible book value per share after this offering		$7.21
Dilution per share to new investors in this offering		$40.68

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Each $1.00 increase (decrease) in the assumed public offering price of $47.89 per share, which is the last reported sale price of our common stock on the NYSE on December 3, 2018, would increase (decrease) the as adjusted net tangible book value per share after this offering by approximately $0.06, and dilution per share to new investors by approximately $0.94, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters' option to purchase additional shares of our common stock is exercised in full, our as adjusted net tangible book value per share after this offering would be $7.82, the increase in net tangible book value per share attributable to new investors in this offering would be $3.22 and the dilution per share to new investors would be $40.07, in each case assuming a public offering price of $47.89 per share, which is the last reported sale price of our common stock on the NYSE on December 3, 2018.

The following table summarizes, on the as adjusted basis described above, as of September 30, 2018, the differences between the number of shares purchased from us, the total consideration paid to us in cash and the average price per share that existing stockholders and new investors paid. The calculation below is based on an assumed public offering price of $47.89 per share, which is the last reported sale price of our common stock on the NYSE on December 3, 2018, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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	Shares Purchased		Total Consideration		Average Price
	Number	Percent	Amount	Percent	Per Share
Existing stockholders	21,391,590	93%	$245,133,000	77%	$11.46
New investors	1,500,000	7%	71,835,000	23%	47.89
Total	22,891,590	100%	$316,968,000	100%	

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The dilution information discussed above is illustrative only and will change based on the actual offering price, the number of shares we sell and other terms of this offering that will be determined at pricing. Each $1.00 increase (decrease) in the assumed public offering price of $47.89 per share, which is the last reported sale price of our common stock on the NYSE on December 3,

2018, would increase (decrease) the total consideration paid by new investors and the average price per share paid by new investors by $1.5 million and $1.00 per share, respectively.

If the underwriters exercise their option to purchase additional shares of our common stock in full, the total consideration paid by new investors and the average price per share paid by new investors would be approximately $89.8 million and $47.89 per share, respectively, in each case assuming a public offering price of $47.89 per share, which is the last reported sale price of our common stock on the NYSE on December 3, 2018.

The foregoing tables and calculations are based on the number of shares of our common stock outstanding as of September 30, 2018 and exclude:

- 2,198,130 shares of our common stock issuable upon the exercise of options outstanding as of September 30, 2018, at a weighted average exercise price of $3.80 per share;
- 1,209,585 additional shares of our common stock reserved for future issuance under our 2018 Plan as of September 30, 2018, as well as shares of our common stock that may be issued pursuant to provisions of our 2018 Plan that automatically increase the common stock reserve under our 2018 Plan;
- 80,884 shares of our common stock issuable upon the exercise of warrants to purchase shares of our common stock outstanding as of September 30, 2018 at a weighted average exercise price of $9.61 per share, 31,270 of which were issued pursuant to the net exercise of certain warrants subsequent to September 30, 2018;
- 277,362 shares of our common stock reserved for future issuance under our ESPP as of September 30, 2018 as well as shares of our common stock that may be issued pursuant to provisions in our ESPP that automatically increase the common stock reserve under the ESPP.

To the extent any of the outstanding options or warrants described above are exercised, new options are issued or we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to investors participating in this offering. If all of the outstanding options and warrants described above had been exercised as of September 30, 2018, the as adjusted net tangible book value per share after this offering would be $6.92, and total dilution per share to new investors would be $40.97.

Selected Historical Financial Data

SELECTED HISTORICAL FINANCIAL DATA

The following tables set forth, for the periods and as of the dates indicated, our selected historical financial data. The statements of operations data for the years ended December 31, 2015, 2016 and 2017 and the balance sheet data as of December 31, 2016 and 2017 are derived from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the nine months ended September 30, 2017 and 2018 and the balance sheet data as of September 30, 2018 are derived from our unaudited interim condensed financial statements included elsewhere in this prospectus. In our opinion, these unaudited interim condensed financial statements have been prepared on a basis consistent with our audited financial statements and contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such financial data.

Our historical results are not necessarily indicative of the results that may be expected in the future and our operating results for the nine month period ended September 30, 2018 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2018 or any other interim periods or any future year or period. You should read the following information together with the more detailed information contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus.

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	Year ended December 31,			Nine Months Ended September 30,	
	2015	2016	2017	2017	2018
				(unaudited)	
	(in thousands, except share and per share data)				
Statement of Operations Data:					
Revenue	$8,012	$16,427	$28,567	$18,610	$34,034
Cost of goods sold	2,809	3,905	6,018	4,137	6,863
Gross profit	5,203	12,522	22,549	14,473	27,171
Operating expenses:					
Selling and marketing	15,291	20,019	28,552	19,566	31,913
Research and development	7,079	7,091	6,194	4,512	5,236
General and administrative	2,631	2,665	3,806	2,552	5,503
Total operating expenses	25,001	29,775	38,552	26,630	42,652
Operating loss	(19,798)	(17,253)	(16,003)	(12,157)	(15,481)
Other expense (income):					
Interest income	(66)	(57)	(203)	(119)	(1,049)
Interest expense	1,564	1,303	1,753	1,224	2,615
Other expense (income), net	41	29	(42)	(2)	3
Loss before income taxes	(21,337)	(18,528)	(17,511)	(13,260)	(17,050)
Income taxes	—	—	—	—	—
Net loss	(21,337)	(18,528)	(17,511)	(13,260)	(17,050)
Net loss per share, basic and diluted(1)	$(20.74)	$(16.90)	$(14.88)	$(11.45)	$(1.40)
Weighted average shares of common stock outstanding used to compute net loss per share, basic and diluted(1)	1,027,925	1,096,013	1,176,650	1,158,548	12,137,512

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(1) See note 12 to our audited financial statements included elsewhere in this prospectus and note 13 to our unaudited interim condensed financial statements included elsewhere in this prospectus for an explanation of the method used to calculate our basic and diluted net loss per share.

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	As of December 31,		As of September 30,
	2016	2017	2018
			(unaudited)
		(in thousands)	
Balance Sheet Data:			
Cash, cash equivalents and short-term investments	$6,685	$16,143	$120,426
Working capital(1)	4,959	16,950	122,360
Total assets	13,116	25,091	130,720
Total liabilities	19,724	23,764	32,409
Convertible preferred stock	94,138	119,106	—
Total stockholders' (deficit) equity	(6,608)	1,327	98,311

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(1)
We define working capital as current assets less current liabilities.

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Management's Discussion and Analysis of Financial Condition and Results of Operations

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 prospectus. 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 "Risk Factors" and elsewhere in this prospectus.*

Overview

We are a medical technology company focused on the development and commercialization of innovative and minimally invasive solutions for patients with obstructive sleep apnea. Our proprietary Inspire system is the first and only FDA-approved neurostimulation technology that provides a safe and effective treatment for moderate to severe obstructive sleep apnea. 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 obstructive sleep apnea 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 must have been confirmed to fail or be unable to tolerate positive airway pressure treatments, such as CPAP, and be 22 years of age or older, though there are no similar requirements for patients in Europe.

We sell our Inspire system to hospitals and ASCs in the United States and in select countries in Europe through a direct sales organization. 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-patient 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 and frequently results in patient leads. We increased the number of employees in our sales, marketing and reimbursement organizations from 40 as of December 31, 2015 to 117 as of September 30, 2018.

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, on a medical necessity basis for most patients covered by Medicare, and under U.S. government contract for patients who are treated by the Veterans Health Administration. To date, approximately 300 commercial payors have reimbursed hospitals and ASCs for patients' treatment with our Inspire therapy through the prior authorization process. In July 2018, Aetna Inc., one of the leading health plans in the United States, began providing coverage for our Inspire therapy, bringing the number of our secured positive coverage policies to nine U.S. commercial payors. In June 2018, Japan's Ministry of Health, Labour and Welfare approved our Inspire therapy to treat moderate to severe OSA, and we will now seek reimbursement coverage in Japan. For the nine months ended September 30, 2018, 86.9% of our revenue was derived in the United States and 13.1% was derived in Europe. No single customer accounted for more than 3% 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 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. In the United States, we currently ship our Inspire system from our facility in Minnesota directly to our customers on a purchase order basis. Warehousing and shipping operations for our European customers are handled by a third-party vendor with facilities located in the Netherlands. Customers do not have the right to return 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 credit facility, and the initial public offering of our common stock, which closed in May 2018. 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 nine months ended September 30, 2018, we generated revenue of $34.0 million with a gross margin of 79.8% and a net loss of $17.1 million compared to revenue of $18.6 million with a gross margin of 77.8% and a net loss of $13.3 million for the nine months ended September 30, 2017. Our accumulated deficit as of September 30, 2018 was $142.1 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 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-patient marketing efforts in existing and new markets throughout the United States and in Europe. We also intend to 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 Europe and Japan. Because of these and other factors, we expect to continue to incur net losses for the next several years and we expect to require substantial additional funding, which may include future equity and debt financings.

On May 7, 2018, we completed our IPO by issuing 7,762,500 shares of common stock, at an offering price of $16.00 per share, for net proceeds of approximately $112.0 million after deducting underwriting discounts and commissions and offering expenses payable by us.

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 United States and select countries in Europe. Recent revenue growth has been driven by, and we expect continued growth as a result of, increased patient and physician awareness of the Inspire system, additional sales representatives and an increase in approvals of prior authorization submissions. Any reversal in these recent trends, however, could have a negative impact on our future revenue. In addition, we have expanded our sales and marketing organization to help us drive and support revenue growth and intend to continue this expansion. Moreover, we expect that our revenue growth will be positively impacted by, and to the extent we obtain,

additional positive coverage policies. Our revenue has fluctuated, and we expect our revenue to 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.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of acquisition costs of the components of the Inspire system, overhead costs, scrap and inventory obsolescence, as well as distribution-related expenses such as logistics and shipping costs, net of costs charged to customers. The overhead costs include the cost of material procurement and operations supervision and management personnel. We expect overhead costs as a percentage of revenue to continue to decrease as our sales volume increases. We expect cost of goods sold to increase in absolute dollars primarily as, and to the extent, our revenue grows.

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 United States and Europe as our average selling price in the United States tends to be higher than in Europe. Our gross margin may increase over the long term 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. However, our gross margin may fluctuate from quarter to quarter due to seasonality.

Selling and Marketing Expenses

Selling and marketing expenses consist primarily of compensation for personnel, including base salaries, stock-based compensation and commissions associated with sales results, spending related to marketing, sales operations and training and reimbursement personnel. Other selling and marketing expenses include training physicians, travel expenses, advertising, direct-to-patient promotional programs, conferences, trade shows and consulting services. We expect selling and marketing expenses to continue to increase in absolute dollars as we expand our commercial infrastructure to both drive and support our planned growth in revenue.

Research and Development Expenses

Research and development expenses consist primarily of product development, engineering, clinical studies to develop and support our products, regulatory expenses, testing, consulting services and other costs associated with the next generation versions of the Inspire 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 trial management and monitoring, payments to clinical investigators, data management and travel expenses for our various clinical trials. We expect research and development expenses to increase in the future as we develop next generation versions of our Inspire system and continue to expand our clinical studies to secure positive coverage policies from private commercial payors in the United States and enter into new markets such as Europe and Japan. 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.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll and personnel-related costs, including stock-based compensation, and spending related to finance, information technology and human resource functions. Other general and administrative expenses include travel expenses, professional services fees, audit fees, insurance costs and general corporate expenses, including facilities-related expenses. We expect our general and administrative expenses will significantly increase as we increase our headcount and expand administrative personnel to support our growth and operations as a public company including finance personnel and information technology services.

Additionally, we anticipate increased expenses related to audit, legal, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company. We also expect to see an increase in our stock-based compensation expense with the establishment of a new equity plan in connection with our IPO and related grants either in the form of restricted stock or options.

Other Expense, Net

Other expense, net consists primarily of interest expense payable under our credit facility. Other items include interest income and fair value adjustments related to convertible preferred stock warrants, which were accounted for as a liability and marked-to-market at each reporting period. Immediately prior to the closing of our IPO, our outstanding convertible preferred stock warrants automatically converted into warrants to purchase shares of our common stock.

Results of Operations

Comparison of the Nine Months Ended September 30, 2018 and 2017

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	Nine Months Ended September 30,			
	2018	2017	$ Change	% Change
	(in thousands, except percentages)			
Revenue	$34,034	$18,610	$15,424	82.9%
Cost of goods sold	6,863	4,137	2,726	65.9%
Gross profit	27,171	14,473	12,698	87.7%
Gross margin	*79.8%*	*77.8%*		
Operating expenses:				
Selling and marketing	31,913	19,566	12,347	63.1%
Research and development	5,236	4,512	724	16.0%
General and administrative	5,503	2,552	2,951	115.6%
Total operating expenses	42,652	26,630	16,022	60.2%
Operating loss	(15,481)	(12,157)	(3,324)	27.3%
Other expense, net	1,569	1,103	466	42.2%
Net loss	$(17,050)	$(13,260)	$(3,790)	28.6%

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Revenue

Revenue increased $15.4 million, or 82.9%, to $34.0 million for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017. The increase was attributable to an increase in sales of our Inspire system of $13.7 million in the United States and an increase of $1.8 million in Europe, primarily in Germany.

Revenue information by region is summarized as follows:

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	Nine Months Ended September 30,					
	2018		2017		Change	
	Amount	% of Revenue	Amount	% of Revenue		$%
United States	$29,580	86.9%	$15,922	85.6%	$13,658	85.8%

Europe	4,454	13.1%	2,688	14.4%	1,766	65.7%
Total revenue	$34,034	100.0%	$18,610	100.0%	$15,424	82.9%

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Revenue generated in the United States was $29.6 million for the nine months ended September 30, 2018, an increase of $13.7 million or 85.8% over the nine months ended September 30, 2017. Revenue growth in the United States was primarily due to increased market penetration in existing territories, the expansion of our U.S. sales representatives into new territories, increased physician and patient awareness of our Inspire system, and a greater number of prior authorization approvals. Additionally, $1.0 million of the increase in revenue was attributable to an increase in our average selling price with the introduction of the fourth generation Inspire system in the United States in July 2017.

Revenue generated in Europe was $4.5 million in the nine months ended September 30, 2018, an increase of $1.8 million or 65.7% over the nine months ended September 30, 2017. Revenue growth in Europe was primarily due to increased market penetration in existing territories and increased physician and patient awareness of our Inspire system. Additionally, $0.5 million of the increase in revenue was attributable to an increase in our average selling price.

Cost of Goods Sold and Gross Margin Cost of goods sold increased $2.8 million, or 65.9%, to $6.9 million for the nine months ended September 30, 2018 compared to $4.1 million for the nine months ended September 30, 2017. The increase was primarily due to increased purchases of manufactured products due to higher sales volume of our Inspire system.

Gross margin was 79.8% for the nine months ended September 30, 2018 compared to 77.8% for the nine months ended September 30, 2017. The lower gross margin for the nine months ended September 30, 2017 was primarily due to higher cost of goods sold resulting from an excess inventory charge of $0.5 million for the anticipated introduction of the fourth generation Inspire system in the United States in July 2017.

Selling and Marketing Expenses Selling and marketing expenses increased $12.3 million, or 63.1%, to $31.9 million for the nine months ended September 30, 2018 compared to $19.6 million for the nine months ended September 30, 2017. The increase in selling and marketing expenses was primarily due to an increase of $9.3 million related to compensation, travel and other employee-related expenses of our sales and marketing organizations, primarily as a result of increased headcount. Other drivers included an increase of $2.1 million of direct-to-patient marketing programs, trade show and conference expenses, an increase of $0.8 million of expenses related to increased headcount in our reimbursement organization, and an increase of $0.1 million due to increased physician training costs.

Research and Development Expenses Research and development expenses increased $0.7 million, or 16.0%, to $5.2 million for the nine months ended September 30, 2018 compared to $4.5 million for the nine months ended September 30, 2017. This change was primarily due to an increase of $0.5 million of compensation and employee-related expenses, and $0.2 million for ongoing research and development projects.

General and Administrative Expenses General and administrative expenses increased $2.9 million, or 115.6%, to $5.5 million for the nine months ended September 30, 2018 compared to $2.6 million for the nine months ended September 30, 2017. The primary driver of this increase was an increase of $1.3 million due to compensation, travel and other employee-related expenses for administrative personnel. In addition, general and administrative expenses increased $1.1 million related to legal fees, financial audit fees, and insurance costs, which increased primarily as a result of becoming a public company, as well as out-sourced information technology services and facilities costs.

Other Expense, Net

Other expense, net increased $0.5 million, or 42.2%, to $1.6 million for the nine months ended September 30, 2018 compared to $1.1 million for the nine months ended September 30, 2017. The change was primarily due to an increase in interest expense of $0.5 million related to additional borrowings under our credit facility, the fair value adjustment of $0.6 million of our previously

outstanding convertible preferred stock warrants, and $0.2 million related to the final payment fee under our credit facility. This increase was partially offset by an increase of $0.9 million of interest income related to our higher cash, cash equivalents and short-term investments balances.

Fiscal Year Ended December 31, 2017 Compared to Fiscal Year Ended December 31, 2016

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	Year Ended December 31,			
	2016	2017	$ Change	% Change
	(in thousands, except percentages)			
Revenue	$16,427	$28,567	$12,140	73.9%
Cost of goods sold	3,905	6,018	2,113	54.1%
Gross profit	12,522	22,549	10,027	80.1%
Gross margin	*76.2%*	*78.9%*		
Operating expenses:				
Selling and marketing	20,019	28,552	8,533	42.6%
Research and development	7,091	6,194	(897)	(12.6)%
General and administrative	2,665	3,806	1,141	42.8%
Total operating expenses	29,775	38,552	8,777	29.5%
Operating loss	(17,253)	(16,003)	1,250	(7.2)%
Other expense, net	1,275	1,508	233	18.3%
Net loss	$(18,528)	$(17,511)	$1,017	(5.5)%

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Revenue

Revenue increased $12.1 million, or 73.9%, to $28.6 million in fiscal year 2017 compared to $16.4 million in fiscal year 2016. The increase was attributable to an increase in sales of our Inspire system of $10.5 million in the United States and an increase of $1.6 million in Europe, primarily in Germany.

Revenue information by region is summarized as follows:

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	Year Ended December 31,					
	2016		2017		Change 2016 / 2017	
	Amount	% of Revenue	Amount	% of Revenue	$	%
	(in thousands, except percentages)					
United States	$13,789	83.9%	$24,293	85.0%	$10,504	76.2%
Europe	2,638	16.1	4,274	15.0	1,636	62.0

Total revenue	$16,427	100.0%	$28,567	100.0%	$12,140	73.9%

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Revenue generated in the United States was $24.3 million in fiscal year 2017, an increase of $10.5 million or 76.2% over fiscal year 2016. Revenue growth in the United States was primarily due to increased market penetration in existing territories, the expansion of our sales representatives into new territories, increased physician and patient awareness of our Inspire system, increased prior authorization approvals, and an increase in our average selling price.

Revenue generated in Europe was $4.3 million in fiscal year 2017, an increase of $1.6 million or 62.0% over fiscal year 2016. Revenue growth in Europe was primarily due to increased market penetration in existing territories and increased physician and patient awareness of our Inspire system.

Cost of Goods Sold and Gross Margin Cost of goods sold increased $2.1 million, or 54.1%, to $6.0 million in fiscal year 2017 compared to $3.9 million in fiscal year 2016. The increase was primarily due to increased costs to purchase manufactured products due to higher sales volume of our Inspire system.

Gross margin increased to 78.9% in fiscal year 2017 compared to 76.2% in fiscal year 2016. The increase in gross margin was primarily due to the growth in revenue, which enabled us to spread the fixed portion of our operations costs, including distribution-related expenses and management salaries, over more units.

Selling and Marketing Expenses Selling and marketing expenses increased $8.5 million, or 42.6%, to $28.6 million in fiscal year 2017 compared to $20.0 million in fiscal year 2016. As a percentage of revenue, selling and marketing expenses decreased to 99.9% in fiscal year 2017 compared to 121.9% in fiscal year 2016. The increase in selling and marketing expenses was primarily due to an increase of $3.9 million and $1.1 million related to compensation, travel and other employee-related expenses of our U.S. and European sales and marketing organizations, respectively, primarily as a result of increased headcount. Other drivers included an increase of $2.3 million of direct-to-patient marketing programs, trade show and conference expenses, an increase of $0.7 million of expenses related to increased headcount in our reimbursement organization and an increase of $0.4 million due to increased physician training costs.

Research and Development Expenses Research and development expenses decreased $0.9 million, or 12.6%, to $6.2 million in fiscal year 2017 compared to $7.1 million in fiscal year 2016. As a percentage of revenue, research and development expenses decreased to 21.7% in fiscal year 2017 compared to 43.2% in fiscal year 2016. The decrease in research and development expenses was primarily attributable to a decrease in product development costs and consulting costs of $1.4 million relating to the completion of the fourth generation of our Inspire system in fiscal year 2016, partially offset by higher research study costs of $0.2 million and an increase of $0.3 million in regulatory expenses due to the commencement of regulatory activities in Japan during 2017.

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General and Administrative Expenses General and administrative expenses increased $1.1 million, or 42.8%, to $3.8 million in fiscal year 2017 compared to $2.7 million in fiscal year 2016. As a percentage of revenue, general and administrative expenses decreased to 13.3% in fiscal year 2017 compared to 16.2% in fiscal year 2016. The primary driver of this increase was an increase of $0.7 million related to legal fees, financial audit fees, insurance costs, out-sourced information technology services and facilities costs. In addition, general and administrative expenses increased $0.3 million due to compensation, travel and other employee-related expenses for administrative personnel.

Other Expense, Net

Other expense, net increased $0.2 million, or 18.2%, to $1.5 million in fiscal year 2017 compared to $1.3 million in fiscal year 2016. The increase in other expense, net was due to an increase in interest expense of $0.5 million related to additional borrowings under our credit facility and the fair value adjustment of $0.1 million of our outstanding convertible preferred stock

warrants, which are accounted for as a liability and marked-to-market at each reporting period. This increase was partially offset by $0.1 million due to foreign currency exchange and by $0.1 million of interest income with our higher cash, cash equivalents and short-term investments balances compared to 2016.

Fiscal Year Ended December 31, 2016 Compared to Fiscal Year Ended December 31, 2015

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	Year Ended December 31,			
	2015	2016	$ Change	% Change
	(in thousands, except percentages)			
Revenue	$8,012	$16,427	$8,415	105.0%
Cost of goods sold	2,809	3,905	1,096	39.0%
Gross profit	5,203	12,522	7,319	140.7%
Gross margin	*64.9%*	*76.2%*		
Operating expenses:				
Selling and marketing	15,291	20,019	4,728	30.9%
Research and development	7,079	7,091	12	0.2%
General and administrative	2,631	2,665	34	1.3%
Total operating expenses	25,001	29,775	4,774	19.1%
Operating loss	(19,798)	(17,253)	2,545	(12.9)%
Other expense, net	1,539	1,275	(264)	(17.2)%
Net loss	$(21,337)	$(18,528)	$2,809	(13.2)%

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Revenue

Revenue increased $8.4 million, or 105.0%, to $16.4 million in fiscal year 2016 compared to $8.0 million in fiscal year 2015. The increase was attributable to an increase in sales of our Inspire system of $7.6 million in the United States and $0.8 million in Europe.

Revenue information by region is summarized as follows:

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	Year Ended December 31,					
	2015		2016		Change 2015 / 2016	
	Amount	% of Revenue	Amount	% of Revenue		$%
	(in thousands, except percentages)					
United States	$6,132	76.5%	$13,789	83.9%	$7,657	124.8%
Europe	1,880	23.5	2,638	16.1	758	40.3%
Total revenue	$8,012	100.0%	$16,427	100.0%	$8,415	105.0%

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Revenue generated in the United States was $13.8 million in fiscal year 2016, an increase of $7.6 million or 124.8% over fiscal year 2015. Revenue growth in the United States was primarily due to the expansion of our sales representatives into new territories, increased physician and patient awareness of our Inspire system, increased prior authorization approvals and an increase in our average selling price.

Revenue generated in Europe was $2.6 million in fiscal year 2016, an increase of $0.8 million or 40.3% over fiscal year 2015. Revenue growth in Europe was primarily due to increased market penetration in existing territories and increased physician and patient awareness of our Inspire system.

Cost of Goods Sold and Gross Margin Cost of goods sold increased $1.1 million, or 39.0%, to $3.9 million in fiscal year 2016 compared to $2.8 million in fiscal year 2015. The increase was primarily due to increased costs to purchase manufactured products due to higher sales volume of our Inspire system.

Gross margin increased to 76.2% in fiscal year 2016 compared to 64.9% in fiscal year 2015. The increase in gross margin was primarily due to the growth in sales which enabled us to spread the fixed portion of our operations costs, including distribution-related expenses and management salaries, over more units as well as the introduction of our new patient remote control in 2016.

Selling and Marketing Expenses Selling and marketing expenses increased $4.7 million, or 30.9%, to $20.0 million in fiscal year 2016 compared to $15.3 million in fiscal year 2015. As a percentage of revenue, selling and marketing expenses decreased to 121.9% in fiscal year 2016 compared to 190.8% in fiscal year 2015. The increase in selling and marketing expenses was primarily due to an increase of $2.7 million related to compensation and other employee-related expenses of our sales and marketing organization as a result of increased headcount, an increase of $0.9 million related to direct-to-patient marketing programs, trade show and conference expenses and an increase of $0.6 million due to increased field sales travel expenses and physician training costs.

Research and Development Expenses Research and development expenses for each of fiscal years 2016 and 2015 was $7.1 million, consisting primarily of clinical monitoring costs of our long-term and post-market clinical trials as well as product development costs and consulting costs in fiscal year 2015 relating to the completion of our patient remote control.

General and Administrative Expenses General and administrative expenses increased $0.1 million, or 1.3%, to $2.7 million in fiscal year 2016 compared to $2.6 million in fiscal year 2015, primarily as a result of increased facilities costs.

As a percentage of revenue, general and administrative expenses decreased to 16.2% in fiscal year 2016 compared to 32.7% in fiscal year 2015.

Other Expense, Net

Other expense, net decreased $0.2 million, or 17.1%, to $1.3 million in fiscal year 2016 compared to $1.5 million in fiscal year 2015. The decrease in other expense, net was primarily related to the decrease in fair value adjustment of $0.2 million of our outstanding convertible preferred stock warrants, which are accounted for as a liability and marked-to-market at each reporting period.

Seasonality

Historically, we have experienced seasonality in our first and fourth quarters, and we expect this trend to continue. 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. In the first quarter of each year in Europe, we have experienced, and may in the future experience, reduced demand for our Inspire therapy as Neue Untersuchungs-und Behandlungsmethoden, or NUB, coverage status is being determined and as hospitals are establishing their budgets pertaining to allocation of funds to purchase our Inspire therapy.

Liquidity and Capital Resources

As of September 30, 2018, we had cash, cash equivalents and short-term investments of $120.4 million and an accumulated deficit of $142.1 million, compared to cash, cash equivalents and short-term investments of $16.1 million and an accumulated deficit of $125.1 million as of December 31, 2017. On May 7, 2018, we completed our IPO by issuing 7,762,500 shares of common stock, at an offering price of $16.00 per share, for net proceeds of approximately $112.0 million after deducting underwriting discounts and commissions and offering expenses payable by us. Prior to our IPO, our primary sources of capital were from private placements of our convertible preferred securities, sales of our Inspire system and amounts borrowed under credit facilities. Since inception and prior to the IPO, we raised a total of $119.1 million in net proceeds from private placements of our convertible preferred securities. In August 2015, we entered into a loan and security agreement with Oxford Finance LLC, or Oxford Finance, for up to $25.5 million of debt financing. As of September 30, 2018, we had $24.5 million of outstanding borrowings under the credit facility.

We believe that our existing cash resources will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. If these sources are insufficient to satisfy our liquidity requirements, however, we may seek to sell additional equity or make additional borrowings under a new credit facility. If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Additional financing may not be available at all, or in amounts or on terms unacceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our Inspire therapy.

Cash Flows

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

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	Year ended December 31,			Nine Months Ended September 30,	
	2015	2016	2017	2017	2018
				(unaudited)	
			(in thousands)		
Net cash provided by (used in):					
Operating activities	$(22,254)	$(17,949)	$(15,791)	$(12,514)	$(16,105)
Investing activities	23,564	(306)	(7,600)	(5,152)	(87,011)
Financing activities	2,542	12,814	25,661	25,521	120,473
Net increase (decrease) in cash and cash equivalents	$3,852	$(5,441)	$2,270	$7,855	$17,357

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Operating Activities The net cash used in operating activities was $16.1 million for the nine months ended September 30, 2018 and consisted primarily of a net loss of $17.1 million, an increase in net operating assets of $1.1 million and non-cash charges of $2.1 million. Net operating assets consisted primarily of accounts receivable and inventory to support the growth of our operations and accrued compensation as annual bonuses were paid. The increase in net operating assets was also attributed to the increase in prepaid expenses and other assets. Non-cash charges consisted of stock-based compensation, the change in fair value of preferred stock warrants, accretion of debt discount, and depreciation.

The net cash used in operating activities was $12.5 million for the nine months ended September 30, 2017 and consisted primarily of a net loss of $13.3 million, an increase in net operating assets of $0.2 million and non-cash charges of $0.6 million. Net operating assets consisted primarily of accounts receivable to support the growth of our operations and accrued

compensation as annual bonuses were paid. Non-cash charges consisted primarily of accretion of debt discount, stock-based compensation, and depreciation.

The net cash used in operating activities was $15.8 million in 2017 and consisted primarily of a net loss of $17.5 million, a decrease in net operating assets of $0.8 million and non-cash charges of $0.9 million. Net operating assets consisted primarily of accounts receivable and inventory to support the growth of our operations and accrued compensation as annual bonuses were paid. Non-cash charges consisted primarily of depreciation and stock-based compensation.

The net cash used in operating activities was $17.9 million in 2016 and consisted primarily of a net loss of $18.5 million, a decrease in net operating assets of $0.3 million and non-cash charges of $0.3 million. Net operating assets consisted primarily of accounts receivable to support the growth of our operations and accrued compensation as annual bonuses were paid. Non-cash charges consisted primarily of depreciation and stock-based compensation.

The net cash used in operating activities was $22.3 million in 2015 and consisted primarily of a net loss of $21.3 million and an increase in net operating assets of $1.4 million, offset by $0.5 million in non-cash charges. Non-cash charges consisted primarily of depreciation and stock-based compensation.

Investing Activities Net cash provided by investing activities for the nine months ended September 30, 2018 was $87.0 million and consisted primarily of purchases of short-term investments of $98.9 million, offset by proceeds from sales or maturities of short-term investments of $12.0 million.

Net cash used in investing activities was $5.2 million for the nine months ended September 30, 2017 and consisted of purchases of short-term investments of $4.8 million and purchases of property and equipment of $0.4 million.

Net cash used in investing activities was $7.6 million in 2017 and consisted of $7.2 million of investments in short-term marketable securities and $0.4 million of purchases of property and equipment.

Net cash used in investing activities in 2016 was $0.3 million and consisted of purchases of property and equipment.

Net cash provided by investing activities in 2015 was $23.6 million and consisted primarily of net proceeds from short-term investments of $23.9 million, partially offset by purchases of property and equipment of $0.3 million.

Financing Activities Net cash provided by financing activities was $120.5 million for the nine months ended September 30, 2018 and consisted primarily of $112.0 million of net proceeds from the IPO in May 2018 and borrowings of $8.0 million under our credit facility.

Net cash provided by financing activities was $25.5 million for the nine months ended September 30, 2017 and consisted primarily of $25.0 million of net proceeds from the issuance of Series F convertible preferred stock and borrowings of $1.0 million under our credit facility less $0.5 million of expenses.

Net cash provided by financing activities was $25.7 million in 2017 and consisted primarily of $25.0 million of net proceeds from the issuance of Series F convertible preferred stock, borrowings of $1.0 million under our credit facility less $0.5 million of expenses and $0.2 million in proceeds from the exercise of stock options.

Net cash provided by financing activities was $12.8 million in 2016 and consisted primarily of $12.3 million of net proceeds from the issuance of Series F convertible preferred stock, $0.3 million from the purchase of preferred shares under preferred stock warrants and $0.2 million in proceeds from the exercise of stock options.

Net cash provided by financing activities was $2.5 million in 2015 and consisted primarily of $2.5 million received when we amended our credit facility in 2015.

Indebtedness

In August 2015, we entered into a loan and security agreement with Oxford Finance, as lender and collateral agent. The loan and security agreement initially provided for a term A loan facility in the amount of $15.5 million, which was fully funded on the closing date, and a term B loan facility in an amount of at least $3.5 million but no more than $10.0 million, to be available in the future subject to our achievement of certain revenue milestones. We refer to our term A loan facility and our term loan B facility together as our credit facility. In February 2017, we amended the loan and security agreement to, among other things, increase

borrowings under the term A loan facility by $1.0 million, increase the minimum amount of the term B loan facility to $5.0 million and reduce the maximum amount of the term B loan facility to $9.0 million. On February 7, 2018, we borrowed $8.0 million under the term B loan facility.

The credit facility is secured by substantially all of our personal property other than our intellectual property. Outstanding borrowings under the credit facility bear interest at an annual rate equal to the greater of (i) 7.95% and (ii) the sum of (a) the 30-day U.S. LIBOR rate on the last business day of the month that immediately precedes the month in which such interest will accrue, plus (b) 6.90%. We are required to make monthly payments of interest only through March 1, 2019, or the interest-only period; provided that the interest-only period will be extended to March 1, 2020 if we have revenue, measured on a trailing 12-month basis as of December 31, 2018, of at least $25.0 million, which was met during the nine months ended September 30, 2018, and, therefore, the interest-only period is extended to March 1, 2020. Following the interest-only period, we will be required to make monthly payments of interest and principal in 24 consecutive monthly installments. Outstanding borrowings under the credit facility mature on February 1, 2022. On the maturity date, in addition to our regular monthly payments of principal and accrued interest, we will be required to make a payment of 5.0% (or 5.5% if the interest-only period has been extended to March 1, 2020) of the total amount borrowed under the credit facility, which we refer to as the Final Payment, unless we have not already made such payment in connection with an acceleration or prepayment of borrowings under the credit facility. Because the interest-only period has been extended, the Final Payment fee will be 5.5%.

Borrowings under the term A loan facility are prepayable at our option in whole, but not in part, together with all accrued and unpaid interest thereon and, if not previously made, the Final Payment, subject to a prepayment fee of 1.5% if such borrowings are prepaid prior to February 24, 2019 and 1.00% if such borrowings are prepaid on or after February 24, 2019. The Final Payment is being accrued over the life of the credit facility and will be due at the earlier of maturity or prepayment. Borrowings under the term B loan facility are prepayable at our option in whole, but not in part, together with all accrued and unpaid interest thereon and, if not previously made, the Final Payment, subject to a prepayment fee of 2.5% if the such borrowings are prepaid prior to February 7, 2019, 1.5% if such borrowings are prepaid on or after February 7, 2019 but prior to February 7, 2020 and 1.00% if such borrowings are on or after February 7, 2020. We are also required to prepay the amounts outstanding under the credit facility upon the occurrence of certain customary events of default, as well as the occurrence of certain material adverse events. The credit facility also includes certain customary affirmative and negative covenants, but does not include any financial covenants. We were in compliance with all covenants under the credit facility as of September 30, 2018.

In August 2015, we issued to Oxford Finance warrants to purchase 12,404 and 17,176 shares, respectively, of our Series E convertible preferred stock, having an exercise price of $2.62 per share. In February 2017 and February 2018, we issued warrants to Oxford Finance to purchase 29,197 and 233,577 shares, respectively, of our Series F convertible preferred stock, having an exercise price of $1.37 per share. Each of the warrants described above has a term of 10 years.

Upon the closing of the IPO, the warrants to purchase 630,372 shares of preferred stock at a weighted average exercise price of $1.46 per share became exercisable to purchase 100,558 shares of common stock at a weighted average exercise price of $9.38 per share.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by applicable regulations of the SEC, that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Contractual Obligations and Commitments

Our contractual obligations and commitments as of December 31, 2017 are summarized in the table below:

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		Payments Due by Year			
($ in thousands)	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Long-term debt(1)	$20,250	$1,384	$17,939	$926	$—
Operating leases(2)	239	191	48	—	—

Total contractual obligations	$20,489	$1,575	$17,987	$926	$—

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(1) The total amount outstanding under the credit facility was $16.5 million at December 31, 2017. Assumes a 36 month amortization period for repayment of the debt. On February 7, 2018, we borrowed an additional $8.0 million under the credit facility, which amount is not reflected in the table above. As of December 31, 2017, all amounts borrowed under the credit facility are interest-only through March 1, 2019, after which monthly payments of principal and interest are due through March 1, 2022; provided that the interest-only period will be extended to March 1, 2020 if we have revenue, measured on a trailing 12-month basis as of December 31, 2018, of at least $25.0 million. We met this trailing revenue measurement during the nine months ended September 30, 2018 and, accordingly, the interest-only period is extended to March 1, 2020, after which payments of interest and principal will be payable in 24 consecutive monthly installments. The extension of the interest-only period is not reflected in the table above.

(2) We currently lease approximately 9,300 square feet for our headquarters in Maple Grove, Minnesota under a lease that expires in March 2019. In September 2018, we entered into a non-cancelable operating lease agreement to sublease approximately 44,000 square feet of office space for our corporate headquarters, which lease is scheduled to commence on January 15, 2019 and expire November 30, 2020. Under the terms of the sublease, our total lease obligation is $1.9 million, payable in equal monthly installments during the term of the sublease, which is not reflected in the table above.

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. If overall interest rates had increased by 100 basis points during the nine months ended September 30, 2018 our interest income would not have been materially affected. We do not currently use or plan to use financial derivatives in our investment portfolio. Additionally, the interest rate for our outstanding debt is variable. If overall interest rates had increased by 100 basis points during the nine months ended September 30, 2018 our interest expense would have increased by approximately $0.2 million.

Credit Risk

As of September 30, 2018 and December 31, 2017, our cash and cash equivalents were maintained with one financial institution in the United States, and our current deposits are likely in excess of insured limits. We believe this institution has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us.

Our accounts receivable primarily relate to revenue from the sale of our Inspire system to hospitals in the United States and Europe, primarily in Germany. No single customer represented more than 3% of our accounts receivable as of September 30, 2018 or December 31, 2017.

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.

Related Parties

For a description of our related party transactions, see "Certain Relationships and Related Party Transactions."

Critical Accounting Policies and Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the audited financial statements and accompanying notes included elsewhere in this prospectus. Management believes 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.

Significant areas requiring management estimates or judgments include the following key financial areas:

Revenue Recognition

We recognize revenue when persuasive evidence of an arrangement exists, product shipment has occurred, or there are no further obligations yet to be performed, pricing is fixed or determinable, and collection is reasonably assured. We make reasonable assumptions regarding the future collectability of amounts receivable from customers to determine whether the revenue recognition criteria have been met. Taxes assessed by a governmental authority that are directly imposed on revenue-producing transactions between a seller and a customer are not recorded as revenue. In general, our standard terms and conditions of sale do not allow for product returns. Sales returns have been limited to damaged product and have not been material. We expense shipping and handling costs as incurred and includes them in the cost of goods sold. 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.

Common Stock Valuation and Stock-Based Compensation

We maintain an equity incentive plan to provide long-term incentives for employees, consultants, and members of the board of directors. The plan allows for the issuance of non-statutory and incentive stock options to employees and non-statutory stock options to consultants and non-employee directors.

We recognize equity-based compensation expense for awards of equity instruments to employees and non-employees based on the grant date fair value of those awards in accordance with FASB ASC Topic 718, Stock Compensation (ASC 718). ASC 718 requires all equity-based compensation awards to employees and nonemployee directors, including grants of restricted shares and stock options, to be recognized as expense in the statements of operations and comprehensive loss based on their grant date fair values. We estimate the fair value of stock options using the Black-Scholes option pricing model. We use the value of our common stock to determine the fair value of restricted shares.

We account for restricted stock and common stock options issued to nonemployees under FASB ASC Topic 505-50, Equity-Based Payments to Non-Employees (ASC 505-50). As such, the value of such options is periodically remeasured and income or expense is recognized over their vesting terms. Compensation cost related to awards with service-based vesting schedules is recognized using the straight-line method. We determine the fair value of the restricted stock and common stock granted to nonemployees as either the fair value of the consideration received or the fair value of the equity instruments issued. We have not granted any share-based awards to our consultants.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (i) the expected share price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) the expected dividend yield. Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The group of representative companies have characteristics similar to us, including stage of product development and focus on the life science industry. We use the simplified method, which is the average of the final vesting tranche date and the contractual term, to calculate the expected term for options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to non-employees, we utilize the contractual

term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. We use an assumed dividend yield of zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

We expense the fair value of our equity-based compensation awards granted to employees on a straight-line basis over the associated service period, which is generally the period in which the related services are received. We measure equity-based compensation awards granted to nonemployees at fair value as the awards vest and recognizes the resulting value as compensation expense at each financial reporting period. We account for award forfeitures as they occur.

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 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. Our review of inventory for excess and obsolete quantities is based primarily on the estimated forecast of future product demand, product life cycles, and introduction of new products. The reserve for excess and obsolete inventory was $0.8 million and $0.5 million as of September 30, 2018 and December 31, 2017, respectively.

Impairment of Long-lived Assets

Long-lived assets consist primarily of property and equipment and 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 during the nine months ended September 30, 2018 nor the year ended December 31, 2017.

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 its net deferred tax assets, and there is no provision for income taxes. Our policy is to record interest and penalties expense related to uncertain tax positions as other expense in the statements of operations and comprehensive loss.

Recent Accounting Pronouncements

A discussion of recent accounting pronouncements is included in Note 2 to our audited financial statements included elsewhere in this prospectus.

JOBS Act

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company," as defined in the JOBS Act. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;

- reduced disclosure obligations regarding executive compensation in this prospectus and in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenue exceeds $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in this registration statement and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different from what you might receive from other public reporting companies in which you hold equity interests.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, as a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable.

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Business

BUSINESS

`Overview`

We are a medical technology company focused on the development and commercialization of innovative and minimally invasive solutions for patients with obstructive sleep apnea. Our proprietary Inspire system is the first and only FDA-approved neurostimulation technology that provides a safe and effective treatment for moderate to severe obstructive sleep apnea. 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* and more than 70 peer-reviewed publications, supports the safety and efficacy of Inspire therapy. Inspire therapy received premarket approval, or PMA, from the U.S. Food and Drug Administration, or FDA, in April 2014 and has been commercially available in certain European markets since November 2011. Inspire therapy is indicated for patients with moderate to severe obstructive sleep apnea 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 must have been confirmed to fail or be unable to tolerate positive airway pressure treatments, such as CPAP, and be 22 years of age or older, though there are no similar requirements for patients in Europe. Physicians have treated more than 4,000 patients with Inspire therapy at over 220 medical centers across the United States and Europe.

Sleep apnea is a serious and chronic disease that negatively impacts a patient's sleep, health and quality of life. According to the World Health Organization, sleep apnea affects more than 100 million people worldwide. Obstructive sleep apnea, or 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, or 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.

Continuous positive airway pressure, or 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. Based on industry sources, we estimate that approximately 2 million patients are prescribed a CPAP device annually in the United States. Based on published literature, we estimate that only approximately 35% to 65% of patients prescribed a CPAP device are compliant with the therapy. 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.

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 94% at an average of 12 months from initial treatment in the first 508 patients in our ongoing global patient registry.
- **Strong patient compliance**, with 80% of patients reporting continued nightly use through five years from initial treatment in our 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 market for OSA treatment is large and growing. Currently, there are approximately 17 million individuals in the United States with moderate to severe OSA, and, based on industry sources, we estimate that approximately 2 million patients are prescribed a CPAP device annually in the United States. A report by McKinsey & Company in 2010 estimated the annual economic costs of untreated moderate to severe OSA in the United States to be between $65 billion and $165 billion, potentially greater than the costs of asthma, heart failure, stroke or hypertensive disease, which range from $20 billion to $80 billion according to certain estimates.

We believe there is a significant population in the United States with moderate to severe OSA who are unable to use or get consistent benefit from CPAP and who are eligible for our Inspire therapy. We estimate that this market is growing by approximately 500,000 new patients, or approximately $10 billion, per year in the United States. We also believe there is a substantial market opportunity outside the United States.

The results from multiple clinical trials, which include four sponsored and 12 independent clinical studies that evaluated approximately 980 patients, including more than 280 patients evaluated in independent clinical studies, together with patient-reported outcomes, 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 Stimulation Therapy for Apnea Reduction, or 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. Ongoing 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, or ASCs, in the United States and in select countries in Europe through a direct sales organization. We have 40 sales representatives in the United States and six in Europe. Our direct sales force engages in sales efforts and promotional activities focused on ear, nose and throat, or 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-patient 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 and frequently results in patient leads.

Our customers are reimbursed the cost required to treat each patient through various third-party payors, such as commercial payors and government agencies. We are in active discussions with commercial payors to establish positive national coverage policies to support reimbursement of Inspire therapy. In July 2018, Aetna Inc., one of the leading health plans in the United States, began providing coverage for our Inspire therapy, bringing the number of our secured positive coverage policies to nine U.S. commercial payors. In parallel, our 15 person reimbursement team, which we refer to as our market access team, is focused on assisting patients and physicians in obtaining appropriate prior authorization approvals from commercial payors on a case-by-case basis in advance of treatment with our Inspire therapy. We have been successful in obtaining prior authorization approvals from approximately 300 commercial payors. In addition, Medicare may cover our procedure on a medical necessity basis. We also have a U.S. government contract for patients who are treated by the Veterans Health Administration.

We generated revenue of $28.6 million, with a gross margin of 78.9% and a net loss of $17.5 million, for the year ended December 31, 2017, compared to revenue of $16.4 million, with a gross margin of 76.2% and a net loss of $18.5 million, for the year ended December 31, 2016, and revenue of $8.0 million, with a gross margin of 64.9% and a net loss of $21.3 million for the year ended December 31, 2015. For the nine months ended September 30, 2018, we generated revenue of $34.0 million with a gross margin of 79.8% and a net loss of $17.1 million compared to revenue of $18.6 million with a gross margin of 77.8% and a net loss of $13.3 million for the nine months ended September 30, 2017. Our accumulated deficit as of September 30, 2018 was $142.1 million.

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 positive airway pressure treatments, such as CPAP. We received a PMA from the FDA in April 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 4,000 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 four sponsored and 12 independent clinical studies that evaluated approximately 980 patients, including more than 280 patients evaluated in independent clinical studies, and have been highlighted in more than 70 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-patient marketing initiative that further drives demand through patient empowerment. This outreach helps to educate thousands of patients on our Inspire therapy and frequently results in patient leads. 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 highly efficient approach to advance patients, once identified, to placement of the Inspire system. Our dedicated market access team helps patients and providers work with payors to secure the appropriate prior authorization approvals in advance of initial treatment. In addition, this team proactively works with payors to establish positive coverage policies by highlighting the compelling clinical data and the economic benefit of our Inspire therapy. This highly leverageable team has been successful in helping to secure reimbursement from approximately 300 commercial payors to date, and positive coverage policies from nine U.S. commercial payors, including Aetna, Inc., one of the leading health plans in the United States.

- ***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 the United States, we launched in July 2017 the fourth generation of our Inspire system, with a neurostimulator that is 40% smaller and 18% thinner than the neurostimulator in the previous generation while maintaining an approximate 11-year battery life without needing to be recharged. In addition, patients treated with this fourth generation device may now undergo an MRI scan of the head or extremities. We launched our fourth generation Inspire system in Europe in the second quarter of 2018. We have a comprehensive patent portfolio to protect our intellectual property and technology, with rights as of September 30, 2018 to 20 issued U.S. patents, 22 issued foreign patents, 25 pending U.S. patent applications and 39 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:

- ***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-patient marketing initiatives, which include paid search, radio, social media and online videos.

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Expand our U.S. sales and marketing organization to drive adoption of our Inspire therapy. We plan to expand our sales and marketing organization and seek to recruit and train exceptionally talented sales representatives in existing and new markets in the United States to help facilitate further adoption and broaden awareness of our Inspire therapy. Our success in developing new markets is 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.

- ***Leverage our prior authorization model while we work with payors to broaden coverage.*** Our dedicated in-house market access team will continue to assist patients and physicians in obtaining prior authorization approvals from commercial payors for treatment with our Inspire therapy. In parallel, we are in active discussions with commercial payors to establish positive national coverage policies and continue to highlight our compelling and robust clinical data, the economic cost savings associated with highly compliant OSA treatment and our increased support from leading medical organizations and key opinion leaders. We believe increased positive payor coverage policies could substantially expand patient access by reducing hurdles to treatment.

- ***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. An example of our efforts to expand our label indications includes our clinical study that is evaluating the use of Inspire therapy in pediatric patients with Down syndrome.

- ***Further penetrate and expand into existing and new international markets.*** We plan 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 expand our reach to new markets, such as Japan. 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.

Market Overview

Overview of Obstructive Sleep Apnea

Sleep apnea is a common sleep disorder in which a patient's breathing repeatedly stops during sleep, temporarily decreasing the oxygen concentration in the blood. In OSA, the cessation in breathing is caused by the relaxation of the airway muscles during sleep, which causes a functional obstruction in the airway and prevents the passage of airflow, even though the patient is attempting to breathe. The lack of airflow can last anywhere from ten seconds to more than a minute, and in severe cases may occur 30 or more times during an hour of sleep. The reduction in blood oxygen triggers a startle response that transiently wakens the patient and opens the airway leading to a temporary restoration of normal breathing. This cycle occurs throughout the night, decreasing the overall quality of a patient's sleep, negatively affecting a patient's health and significantly reducing their quality of life.

The following diagram depicts a typical OSA event in which the base of the tongue falls back and restricts airflow.

Typical Obstructive Sleep Apnea Event

The severity of OSA is measured by the frequency of apnea or hypopnea events per hour. Apneas are a complete restriction of the airway and hypopneas are a greater than 50% restriction in the airway, both of which are accompanied by a significant decrease in the oxygen levels in the blood. The total number of apneas and hypopneas per hour of sleep is referred to as the Apnea-Hypopnea Index, or AHI. The severity of OSA is based on the following AHI ranges:

- Normal range: AHI < 5 events per hour

-

Mild OSA: 5 £ AHI < 15 events per hour

- Moderate OSA: 15 £ AHI < 30 events per hour
- Severe OSA: AHI ³ 30 events per hour

Symptoms and Diagnosis of Obstructive Sleep Apnea

Patients struggling with OSA are typically unaware of their condition. Patients who are obese, male or of advanced age are at higher risk for OSA. A common first indicator is that a patient is a heavy snorer. Beyond snoring, a patient may also experience lack of energy, headaches, depression, memory or concentration problems, excessive daytime sleepiness, nighttime gasping and dry mouth.

The impact of heavy snoring creates unrest for both the patient and his or her bed partner. The bed partner's inability to sleep without interruption often drives the patient to obtain medical advice. Once a physician makes a preliminary diagnosis, the patient must undergo a sleep study, or polysomnogram, to determine a definitive diagnosis of OSA. This type of sleep study often requires the patient to stay overnight at the sleep center, attached to a variety of monitors and sensors that measure the patient's airflow, sleep quality, blood oxygen levels and breathing patterns. More recently, physicians have begun prescribing home sleep tests, or HSTs, in lieu of in-office polysomnograms, to help diagnose OSA. We expect that as the use of HSTs, which are more convenient for patients than in-office polysomnograms, continues to increase, the number of patients diagnosed with OSA will also increase.

Comorbidities Associated with OSA

Repetitive cessation of breathing during sleep can have a substantial negative impact on affected patients and their quality of life. In a third-party independent study, the reduction in quality of life with OSA was reported to be equivalent to that observed with diabetes or hypertension. Published research shows a strong correlation between OSA and negative health outcomes, including:

- heart failure;
- hypertension;
- stroke;
- atrial fibrillation;
- type 2 diabetes;
- obesity;
- heart attack;
- acute coronary syndrome; and
- depression.

An 18-year mortality follow-up study at the University of Wisconsin based on the 1,522-person Wisconsin Sleep Cohort sample noted reduced survival rates for individuals with untreated OSA. As depicted in the chart below, participants with untreated moderate and severe OSA experienced a significant decline in survival rates, to approximately 85% and approximately 60%, respectively.

Prevalence of OSA and Economic Costs if Untreated

We believe the prevalence of OSA is large and growing. According to the World Health Organization, sleep apnea affects more than 100 million people worldwide. There are two types of sleep apnea: Obstructive Sleep Apnea, or OSA, and Central Sleep Apnea, or CSA. OSA is the most common form of sleep apnea and is caused by a functional obstruction of the airway. By contrast, CSA is far less common and is caused by the brain's inability to send appropriate signals to the muscles in the chest that control breathing. There are an estimated 17 million individuals in the United States with moderate to severe OSA. Untreated OSA is associated with a significant economic burden to society. A report by McKinsey & Company in 2010 estimated the annual economic costs of untreated moderate to severe OSA in the United States to be between $65 billion and $165 billion, potentially greater than the cost of asthma, heart failure, stroke or hypertensive disease, which range from $20 billion to $80 billion according to certain estimates.

OSA is associated with an increase in the rate and severity of motor vehicle and train accidents, increased healthcare utilization, reduction of work performance and occupational injuries. For example, several studies suggest that treating OSA in drivers can reduce the number of motor-vehicle accidents and overall medical costs. Published studies examining the results of treatment in commercial drivers for Waste Management, the nation's largest waste removal company, and Schneider National, Inc., a trucking company, showed that treatment led to reductions in health plan costs, short-term disability claims, missed workdays, monthly medical costs and preventable driving accidents.

Current Treatments for OSA and their Limitations

There are several treatment options for OSA patients depending on the level of severity of the disease, ranging from lifestyle changes to surgery. When lifestyle changes, such as weight loss, are insufficient to address OSA, physicians explore alternative therapies. CPAP is the leading therapy for patients with moderate to severe OSA. For mild to slightly moderate OSA, physicians may prescribe an oral device designed to prevent the airway from collapsing by shifting the position of the jaw forward, creating space at the back of the tongue, but these devices are not effective for everyone with OSA.

Cpap

CPAP is delivered through a face or nasal mask that connects through a hose to a bedside air pump. The pump blows air through the hose to the mask and down the patient's throat, keeping the airway open and allowing the patient to breathe. In order for treatment with 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.

CPAP has demonstrated improvements in patient-reported sleep quality and reductions in daytime sleepiness associated with the number of hours of use. Moreover, controlled studies have shown associations between CPAP device use and a decline in the incidence of strokes and heart attacks. Many patients who use a CPAP device experience immediate symptom relief and increased energy and mental sharpness during the day.

Despite the effective treatment CPAP offers, it also faces significant limitations as a therapeutic option, primarily due to low patient compliance. Medicare defines compliance as using a CPAP device at least four hours a night for 70% of nights during any consecutive 30 day period within the first three months of initial usage. Based on published literature, we estimate that only approximately 35% to 65% of patients prescribed a CPAP device are compliant with the therapy. Commonly cited reasons patients fail to use their CPAP device on a regular basis include:

- mask discomfort;
- mask leakage;
- pressure intolerance;
- skin irritation;
- nasal congestion;

- nasal drying;
- nosebleeds;
- claustrophobia; and
- lack of intimacy.

Low patient compliance persists despite the development of various CPAP devices designed to improve patient comfort and treatment through a variety of methods, including coaching, patient education and remote monitoring.

Surgical Procedures

In cases of OSA where CPAP has failed or patients have discontinued treatment, surgery may be an alternate therapy. Two of the primary surgical procedures for treating OSA are uvulopalatopharyngoplasty, or UPPP, and maxillomandibular advancement, or MMA. In a UPPP procedure the surgeon remodels the structure of the airway by removing excess tissue that is believed to be responsible for obstructing the airway. This can include the uvula, part of the soft palate or roof of the mouth, excess throat tissue, tonsils, adenoids and part of the tongue. In a MMA procedure, a surgeon reconstructs the lower jaw by breaking the jaw and adding in spacers to reposition it forward by approximately 10 millimeters. Both of these are invasive in-patient procedures that irreversibly alter the patient's anatomy and require extended and painful recovery periods. The typical recovery period for a UPPP procedure is three weeks, and for an MMA procedure is several months. While these procedures may be effective in reducing OSA, the success rates vary widely. Other surgical options for the treatment of OSA include coblation tongue reduction surgery, a procedure in which a probe inserted into the tongue uses radiofrequency energy to shrink the soft tissue inside the base of the tongue, and transoral robotic tongue base reduction surgery, a procedure in which a surgeon uses a surgical robot to remove a portion of the tongue.

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.

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 two hours, during which the neurostimulator, sensing lead and stimulation lead are implanted. The procedure is minimally invasive and performed with a series of three 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 and patient remote control, shown with a quarter 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`

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`

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`

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`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 trials 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. Ongoing 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 on the first 508 patients in our ongoing ADHERE patient registry, which we established to follow patients who have been implanted with an Inspire system, demonstrated that these 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 94%.
- **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.
- **Minimally invasive outpatient procedure.** The Inspire system's implantable components are placed during an approximately two-hour outpatient procedure. The procedure is minimally invasive and performed with three small incisions. Patients typically recover quickly and are able to resume normal activities within a week.
-

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

Inspire Therapy Market Opportunity

We believe there is a significant population in the United States with moderate to severe OSA who are unable to use or get consistent benefit from CPAP and who are eligible for our Inspire therapy. Based on industry sources, we estimate that approximately 2 million patients are prescribed a CPAP device annually in the United States. Based on published literature, we estimate that at least 35% of patients prescribed a CPAP device are not compliant with the therapy. We estimate that approximately 70% of the non-compliant patients are eligible for treatment with Inspire therapy, based on historical data we observed from routine endoscopic evaluations conducted during our STAR trial to determine whether a patient's airway anatomy would allow for effective treatment with Inspire therapy. As a result, we estimate the annual total addressable market for our Inspire therapy in the United States to be approximately 500,000 patients, which, based on our average selling price per implantation, represents an annual market opportunity of approximately $10 billion. We also believe there is a substantial market opportunity outside the United States.

Commercialization of Inspire Therapy

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive FDA clearance. We obtained PMA approval for our Inspire system in 2014. Additionally, we received a CE mark for commercialization of our Inspire system in Europe in 2011, and in June 2018, Japan's Ministry of Health, Labour and Welfare approved our Inspire therapy to treat moderate to severe OSA. To commercialize our Inspire system, both in the United States and Europe, 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-patient 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-patient marketing efforts in existing and new markets throughout the United States, Europe and Japan.

In addition, a significant part of our commercialization effort consists of supporting our customers through the reimbursement process. Our Inspire system is currently reimbursed primarily on a per-patient prior authorization basis for patients covered by commercial payors, on a medical necessity basis for most patients covered by Medicare, and under U.S. government contract for patients who are treated by the Veterans Health Administration. We have also secured positive coverage policies from nine U.S. commercial payors, including Aetna Inc., one of the leading health plans in the United States, and other payors at the local and regional level. Our ability to continue to successfully commercialize our Inspire system will depend in large part on our ability to leverage our prior authorization model while we work with commercial payors to create new positive coverage policies in each market in which we operate.

Treatment with Inspire Therapy

Patient Selection

Inspire therapy is indicated for patients with moderate to severe OSA (AHI of 15 to 65) who do not have significant CSA 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 United States must have been confirmed to fail or be unable to tolerate positive airway pressure treatments, such as CPAP, and be 22 years of age or older, though there are no similar requirements for patients in Europe. Patients who fail positive airway pressure, or 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. We have submitted a PMA supplement to the FDA to expand our indication in the United States to patients as young as 12 years of age, which is currently under review.

Implantation

The Inspire system is implanted under general anesthesia through three 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. The last incision is made near the ribs, where a pressure sensing lead is placed 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 a battery in the neurostimulator 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 two hours. 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 week. 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 of the stimulating pulse, the sensitivity of the detection, the timing and length of the pulse, and which part of the stimulating electrode should be used. 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 out of the way without causing discomfort.

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 four sponsored and 12 independent clinical studies that evaluated approximately 980 patients, including more than 280 patients evaluated in independent clinical studies, supports the safety and effectiveness of our 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 70 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 the first 508 patients in 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.

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	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	*	48 / 49
Time following implantation	12 months	5 years	12 months	12 months	3 months
AHI—Baseline	29.3	29.3	28.6	34.0	35.9 / 35.3
AHI—Therapy	9.0	6.2	9.5	7.0	6.3 / 6.3

ESS—Baseline	11.0	11.0	13.0	12	11.1 / 10.9
ESS—Therapy	6.0	6.0	6.5	7	5.8 / 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% ³20 hours per week	Average 5.7 hours per night	Average >45 hours per week; >75% ³40 hours per week

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*
AHI results for 227 patients; ESS results for 241 patients.

**
Not measured.

(1)
Median results.

(2)
Mean results.

STAR Trial

Overview

We sponsored the STAR trial, a multi-center, prospective, single-group, cohort design study that began in 2010 at 22 medical centers across the United States and Europe. We evaluated 126 patients who were confirmed to fail or were unable to tolerate positive airway treatments, such as CPAP. Of the 126 patients, 83% were men, the mean age was 54.5 years and the mean body-mass index was 28.4.

The primary outcome measures were a reduction in AHI from baseline to 12 months of more than 50% along with final AHI being less than 20 events per hour, and a reduction from baseline to 12 months of more than 50% in oxygen desaturation index, or ODI, which measures the number of times per hour of sleep that the blood's oxygen level drops by at least 4% below baseline. These are objective quantitative metrics that are measured during an in-office sleep study or polysomnogram, which also provides important objective measures of sleep quality.

Secondary outcome measures evaluated a patient's quality of life using two standard and validated patient questionnaires, the Functional Outcomes of Sleep Questionnaire, or FOSQ, and the Epworth Sleepiness Scale, or ESS. A clinically relevant improvement in FOSQ is 2.0 points from baseline, and a normalized patient has a FOSQ score greater than 17.9. ESS scores of 10 or greater reflect excessive daytime sleepiness. An additional secondary outcome measured the percentage of sleep time during which a patient's blood oxygen saturation level was below 90%.

After 12 months, 46 consecutive patients who met the criteria of having a response to therapy were then included in a randomized, controlled therapy-withdrawal trial. These patients were randomly assigned, in a 1:1 ratio, to a therapy-withdrawal group, which had the device turned off for at least five days until a sleep study or polysomnogram was performed, or to a therapy-maintenance group, which continued nightly use of the device.

We have continued to follow patients from the STAR trial to collect data regarding long-term efficacy and utilization. See "—Long-Term Benefits of Inspire Therapy."

Results

The results of the STAR trial were initially published in January 2014 in the *New England Journal of Medicine*. The trial met both of its primary endpoints at 12 months, as well as all secondary endpoints.

The median AHI for patients in the STAR trial decreased from 29.3 events per hour to 9.0 events per hour at 12 months ($p<0.001$). The median ODI decreased from 25.4 events per hour to 7.4 events per hour ($p<0.001$). Patients reported significantly improved quality of life based on the FOSQ, on which median scores increased from 14.6 to 18.2 out of a maximum score of 20

(p<0.001). Patients also had less daytime sleepiness as quantified by a decrease in the median ESS from 11.0 to 6.0 (p<0.001). In the trial, the percentage of sleep time during which a patient's blood oxygen saturation levels was below 90% was reduced from 5.4% to 0.9% at 12 months (p=0.01).

Inspire therapy efficacy data from STAR trial at 12 months

After 12 months' follow-up with 126 implanted patients, 124 patients (98%) remained active users of our Inspire therapy. One patient died unexpectedly due to an unrelated cause, and one participant requested a device removal for personal reasons because the patient was a non-responder. Data at 12 months showed that 86% of patients (106 of 123) used the device daily and 93% (115 of 123) used the device at least five days a week, with data unavailable from one patient.

The effectiveness of Inspire therapy was further demonstrated by the results of the therapy-withdrawal portion of the trial, which showed a significant difference between the therapy-withdrawal group and the therapy-maintenance group with respect to the change in the AHI score from the assessment at 12 months of the cohort study to the assessment at the end of the therapy-withdrawal study. As illustrated in the charts below, a difference in change in mean scores of 16.4 events per hour was observed (p<0.001), and a similar effect was observed for the mean ODI scores.

Withdrawal of Inspire therapy results in reversal of therapeutic benefit as measured by AHI and ODI

Safety

Patients from the STAR trial reported various adverse events, typically mild and resolved within five days, which can be divided into two categories. The first category includes those occurring immediately subsequent to the implantation procedure. In this category, 26% of patients reported incision pain and 25% reported post-operative discomfort. There was only one report of a mild infection associated with the procedure. The second category includes device-related adverse events that were reported in the first 18 months after implantation. In this category, 47% of patients reported discomfort due to stimulation at some point during this period, which was generally resolved with programming adjustments to the device. Other common reports included tongue abrasion, headaches and mouth dryness.

Explants and Revisions Two patients out of 126 in the STAR trial did not complete the trial. One patient died unexpectedly due to an unrelated cause, and one patient requested a device removal because the patient was a non-responder. Two other patients underwent revision surgeries to reposition the device to address patient discomfort.

Long-term Benefits of Inspire Therapy Patients receiving Inspire therapy in the STAR trial have been followed for long-term efficacy and utilization. The median AHI in these patients decreased from 29.3 events per hour to 9.0 events per hour after 12 months and the median ODI decreased from 25.4 events per hour to 7.4 events per hour after 12 months. After five years, the median AHI in these patients was 6.2 events per hour and the median ODI was 4.6 events per hour, as shown below.

Patient-reported outcomes after five years also found a roughly 45% improvement and a roughly 28% improvement in daytime sleepiness as measured by ESS and FOSQ, respectively, and 80% of patients reported nightly usage. These results are shown below.

After five years, approximately 90% of patients reported no or only soft snoring, compared to only 17% at baseline. Before obtaining therapy, 30% of patients reported that their bed partners occasionally had to leave the room because of their snoring. After five years of therapy, this number decreased to 1%.

German Post-Market Study

We sponsored the German Post-Market Study, a multi-center post-approval study that evaluated 60 middle-aged, overweight patients, with measurements at two-, six- and 12-month intervals. The results of this study, which were published in *The Laryngoscope* in 2017, were consistent with the outcomes demonstrated in our STAR trial and showed median AHI being reduced from a baseline of 28.6 events per hour to 9.5 events per hour in 56 patients measured after 12 months. Over the same period, median ESS score improved from a baseline of 13.0 to 6.5 and median FOSQ score improved from a baseline of 13.7 to 18.6. There were three patients lost to follow-up and one patient requested removal of the device for cosmetic and other personal reasons. There were no serious device-related adverse events.

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 2,500 patients. Data gathered to date on the first 508 patients show 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 34.0 events per hour to 7.0 events per hour and median ESS score improved from 12 to 7 over the same period. Overall satisfaction with Inspire therapy was reported by patients to be 94%, with 94% of patients reporting that they would choose the procedure again. In addition, 96% of patients reported a better experience than CPAP.

Independent Evaluations of Inspire Therapy

As the adoption of Inspire therapy continues to expand, many implanting centers have conducted and/or will conduct their own independent studies.

The effectiveness of our Inspire therapy has been documented by researchers at Thomas Jefferson University Hospital, or TJUH, and University of Pittsburgh Medical Center, or UPMC, who published their results in the *Journal of Clinical Sleep Medicine* in 2017. These researchers found that AHI decreased from a mean of over 35 events per hour to approximately six events per hour at both institutions after three months, in a group of 97 patients with a mean age of approximately 62 years and a mean body-mass index, or BMI, of approximately 28.5. Mean ESS scores also improved significantly at both institutions, as shown below. Patients at both institutions used the device for an average of more than 45 hours per week and more than 75% of patients used the device longer than 40 hours per week. One patient in the study requested removal of the device due to perceived lack of symptomatic improvement.

Positive results have been reported from a number of other independent studies to date, including:

- The University of Alabama-Birmingham reported on a study comparing the effect of Inspire therapy on Medicare-aged patients and younger patients in a cohort of 600 patients. The study included 365 patients younger than 65 years and 235 patients who were 65 years or older. After 12 months, mean AHI decreased significantly in both groups, from 36.1 to 7.6 in the Medicare-aged population and from 36.2 to 11.9 in the younger population. Average device use was 6.0 hours/night in the Medicare-aged population and 5.4 hours/night in the younger population.
- The University of Alabama-Birmingham also reported on the outcomes from their first twenty-five consecutive cases treated with Inspire therapy. The median AHI in these patients decreased significantly from 38.5±18.6 to 6.5±13.2 ($p<.0001$). Eighty-three percent of the patients (21/25) achieved an AHI < 5 while 96% (24/25) achieved an AHI < 10, and mean device use was 49.5±10.4 hours/week. No major adverse events were reported.
- Physicians at NewYork-Presbyterian Hospital and Middlesex Hospital (CT) conducted a multi-center study reporting on 27 patients treated with Inspire therapy. Postoperative AHI was significantly reduced from 44.8±16.8 to 6.3±8.8 ($p<0.001$). Of the 27 patients,

  14 (51.9%) achieved an AHI < 5. Twenty-three (85.2%) achieved an AHI < 15. Mean device use was 50.3±9.2 hours/week. A low rate of complications was reported.
- At a non-academic hospital in San Diego, data was collected on 22 consecutive patients treated with Inspire therapy. Implant times for these patients averaged 171±40 minutes. All implantations were completed without complications and AHI reductions were consistent among patients, with all patients measured achieving a titrated AHI < 5. Average device use was 7.0±1.0 hours/night.

Comparison of Inspire Therapy and UPPP

Cleveland Clinic Study A retrospective study comparing the effectiveness of hypoglossal nerve stimulation, or HNS, therapy utilizing our Inspire system to the effectiveness of UPPP was conducted by researchers at the Cleveland Clinic on two cohorts of patients treated for OSA. A cohort of 20 patients, with a mean age at the time of surgery of 42.1 and mean BMI of 27.5, underwent traditional UPPP airway reconstructive surgery, while a cohort of 20 patients, with a mean age at the time of surgery of 62.4 and mean BMI of 28.0, were treated with Inspire therapy. A higher percentage of patients who received Inspire therapy

(65%) achieved reduction in AHI from the moderate to severe range into the normal range (defined as AHI <5) compared to patients who underwent UPPP (20%). Additionally, mean AHI for patients treated with Inspire therapy decreased by 88% while mean AHI for patients treated with UPPP decreased by 29%.

Thomas Jefferson University Hospital Study An additional study comparing the effectiveness of our Inspire therapy to the effectiveness of UPPP was conducted by researchers at Thomas Jefferson University Hospital on two cohorts of patients treated for OSA. A cohort of 33 patients, with a mean age of 43.5 and mean BMI of 29.6, underwent expansion sphincteroplasty, a variant of UPPP, while a cohort of 90 patients, with a mean age of 61.2 and mean BMI of 29.8, were treated with Inspire therapy. A higher percentage of patients who received Inspire therapy (88%) were successfully treated compared to patients who received UPPP (64%), with successful treatment defined as a reduction in AHI of at least 50% from baseline and achieving an AHI of less than 20 events per hour.

Success Rates of Expansion Sphincteroplasty versus Inspire Therapy

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 United States and Europe. The implant procedure for our Inspire therapy is typically performed by an ENT physician or in some cases by neurosurgeons. 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 40 sales representatives, which we refer to as territory managers, in the United States and six in Europe. We seek to recruit territory managers with strong sales backgrounds, direct experience developing markets with new technologies and core knowledge of medical device coding, reimbursement and the prior authorization process.

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 and radio advertisements (either local or satellite). 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.

THIS IS THE END OF A COMPOSITION COMPONENT

We believe our patient outreach efforts have been effective in bringing potential patients to our website and facilitating contact with our clinical sites. During 2017, we received an average of approximately 40,000 individual hits to our website each week and had over 1.1 million "engaged" visitors, defined as visitors who click at least two links while visiting our website and remain on the site for at least 30 seconds. In 2017, we had close to 400,000 visitors who used our website to find a physician in their area, with more than 17,000 visitors calling a clinical site to schedule an appointment.

Commercial Activities Outside of the United States

We have six territory managers in Europe, five of whom are located in Germany. Our general practice is to limit commercial investments in European countries until such time as there is a determined reimbursement pathway. We provide consistent training in Europe as is conducted in the United States and have established a support team in Europe for patient outreach and education, implant support and device programming. We expect to continue to scale our commercial activities in Europe as we continue to develop country-wide reimbursement in additional markets.

Third-Party Reimbursement

Our market access team is responsible for all of our reimbursement processes and initiatives. Our team includes 15 professionals who are focused on all key aspects of reimbursement, which include coding, payment and coverage.

Coding and Payment

In the United States, we sell our products to hospitals and ASCs. These customers in turn bill various third-party payors, such as commercial payors and government agencies, 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, or CPT, codes, which are created and maintained by the American Medical Association, or AMA. Implantation of our Inspire neurostimulator and stimulation lead are described by CPT code 64568, which is the code describing the implantation of a cranial nerve stimulator. Implantation of our Inspire pressure sensing lead is described by CPT code 0466T, a Category III code published by the AMA in January 2017. Although the AMA declined to convert CPT code 0466T into a Category I CPT code in May 2018, we have resubmitted an application to the AMA for the conversion of our pressure sensing lead's CPT code from a temporary Category III CPT code into a permanent Category I CPT code. We expect this application to be reviewed by the AMA in the first half of 2019.

Physician reimbursement under Medicare generally is based on a defined fee schedule, the 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, or HOPPS, which provides bundled amounts generally intended to reimburse the hospital for all facility costs related to procedures performed in the hospital outpatient setting. Under the HOPPS, the national average Medicare payment to the hospital for this procedure is slightly more than $27,000, which covers the hospitals' costs for the device and the implantation procedure. The surgeon is reimbursed an additional physician payment under the Medicare Physician Fee Schedule. 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. We continue to have active discussions with commercial payors to establish positive national coverage policies by highlighting our compelling and robust clinical data, the economic cost-savings associated with highly compliant OSA treatment, increased patient demand and support from leading medical societies and key opinion leaders. Approximately 300 commercial payors have reimbursed hospitals and ASCs for the Inspire device and procedure, although a number of commercial payors have adopted noncoverage policies for hypoglossal nerve stimulation, including procedures involving the Inspire system. In 2017, commercial payors reimbursed approximately 60% of Inspire implants in the United States. We have secured a positive coverage policy from Aetna Inc., one of the leading health plans in the United States, as well as from eight other U.S. commercial payors at the local and regional level, namely the Cleveland Clinic Health Plan, the Ohio State University Health Plan, AvMed, Medica, Preferred One, the Health Alliance Plan (HAP) of Michigan, WEA Trust and Group Health Cooperative of South Central Wisconsin.

Procedures involving our Inspire system may be reimbursed on a medical necessity basis for Medicare patients, though certain local Medicare contractors have adopted noncoverage policies for procedures involving the Inspire system. In 2017, Medicare accounted for approximately 30% of all Inspire system implantations in the United States, although we expect this percentage to decrease over time as commercial policies are developed. 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 accounted for approximately 10% of all Inspire system implantations in 2017 in the United States.

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 on a case-by-case basis where positive coverage policies currently do not exist. We believe our market access team is highly effective in working with patients and physicians to obtain prior authorizations for our Inspire system including handling of the appeals process. In 2017, we received multiple prior authorization approvals from most of the largest commercial payors, for example UnitedHealth, Anthem, Cigna, Blue Cross Blue Shield and Humana. In addition, in 2017, market access team helped approximately 70% of patients who pursued the appeals process fully to secure prior authorizations with an average approval time of approximately two to three months, with only approximately 10% being denied external medical review approval while the remainder were lost to follow-up. Our market access team supported more than 1,500 individual patient submissions in 2017 and more than 1,800 individual patient submissions in the first nine months of 2018.

We believe we will continue to benefit from this efficient prior authorization process in the near-term and in the longer-term by expanding positive coverage policies. We intend to expand our market access team and increase the number of annual patient submissions as we grow our operations.

Reimbursement Outside of the United States

In Germany, the Institut für das Entgeltsystem im Krankenhaus, the German federal reimbursement agency, has granted the Neue Untersuchungs- und Behandlungsmethoden, or NUB, Status 1 coverage for our Inspire system. The NUB process allows for the introduction of new and innovative medical devices prior to reaching reimbursement eligibility and provides for a supplemental payment for new technologies in the German reimbursement system. NUB Status 1 is the highest of four levels and allows for full reimbursement for our Inspire system for the 84 participating hospitals in 2018. Under NUB Status 1, payors at these hospitals are obligated to cover the gaps in treatment costs for the Inspire system.

Reimbursement in European countries outside of Germany is primarily provided by single center hospitals from their operating budgets, but we intend to continue to develop reimbursement in other European countries including the Netherlands, Belgium, France, the Nordic region and any other new market that we may enter in the future, such as Japan.

Research and Development

Product Evolution and Next Generation Products

The first Inspire device was developed by 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 pressure sensing lead to between the intercostal muscle layers.

After our inception and the spin-off of the Inspire business from Medtronic in 2007, 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 January 2014 and we received PMA approval in April 2014. Additionally, we received a CE mark for commercialization in Europe in 2011.

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. Patients with this version of the Inspire system are now able to undergo an MRI scan of the head or extremities. The Inspire IV device was launched in the United States in July 2017, and in Europe in the second quarter of 2018.

A newly designed pressure sensing lead was developed in 2017 and was submitted to the FDA for regulatory review and approval. The new sensor improves handling characteristics over the existing sensor lead, including added guidance for the use of surgical tools and handling locations.

Our fifth generation of the Inspire neurostimulator is in the concept phase of development. We are also developing a cloud-based patient management system called Inspire Cloud, which is being designed to allow physicians to monitor patient compliance and therapy efficacy.

Additional Indications

We have sought and continue to seek to expand the approved indications for our Inspire therapy. For instance, in January 2017, the FDA approved a PMA supplement expanding the indicated AHI range for our Inspire therapy from 20 to 65 events per hour to 15 to 65 events per hour.

We have submitted a PMA supplement to the FDA to expand our indication in the United States to patients as young as 12 years of age. This expanded indication would also allow pediatric patients with Down syndrome to be treated with Inspire therapy.

Patients born with Down syndrome have higher rates of OSA than the general pediatric population. The incidence rate can range from 30% to 60% in children with Down syndrome, compared to 1% in the general population. OSA remains a long-term disability in many of these individuals, and CPAP compliance in this patient population is significantly worse than in the general

population. Results from a six-patient trial in adolescents with Down syndrome were published in 2017 in *JAMA Otolaryngology–Head & Neck Surgery* demonstrating the safety and efficacy of Inspire therapy for treating this patient population. Results from this investigator-initiated trial suggest that Inspire therapy may have therapeutic potential in Down syndrome patients.

Our research and development team focuses on the products currently under development, including our clinical trials, as well as feasibility studies in which we are evaluating different design configurations to enhance product functionality for future generations of the Inspire system. For the years ended December 31, 2015, 2016 and 2017, we incurred research and development expenses of $7.1 million, $7.1 million and $6.2 million, respectively. Research and development expenses for the nine months ended September 30, 2017 and 2018 were $4.5 million and $5.2 million, respectively.

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 United States by the FDA. Outside the United States, we compete with ImThera (now a part of LivaNova), which markets an open-loop neurostimulation device. ImThera is currently conducting clinical trials of its device in the United States. We believe other emerging businesses are in the early stages of developing neurostimulation devices.

We also compete, both within and outside of the United States, with invasive surgical treatment options such as UPPP, 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 positive airway pressure devices because in the United States, Inspire therapy is only indicated for patients who have been confirmed to fail or cannot tolerate positive airway pressure treatments, such as CPAP.

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

- company, product and brand recognition;
- product safety, 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.

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, but we believe physician awareness of our Inspire therapy is increasing.

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.

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 September 30, 2018, we had rights to 20 issued U.S. patents, which will expire between 2019 and 2035 assuming all required fees are paid, 25 pending U.S. patent applications, 22 issued foreign patents and 39 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 September 30, 2018, we had 31 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 assure you that any current or subsequently issued patents will protect our intellectual property rights 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 "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 November 2007, we entered into an assignment and license agreement with Medtronic, or 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 obstructive sleep apnea, or 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 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 targeted to suppliers that meet the requirements of the FDA and the International Organization for Standardization and quality standards supported by internal policies and procedures. Our quality assurance process monitors and maintains 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.

Government Regulation

Our products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in the EEA. Our products are subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act, or 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 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 trials 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 trials and to obtain marketing authorization or approval of our products under the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials or commercialize our products in those countries. The approval 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 United States requires either FDA clearance of a 510(k) premarket notification or PMA approval. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the QSR, facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. 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 commercially available device that was cleared to 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 approval.

PMA Approval Pathway

Class III devices require PMA approval before they can be marketed although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently

complete to permit a substantive review. If 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 Quality System Regulation, or 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 approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

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

Clinical Trials

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

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and

effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

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

`Post-market Regulation`

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

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and 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;
- the federal Physician Sunshine Act and various state and foreign laws on reporting remunerative relationships with health care customers;
- the federal Anti-Kickback Statute (and similar state laws) prohibiting, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not have to have actual knowledge of this statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act (and similar state laws) prohibiting, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing, or knowingly and improperly avoiding or decreasing, an obligation to pay or transmit money to the federal government. The government may assert that claim includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statute;
- 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 new federal law 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 the public health or to provide additional safety and effectiveness data for the device.

We may be subject to similar foreign laws that may include applicable post-marketing requirements such as safety surveillance. Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, 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 PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export or import approvals for our products; or
- criminal prosecution.

Regulation of Medical Devices in the EEA

There is currently no premarket government review of medical devices in the EEA (which is comprised of the 28 Member States of the EU plus Norway, Liechtenstein and Iceland). However, all medical devices placed on the market in the EEA must meet the relevant essential requirements laid down in Annex I of Directive ^{93}/42/EEC concerning medical devices, or the Medical Devices Directive. There is also a directive specifically addressing Active Implantable Medical Devices (Directive 90/385/EEC). The most

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

To demonstrate compliance with the essential requirements laid down in Annex I to the Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare 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 often separate entities and are authorized or licensed to perform such assessments by government authorities. The notified body would typically audit and examine a product's technical dossiers and the manufacturers' 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 EEA. Once the product has been placed on the market in the EEA, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the medical device.

In order to demonstrate safety and efficacy for their medical devices, manufacturers must conduct clinical investigations in accordance with the requirements of Annex X to the Medical Devices Directive, Annex 7 of the Active Implantable Medical Devices Directive, and applicable European and International Organization for Standardization standards, as implemented or adopted in the EEA member states. Clinical trials for medical devices usually require the approval of an ethics review board and approval by or notification to the national regulatory authorities. Both regulators and ethics committees also require the submission of serious adverse event reports during a study and may request a copy of the final study report.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member States, the regulations would be directly applicable, i.e., without the need for adoption of EEA member State laws implementing them, in all EEA member States and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The Medical Devices Regulation will however only become applicable three years after publication (in 2020). Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU;
-

strengthened rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

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 trials;
- 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 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.

We anticipate that the EU Medical Devices Regulation will enter into force in 2016 and become applicable three years thereafter. We expect this revised regulation to include further controls and requirements on the following activities:

- high level of request for premarket clinical evidence for high risk devices;
- increased scrutiny of technical files for implantable devices;
-

monitoring of notified bodies, by independent auditors;

- increased requirements regarding vigilance and product traceability (specifically related to labeling requirements); and
- increased regulation for non-traditional roles such as importer and distributor.

Federal, State and Foreign Fraud and Abuse and Physician Payment Transparency Laws

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

Recognizing that the federal Anti-Kickback Statute is broad and may prohibit many innocuous or beneficial arrangements within the healthcare industry, the DHHS issued regulations in July 1991, which the Department has referred to as "safe harbors." These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure medical device manufacturers, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. 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. Our arrangements with physicians, hospitals and other persons or entities who are in a position to refer may not fully meet the stringent criteria specified in the various safe harbors. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal 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. 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 (described below).

Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid. Liability under the federal Anti-Kickback Statute may also arise because of the intentions or actions of the parties with whom we do business. While we are not aware of any such intentions or actions, we have only limited knowledge regarding the intentions or actions underlying those arrangements. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities. 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.

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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. Penalties for federal civil False Claim Act violations include fines for each false claim, plus up to three times the amount of damages sustained by the federal government and, most critically, may provide the basis for exclusion from the federally funded healthcare program. On May 20, 2009, the Fraud Enforcement Recovery Act of 2009, or FERA, was enacted, which modifies and clarifies certain provisions of the federal civil False Claims Act. In part, the FERA amends the federal civil False Claims Act such that penalties may now apply to any person, including an organization that does not contract directly with the government, who knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim paid in part by the federal government. 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. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,181 to $22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.

The Civil Monetary Penalty Act of 1981 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.

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 our products is subject to EU Directives concerning misleading and comparative advertising and unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws 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. 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. 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 (including physician family members), certain other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of $11,052 per failure up to an aggregate of $165,786 per year (or up to an aggregate of $1.105 million per year for "knowing failures"). Manufacturers must submit reports by the 90th day of each calendar year. 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.

Data Privacy and Security Laws

We are also subject to various federal, state and foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers, such as HIPAA, as amended by HITECH, in the United States.

HIPAA established uniform standards governing the conduct of certain electronic healthcare transactions and requires certain entities, called covered entities, to comply with standards that include the privacy and security of protected health information, or PHI. HIPAA also requires business associates, such as independent contractors or agents of covered entities that have access to PHI in connection with providing a service to or on behalf of a covered entity, of covered entities to enter into business associate agreements with the covered entity and to safeguard the covered entity's PHI against improper use and disclosure.

The HIPAA privacy regulations cover the use and disclosure of protected health information by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain, or transmit protected health information on behalf of a business associate. They also set forth certain rights that an individual has with respect to his or her protected health information maintained by a covered entity, including the right to access or amend certain records containing protected health information, or to request restrictions on the use or disclosure of protected health information. The security regulations establish requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored. HITECH, among other things, established certain health information security breach notification requirements. A covered entity must notify any individual whose protected health information is breached according to the specifications set forth in the breach notification rule. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing protected health information or insofar as such state laws apply to personal information that is broader in scope than protected health information as defined under HIPAA.

HIPAA requires the notification of patients, and other compliance actions, in the event of a breach of unsecured protected health information, or PHI. If notification to patients of a breach is required, such notification must be provided without unreasonable delay and in no event later than 60 calendar days after discovery of the breach. In addition, if the PHI of 500 or more individuals is improperly used or disclosed, we would be required to report the improper use or disclosure to the U.S. Department of Health and Human Services, or HHS, which would post the violation on its website, and to the media. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $55,910 per violation, not to exceed $1.68 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment.

HIPAA authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to 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 file suit against us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities, such as us, and their business associates for compliance with the HIPAA privacy and security standards. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

In the European Union, we may be subject to laws relating to our collection, control, processing and other use of personal data (i.e. data relating to an identifiable living individual). We process personal data in relation to our operations. We process data of both our employees and our customers, including health and medical information. The data privacy regime in the EU includes the EU Data Protection Directive (95/46/EC) regarding the processing of personal data and the free movement of such data, the E-Privacy Directive 2002/58/EC and national laws implementing each of them. Each EU Member State has transposed the requirements laid down by the Data Protection Directive and E-Privacy Directive into its own national data privacy regime and therefore the laws may differ by jurisdiction, sometimes significantly. We need to ensure compliance with the rules in each jurisdiction where we are established or are otherwise subject to local privacy laws.

The requirements include that personal data may only be collected for specified, explicit and legitimate purposes based on a legal grounds set out in the local laws, and may only be processed in a manner consistent with those purposes. Personal data must also be adequate, relevant, not excessive in relation to the purposes for which it is collected, be secure, not be transferred outside of the EEA unless certain steps are taken to ensure an adequate level of protection and must not be kept for longer than necessary

for the purposes of collection. To the extent that we process, control or otherwise use sensitive data relating to living individuals (for example, patients' health or medical information), more stringent rules apply, limiting the circumstances and the manner in which we are legally permitted to process that data and transfer that data outside of the EEA. In particular, in order to process such data, explicit consent to the processing (including any transfer) is usually required from the data subject (being the person to whom the personal data relates).

The new EU-wide General Data Protection Regulation, or GDPR, became applicable on May 25, 2018, replacing the current data protection laws issued by each EU member state based on the Directive 95/46/EC. Unlike the Directive (which needed to be transposed at national level), the GDPR text is directly applicable in each EU member state, resulting in a more uniform application of data privacy laws across the EU. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. It requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of information, increases requirements pertaining to pseudonymized (i.e., key-coded) data, introduces mandatory data breach notification requirements and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for non-compliance with the GDPR are significant—the greater of EUR 20 million or 4% of global turnover. The GDPR provides that EU member states may introduce further conditions, including limitations, to the processing of genetic, biometric or health data, which could limit our ability to collect, use and share personal data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business.

We are subject to the supervision of local data protection authorities in those jurisdictions where we are established or otherwise subject to applicable law.

We depend on a number of third parties in relation to our provision of our services, a number of which process personal data on our behalf. With each such provider we enter into contractual arrangements to ensure that they only process personal data according to our instructions, and that they have sufficient technical and organizational security measures in place. Where we transfer personal data outside the EEA, we do so in compliance with the relevant data export requirements. We take our data protection obligations seriously, as any improper disclosure, particularly with regard to our customers' sensitive personal data, could negatively impact our business and/or our reputation.

Healthcare Reform

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

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The Affordable Care Act imposed, among other things, a 2.3% federal excise tax, with limited exceptions, on any entity that manufactures or imports Class I, II and III medical devices offered for sale in the United States that began on January 1, 2013. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020. The Affordable Care Act also 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 Affordable Care Act has 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. We do not yet know the full impact that the Affordable Care Act will have on our business. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in the future. Moreover, the Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the Tax Cuts and Jobs Acts was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance, beginning in 2019.

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 of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 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.

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

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 under the Organization for Economic Co-operation and Development's Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

Facilities

Our principal office is located at 9700 63rd Ave. N., Suite 200, Maple Grove, MN 55369, where we lease approximately 9,300 square feet of office space. We lease this space under a lease that terminates on March 31, 2019. In September 2018, we entered into a non-cancelable operating lease agreement to sublease approximately 44,000 square feet of office space for our corporate headquarters in Golden Valley, MN, which lease is scheduled to commence January 15, 2019 and expire on November 30, 2020. 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.

Employees

As of September 30, 2018, we had 150 employees. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Legal Proceedings

We are not subject to any material legal proceedings.

Management

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors as of the date of this prospectus.

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Name	Age	Position
Executive Officers		
Timothy Herbert	56	Chief Executive Officer, President and Director
Richard Buchholz	50	Chief Financial Officer

Randy Ban	54	Senior Vice President, Sales and Marketing
Steven Jandrich	52	Chief Compliance Officer and Vice President, Human Resources

Non-Employee Directors

Marilyn Carlson Nelson(3)	79	Chair of the Board
Joyce Erony(3)	58	Director
Jerry Griffin, M.D.(2)(3)	74	Director
Mudit K. Jain(1)	50	Director
Chau Khuong(2)	42	Director
Dana G. Mead, Jr.(1)	59	Director
Shawn T McCormick(1)	54	Director
Casey Tansey(2)	61	Director

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(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

Executive Officers

Timothy Herbert, our founder, has served as our Chief Executive Officer and President and as a member of our board of directors since November 2007. Prior to joining us, Mr. Herbert spent 11 years at Medtronic, a medical equipment development company, where he held management positions in product development, clinical research, sales, marketing, and healthcare reimbursement. Mr. Herbert holds a B.S. in electrical engineering from North Dakota State University and an M.B.A. from the University of St. Thomas. We believe Mr. Herbert's experience in the industry, his role as our Chief Executive Officer and President and his knowledge of the Company enable him to make valuable contributions to our board of directors.

Richard Buchholz has served as our Chief Financial Officer since May 2014. Prior to joining us, Mr. Buchholz served as the Chief Financial Officer, Secretary and Treasurer at superDimension, Ltd., a medical device manufacturer (which was acquired by Covidien plc in May 2012), from August 2006 to July 2013. Mr. Buchholz holds a B.B.A. from the University of Wisconsin, Eau Claire.

Randy Ban has served as our Senior Vice President, Sales and Marketing since 2009. Prior to joining us, Mr. Ban served as Chief Operating Officer at Vertebral Technologies Inc., a medical device company, from 2008 to 2009. From 2006 to 2008, Mr. Ban served as Vice President of Global Marketing, CRM at Boston Scientific. Mr. Ban holds a B.S. in marketing and an M.B.A., both from Indiana University.

Steven Jandrich has served as our Chief Compliance Officer and as our Vice President, Human Resources since September 2017. From May 2015 to September 2017, Mr. Jandrich served as Vice President, Human Resources for Link Snacks, Inc., a multinational retail snack producer, where he led human resources functions including talent management and employee relations. From April 2001 to April 2015, Mr. Jandrich was an employee of St. Jude Medical, Inc., and from January 2013 to April 2015 Mr. Jandrich served as its Vice President of Commercial Operations and was responsible for establishing its global sales training program. Mr. Jandrich holds a B.B.A. and M.B.A., both from the University of St. Thomas.

Non-Employee Directors

Marilyn Carlson Nelson has served as a member of our board of directors and as its Chair since November 2016. Since 1999, Ms. Nelson has served as Co-Chair of the board of directors and Co-Chief Executive Officer of Carlson Holdings, Inc., an international holdings company. Ms. Nelson previously served as a member of the board of directors of Carlson, Inc., a hospitality and travel company, from 1989 to 2015, and as its Chief Executive Officer from 1998 to 2008. Ms. Nelson also served on the board of directors of ExxonMobil from 1991 to 2012. Ms. Nelson holds a B.A. in international economics from Smith College and honorary doctorates from Smith College, the University of Minnesota, Johnson & Wales University, Gustavus Adolphus College and the College of St. Catherine. We believe Ms. Nelson's extensive public and private board experience and her knowledge of the Company as one of our early investors enable her to make valuable contributions to our board of directors.

Joyce Erony has served as a member of our board of directors since November 2016. Since 2015, Ms. Erony has served as Managing Partner at Amzak Health Investors, LLC, a private investment company focused on investments in the healthcare sector. From 2008 to 2016, Ms. Erony served as a Managing Director at Signet Healthcare Partners, a venture capital investment firm. From 2009 to 2014, Ms. Erony served on the board of directors of Teligent, Inc., a specialty generic pharmaceutical company, where she served on its compensation and governance committees. Ms. Erony holds a B.S.C. from Case Western Reserve University and a Graduate Diploma from the London School of Economics. We believe Ms. Erony's extensive experience in the healthcare investment industry enables her to make valuable contributions to our board of directors.

Jerry Griffin, M.D. has served as a member of our board of directors since January 2008. Since 2006, Dr. Griffin has served as President of Griffin & Schwartz, Scientific Services, Inc., a management consulting firm in the healthcare products industry. From September 2000 to June 2006, Dr. Griffin served as President, Chief Executive Officer and a Director of POINT Biomedical Corp., a developer of pharmaceutical products for use with ultrasound imaging. Dr. Griffin has also been a professor or assistant professor in the Department of Medicine, Division of Cardiology at various teaching institutions. Dr. Griffin holds a B.S. from the University of Southern Mississippi and a M.D. from the University of Mississippi. We believe Dr. Griffin's public and private board experience and his extensive experience in the healthcare products industry enable him to make valuable contributions to our board of directors.

Mudit K. Jain has served as a member of our board of directors since May 2009. Mr. Jain currently serves as a Founding General Partner at Strategic Healthcare Investment Partners, LLC, a venture capital investment firm, and previously served as a Managing Director at Synergy Venture Partners, LLC, a venture capital investment firm, from 2013 to September 2018. Mr. Jain holds a B.E. from the Visvesvaraya Regional College of Engineering, an M.B.A. from the Wharton School of the University of Pennsylvania and a Ph.D in biomedical engineering from Duke University. We believe Mr. Jain's experience as a venture capital investor and expertise in biomedical engineering enable him to make valuable contributions to our board of directors.

Chau Khuong has served as a member of our board of directors since April 2014. Mr. Khuong is a Private Equity Partner at OrbiMed Advisors, L.L.C., a venture capital and asset management firm, which he joined in 2003. Mr. Khuong has served on the boards of directors of Aerpio Pharmaceuticals, Inc. since April 2014 and Synlogic, Inc. since February 2016. Mr. Khuong previously served as a member of the boards of directors of Otonomy, Inc. from 2013 to 2016, Pieris, Inc. from 2014 to 2017 and Nabriva Therapeutics plc (formerly Nabriva Therapeutics AG) from 2015 to 2017. Mr. Khuong holds a B.S. in molecular, cellular and development biology and an M.P.H. with concentration in infectious diseases, both from Yale University. We believe Mr. Khuong's extensive public and private board experience and his experience as a venture capital investor enable him to make valuable contributions to our board of directors.

Dana G. Mead, Jr. has served as a member of our board of directors since July 2008. Mr. Mead currently serves as the Chief Executive Officer and President of Beaver-Visitec International, Inc., a surgical device developer and manufacturer. From May 2016 to December 2016, Mr. Mead served on the board of directors of Teladoc, Inc., a telehealth company, where he served on its regulatory committee. From 2005 to 2016, Mr. Mead served as a Partner at Kleiner Perkins Caufield & Byers, a venture capital investment firm. In addition to serving on our board of directors, Mr. Mead has served on the board of directors of Intersect ENT, Inc. since 2015 where he serves on its audit and compensation committees. Mr. Mead holds a B.A. from Lafayette College and an M.B.A. from the University of Southern California. We believe Mr. Mead's extensive directorship experience and his broad experience in the healthcare industry enable him to make valuable contributions to our board of directors.

Shawn T McCormick has served as a member of our board of directors since January 2017. Mr. McCormick served as Chief Financial Officer of Tornier N.V., a global orthopedic company, from September 2012 until October 2015 when Tornier merged with Wright Medical Group, Inc. Before Tornier, Mr. McCormick served as Chief Operating Officer of Lutonix, Inc., a medical

device company, from April 2011 to February 2012 and as Chief Financial Officer and Senior Vice President of ev3 Inc., a global endovascular company, from January 2009 to July 2010, when ev3 was acquired by Covidien plc. From 2002 to 2009, Mr. McCormick held various positions at Medtronic, including as its Vice President, Corporate Development, where he was responsible for leading Medtronic's worldwide business development activities. In addition to serving on our board of directors, Mr. McCormick has served on the board of directors of Nevro Corp. since 2014, and on the board of directors of Surmodics, Inc. since 2015. Mr. McCormick also served on the board of directors of Entellus Medical, Inc. from 2014 to February 2018. Mr. McCormick holds a B.S. in Accounting from Arizona State University and an M.B.A. from the University of Minnesota's Carlson School of Management and is a certified public accountant (inactive). We believe Mr. McCormick's financial expertise and extensive experience in the medical device industry enable him to make valuable contributions to our board of directors.

Casey Tansey has served as a member of our board of directors since January 2008. Since April 2005, Mr. Tansey has served as a General Partner of U.S. Venture Partners, a venture capital investment firm and one of our affiliates. Prior to serving on our board of directors, Mr. Tansey served on the board of directors of Intersect ENT, Inc. from 2006 to 2017. Mr. Tansey holds a B.S. and M.B.A. from the College of Notre Dame. We believe Mr. Casey's extensive experience in the medical device industry enables him to make valuable contributions to our board of directors.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Board Composition and Election of Directors

Our board of directors is currently composed of nine members. Before it was amended and restated in connection with our IPO, our certificate of incorporation provided for one director to be elected by the holders of our common stock, or the Common Director, two directors to be elected by the holders of our Series A convertible preferred stock, or the Series A Directors, one director to be elected by the holders of our Series B convertible preferred stock, or the Series B Director, one director to be elected by the holders of our Series E convertible preferred stock, or the Series E Director, and one director to be elected by the holders of our Series F convertible preferred stock, or the Series F Director. Pursuant to a fifth amended and restated voting agreement, or the Voting Agreement, by and among us, the Timothy P. Herbert 2013 Family Irrevocable GST Trust U/A/D November 27, 2013 and each holder of our convertible preferred stock, each party thereto agreed to vote all shares of common stock or the applicable class of convertible preferred stock, as the case may be, beneficially owned or controlled by such party, to cause the nomination and election of our then-serving chief executive officer as the Common Director, a designee of U.S. Venture Partners IX, L.P. and a designee of Kleiner Perkins Caufield & Byers as the Series A Directors, a designee of Synergy Life Science Partners, LP as the Series B Director, a designee of OrbiMed Private Investment V, L.P. as the Series E Director and a designee of Amzak Health Investors, LLC as the Series F Director. Each party to the Voting Agreement also agreed to vote all shares of common stock and convertible preferred stock beneficially owned or controlled by such stockholder to cause the nomination and election of three individuals designated by a majority of the Common Director, the Series A Directors, the Series B Director, the Series E Director and the Series F Director who are not our employees or officers, which we refer to as the Industry Directors. In accordance with the Voting Agreement, Mr. Herbert was elected as the Common Director, Messrs. Tansey and Mead were elected as the Series A Directors, Mr. Jain was elected as the Series B Director, Mr. Khuong was elected as the Series E Director, Ms. Erony was elected as the Series F Director and Ms. Nelson, Dr. Griffin and Mr. McCormick were elected as the Industry Directors.

The provisions of our pre-IPO certificate of incorporation and the Voting Agreement described above are no longer in effect as of the closing of our IPO, and there are currently no contractual obligations regarding the election of our directors. Each of our current directors will continue to serve until the election and qualification of his or her successor, or his or her earlier death, resignation or removal.

Classified Board of Directors

In accordance with our amended and restated certificate of incorporation, our board of directors is divided into three classes of directors. At each annual meeting of stockholders, a class of directors will be elected for a three-year term to succeed the class whose terms are then expiring, to serve from the time of election and qualification until the third annual meeting following their election or until their earlier death, resignation or removal. Our directors are divided among the three classes as follows:

The Class I directors are Timothy Herbert, Chau Khuong and Shawn T McCormick, and their terms will expire at our first annual meeting of stockholders following this offering.

The Class II directors are Joyce Erony, Mudit K. Jain and Dana G. Mead, Jr., and their terms will expire at our second annual meeting of stockholders following this offering.

The Class III directors are Marilyn Carlson Nelson, Jerry Griffin, M.D. and Casey Tansey, and their terms will expire at our third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation provides that the authorized number of directors may be changed only by resolution of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control. See the section of this prospectus captioned "Description of Capital Stock—Anti-Takeover Provisions—Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws" for a discussion of these and other anti-takeover provisions found in our amended and restated certificate of incorporation and amended and restated bylaws.

Director Independence

Our common stock is listed on the NYSE. Under the rules of NYSE, independent directors must comprise a majority of a listed company's board of directors within one year following the listing date of the company's securities. Under the rules of the NYSE, a director will only qualify as an "independent director" if that company's board of directors affirmatively determines that such person does not have a relationship with the company that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our board of directors has undertaken a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that none of Ms. Erony, Dr. Griffin, Mr. Jain, Mr. Khuong, Mr. McCormick, Mr. Mead, Ms. Nelson or Mr. Tansey, representing eight of our nine directors, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of the NYSE. In making this determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our common stock by certain non-employee directors and the relationships of certain non-employee directors with certain of our significant stockholders.

Board Committees

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and the responsibilities described below. In addition, from time to time, special committees may be established under the direction of our board of directors when necessary to address specific issues.

Each of the audit committee, the compensation committee and the nominating and corporate governance committee operates under a written charter. A copy of each of the audit committee, compensation committee and nominating and corporate governance committee charters is available on the investor section of our corporate website at *www.inspiresleep.com*. The information contained on or that can be accessed through our website is not incorporated by reference into this prospectus, and you should not consider such information to be part of this prospectus.

Audit Committee

Our audit committee oversees our corporate accounting and financial reporting process and assists our board of directors in its oversight of (i) the integrity of our financial statements, (ii) our compliance with legal and regulatory requirements, (iii) our risk management program, (iv) the performance of our independent auditor and (v) the design and implementation of our internal audit function and internal controls. Our audit committee will be responsible for, among other things:

- appointing, compensating, retaining and overseeing the work of our independent auditor and any other registered public accounting firm engaged for the purpose of preparing or issuing an audit report or related work or performing other audit, review or attest services for us;

- discussing with our independent auditor any audit problems or difficulties and management's response;
- pre-approving all audit and non-audit services provided to us by our independent auditor (other than those provided pursuant to appropriate preapproval policies established by the committee or exempt from such requirement under SEC rules);
- reviewing and discussing our annual and quarterly financial statements with management and our independent auditor;
- discussing and overseeing our policies with respect to risk assessment and risk management; and
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters, and for the confidential and anonymous submission by our employees of concerns regarding questionable accounting or auditing matters.

Our audit committee currently consists of Messrs. Jain, McCormick and Mead, with Mr. McCormick serving as chair. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the NYSE. Our board of directors has affirmatively determined that Messrs. Jain, McCormick and Mead meet the definition of "independent director" under Rule 10A-3 of the Exchange Act and the NYSE rules for purposes of serving on the audit committee. In addition, our board of directors has determined that Messrs. Jain, McCormick and Mead each qualify as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K and have the requisite accounting or related financial management expertise and financial sophistication under the applicable rules and regulations of the NYSE.

Compensation Committee

Our compensation committee oversees our compensation policies, plans and benefits programs. Our compensation committee is responsible for, among other things:

- reviewing and approving corporate goals and objectives with respect to the compensation of our Chief Executive Officer, evaluating our Chief Executive Officer's performance in light of these goals and objectives and setting compensation;
- reviewing and setting or making recommendations to our board of directors regarding the compensation of our other executive officers;
- reviewing and making recommendations to our board of directors regarding director compensation;
- reviewing and approving or making recommendations to our board of directors regarding our incentive compensation and equity-based plans and arrangements; and
- appointing and overseeing any compensation consultants.

Our compensation committee currently consists of Dr. Griffin and Messrs. Khuong and Tansey, with Mr. Tansey serving as chair. Our board of directors has determined that Dr. Griffin and Messrs. Khuong and Tansey meet the definition of "independent director" under the applicable NYSE rules for purposes of serving on the compensation committee, are "outside directors" as defined in Rule 162(m) of the Internal Revenue Code and "non-employee directors" as defined in Section 16b-3 of the Exchange Act.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee oversees and assists our board of directors in reviewing and recommending nominees for election as directors. Our nominating and corporate governance committee is responsible for, among other things:

- identifying individuals qualified to become members of our board of directors, consistent with criteria approved by our board of directors;
- recommending to our board of directors the nominees for election to our board of directors at annual meetings of our stockholders;
- overseeing the annual self-evaluations of our board of directors and management; and
- developing and recommending to our board of directors a set of corporate governance guidelines and principles.

Our nominating and corporate governance committee currently consists of Ms. Erony, Dr. Griffin and Ms. Nelson, with Ms. Erony serving as chair. Our board has determined that Ms. Erony, Dr. Griffin and Ms. Nelson meet the definition of "independent director" under applicable NYSE rules for purposes of serving on the nominating and corporate governance committee.

Role of the Board in Risk Oversight

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks and operational risks. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee is responsible for overseeing the management of risks relating to accounting matters and financial reporting. The nominating and corporate governance committee is responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through discussions from committee members about such risks. Our board of directors believes its administration of its risk oversight function has not negatively affected our board of directors' leadership structure.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is available on the investor section of our website.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is an officer or one of our employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

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Executive and Director Compensation

EXECUTIVE AND DIRECTOR COMPENSATION

This section discusses the material components of the executive compensation program for our executive officers who are named in the "Summary Compensation Table" below. As an "emerging growth company" as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies. In 2017, our "named executive officers" and their positions were as follows:

- Timothy Herbert, President and Chief Executive Officer;
- Randy Ban, Senior Vice President of Marketing; and

- Richard Buchholz, Chief Financial Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs.

Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2017.

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Name and Principal Position	Year	Salary ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(2)	Total ($)
Timothy Herbert	2017	380,000	83,901	135,660	599,561
President and Chief Executive Officer					
Randy Ban	2017	278,168	19,818	215,225	513,211
Senior Vice President of Marketing					
Richard Buchholz	2017	255,748	8,708	65,216	329,672
Chief Financial Officer					

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(1) Amounts reflect the full grant-date fair value of stock options granted during 2017 computed in accordance with FASB ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of all stock option awards made to named executive officers in Note 8 to our audited financial statements included elsewhere in this prospectus.

(2) Amounts for Messrs. Herbert and Buchholz represent 2017 earned annual bonuses under our Management Incentive Program, or MIP, of $135,660 and $65,216. Amount for Mr. Ban represents 2017 earned commissions of $215,225.

Narrative to Summary Compensation Table

2017 Salaries

The named executive officers receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Each named executed officer's initial base salary was provided in his employment agreement. For 2017, the base salaries for Messrs. Herbert, Ban and Buchholz were equal to $380,000, $278,168 and $255,748, respectively. For 2018, the base salaries for Messrs. Herbert, Ban and Buchholz were increased to $397,860, $287,907 and $282,346, respectively. Effective April 9, 2018, base salaries for Messrs. Herbert and Buchholz were increased to $425,000 and $322,100, respectively.

2017 Bonuses and Commissions

Each of Messrs. Herbert and Buchholz are eligible to participate in our MIP, under which eligible participants may receive cash bonuses based on our achievement of certain performance metrics. For 2017, the annual target bonus amounts under the MIP expressed as a percentage of base salary for Messrs. Herbert and Buchholz equaled 35% and 25%, respectively. For 2017, Messrs. Herbert and Buchholz earned cash bonuses under the MIP equal to 102% of their respective target bonus amounts, totaling $135,660 and $65,216, respectively. For 2018, the target bonus amounts under the MIP expressed as a percentage of base salary for Messrs. Herbert and Buchholz were increased to 60% and 40%, respectively, and, effective April 9, 2018, were further increased to 75% and 45%, respectively.

Mr. Ban is eligible to receive commissions based on achievement of certain performance metrics, which are determined and paid on a quarterly basis. For 2017, Mr. Ban earned quarterly cash commissions totaling $215,225.

The actual cash bonuses and commissions earned by each named executive officer for 2017 performance are set forth above in the Summary Compensation Table in the column entitled "Non-Equity Incentive Plan Compensation."

Equity Compensation

Prior to the IPO, we maintained two equity incentive plans, the 2007 Stock Incentive Plan, as amended, or 2007 Plan, and the 2017 Stock Incentive Plan, as amended, or 2017 Plan, which have provided our employees (including the named executive officers), non-employee directors, consultants and independent contractors the opportunity to participate in the equity appreciation of our business through the receipt of stock options to purchase shares of our common stock. We believe that such stock options function as a compelling retention tool. The 2007 Plan terminated in accordance with its terms on November 28, 2017. Accordingly, we may no longer grant stock options under the 2007 Plan; however, outstanding stock options may continue to be exercised in accordance with their terms. Immediately following the termination of the 2007 Plan, we adopted the 2017 Plan, which contains substantially similar terms and conditions as the 2007 Plan. The 315,724 shares of our common stock reserved for issuance under the 2017 Plan is equal to the number of unissued shares of our common stock under the 2007 Plan as of its termination on November 28, 2017.

On August 15, 2009, we granted incentive stock options to purchase 30,075 shares of our common stock to each of Messrs. Herbert and Ban. Mr. Ban subsequently exercised a portion of his stock option corresponding to 12,000 shares of our common stock following vesting. Each such stock option has a $3.26 per share exercise price.

On May 1, 2012, we granted incentive stock options to purchase 167,067 shares of our common stock and 56,390 shares of our common stock to Messrs. Herbert and Ban, respectively. Each such stock option has a $1.47 per share exercise price.

On September 12, 2013, we granted incentive stock options to purchase 134,586 shares of our common stock and 75,187 shares of our common stock to Messrs. Herbert and Ban, respectively. Each such stock option has a $1.14 per share exercise price.

On March 31, 2014, we granted incentive stock options to purchase 176,691 shares of our common stock and 27,067 shares of our common stock to Messrs. Herbert and Ban, respectively. Each such stock option has a $2.07 per share exercise price. On June 1, 2014, we granted an incentive stock option to purchase 82,706 shares of our common stock to Mr. Buchholz, with a $2.07 per share exercise price.

We did not grant any stock options to our named executive officers in 2015 or 2016.

On January 1, 2017, we granted incentive stock options to purchase 57,894 shares of our common stock, 13,533 shares of our common stock and 6,015 shares of our common stock to Messrs. Herbert, Ban and Buchholz, respectively. Each such stock option has a $0.94 per share exercise price. On April 1, 2017, we granted incentive stock options to purchase 152,180 shares of our common stock, 36,090 shares of our common stock and 15,789 shares of our common stock to Messrs. Herbert, Ban and Buchholz, respectively. Each such stock option has a $0.94 per share exercise price.

On April 9, 2018, we granted incentive stock options to purchase 112,781 shares of our common stock and 22,556 shares of our common stock to Messrs. Herbert and Buchholz, respectively. Each such stock option has a $10.38 per share exercise price.

The share totals and exercise prices listed above reflect adjustments made in connection with the 1-for-6.650 reverse stock split of our common stock effected on April 20, 2018.

All stock options have the same vesting schedule, which provides for 25% to vest on the first anniversary of the grant date and the remaining 75% to vest in 36 equal monthly installments thereafter (such that the stock option would fully vest on the fourth anniversary of the grant date), subject to the recipient's continuous employment through the relevant vesting dates; provided that a stock option award will fully accelerate in vesting in the event of a termination of the recipient's employment by us without "Cause" (as defined in the named executive officer's employment agreement) within one year following a "Change in Control". A "Change of Control" does not include a public offering and so, for purposes of the stock options, will not occur in connection with this offering.

"Change in Control" is defined in the 2007 Plan and 2017 Plan as (i) any voluntary or involuntary liquidation, dissolution or winding up, (ii) our acquisition by another entity by means of any transaction or series of related transactions to which we are party (including, without limitation, any stock acquisition, reorganization, merger or consolidation but excluding any sale of stock

for capital raising purposes), other than by means of a transaction or series of transactions in which the holders of our voting securities outstanding immediately prior to such transaction continue to retain (either by such voting securities remaining outstanding or by such voting securities being converted into voting securities of the surviving entity), at least fifty percent (50%) of the total voting power represented by the voting securities of the surviving or acquiring corporation outstanding immediately after such transaction or series of transactions; or (iii) a sale or other conveyance of all or substantially all of our assets, by means of a transaction or series of transactions.

In connection with the IPO we adopted, and our shareholders approved, the 2018 Plan in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of us and certain of our affiliates and to enable us and certain of its affiliates to obtain and retain services of these individuals, which is essential to our long-term success. For additional information about the 2018 Plan, please see the section titled "Equity Incentive Plans" below.

Other Elements of Compensation

Retirement Plans

We currently maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. Our named executive officers are eligible to participate in the 401(k) plan on the same terms as other full-time employees. The Code allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) plan. We believe that providing a vehicle for tax-deferred retirement savings though our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies.

Employee Benefits and Perquisites Health/Welfare Plans. All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including:

- medical, dental and vision benefits;
- medical and dependent care flexible spending accounts;
- short-term and long-term disability insurance; and
- life insurance.

We believe the perquisites described above are necessary and appropriate to provide a competitive compensation package to our named executive officers.

No Tax Gross-Ups

We do not make gross-up payments to cover our named executive officers' personal income taxes that may pertain to any of the compensation or perquisites paid or provided by our company.

Employment Agreements

Timothy Herbert

We entered into an employment agreement with Mr. Herbert, dated November 16, 2007, or the Herbert Employment Agreement, providing for his position as President and Chief Executive Officer and an initial annual base salary of $200,000 (which has been increased to $397,860 for 2018 and, effective April 9, 2018, was further increased to $425,000). The Herbert Employment Agreement provides for an indefinite term and is terminable at will by us or Mr. Herbert, provided that one month's advance notice must be provided by the terminating party in the event of a termination of employment without "Cause" by us or a resignation without "Good Reason" by Mr. Herbert.

The Herbert Employment Agreement provides for Mr. Herbert's eligibility to receive discretionary annual bonuses and/or long term incentive compensation with an initial target of 25% of Mr. Herbert's annual base salary (which has been increased to 60% for 2018 and, effective April 9, 2018, was further increased to 75%), based upon achievement of annual performance targets. Pursuant to the Herbert Employment Agreement, upon termination of employment by us without Cause, by Mr. Herbert for

Good Reason or following a "Change of Control" if Mr. Herbert does not receive an offer of employment with the new controlling entity under an agreement that provides him with the same base pay and comparable incentives, benefits and terms, Mr. Herbert will receive the sum of his then current annual base salary and an additional one month of his then current base salary for each year of Mr. Herbert's employment with us beyond his second year of employment, with such amount payable in a lump sum, as well as subsidized COBRA premiums for 12 months following his termination of employment. Mr. Herbert will be required to execute a release of claims in favor of us in order to receive his severance benefits.

"Change of Control" is defined in the Herbert Employment Agreement as the occurrence of one of the following: (i) a sale by our stockholders of a substantial portion of their stock in us, or a merger, reorganization or consolidation, whereby our equity holders existing immediately prior to such sale, merger, reorganization or consolidation do not, immediately after consummation of such sale, reorganization, merger or consolidation, own more than fifty percent (50%) of the combined voting power of the surviving entity's then outstanding voting securities entitled to vote generally in the election of directors but only if such event results in a change in board of directors composition such that the directors immediately preceding such events do not comprise a majority of the board of directors following such event, or (ii) the sale or other disposition of all or substantially all of our assets to an entity in which we, any of our subsidiaries, or our equity holders existing immediately prior to such sale beneficially own less than fifty percent (50%) of the combined voting power of such acquiring entity's then outstanding voting securities entitled to vote generally in the election of directors but only if such event results in a change in board of directors composition such that the directors immediately preceding such events do not comprise a majority of the board of directors following such event.

"Cause" is defined in the Herbert Employment Agreement as (i) Mr. Herbert's material breach of his obligations under the Herbert Employment Agreement, or his repeated failure or refusal to perform or observe his duties, responsibilities and obligations as an executive, for reasons other than disability, if such breach, failure or refusal continues or it or another breach, failure or refusal is repeated following written notice thereof to him; (ii) any material dishonesty or other breach of the duty of loyalty affecting us or any of our customers, vendors or employees; (iii) use of alcohol or other drugs in a manner which materially affects the performance of Mr. Herbert's duties, responsibilities and obligations as an employee, if such use continues or is repeated following written notice thereof to him; (iv) conviction of, or a plea of guilty or *nolo contendre* to, a charge of commission of a felony or of any crime involving misrepresentation, moral turpitude or fraud; (v) commission by Mr. Herbert of any other willful or intentional act which materially injures our reputation, business or business relationships if such act occurs or continues following written notice to him of the same or of a prior willful or intentional act injuring our reputation, business or business relationships; or (vi) the existence of any court order or settlement agreement prohibiting Mr. Herbert's continued employment with us.

"Good Reason" is defined in the Herbert Employment Agreement as (i) a material reduction, without Mr. Herbert's consent, in Mr. Herbert's duties or responsibilities, (provided no such reduction shall be deemed to have occurred solely by reason of our having hired a new Chief Executive or President as long as Mr. Herbert continues to have responsibilities that are consistent with executive status); (ii) a material reduction of Mr. Herbert's base salary, unless such reduction is part of an overall reduction in salary for executive employees and Mr. Herbert's reduction is proportionate to the overall reduction in salary; (iii) us moving Mr. Herbert's place of employment, without his consent, more than 50 miles from the place of his employment prior to such move, although business travel shall not be deemed to be a move of his place of employment; or (iv) our material breach of the Herbert Employment Agreement, provided Mr. Herbert has provided us detailed written notice of such alleged breach and we have not, within thirty (30) days of receipt of such notice, cured such alleged breach.

The Herbert Employment Agreement contains non-competition and employee non-solicitation covenants that apply through one year following termination of employment.

Randy Ban

We entered into an employment agreement with Mr. Ban, dated July 20, 2009, or the Ban Employment Agreement, providing for his position as Senior Vice President of Marketing and an initial annual base salary of $200,000 (which has been increased to $287,907 for 2018). The Ban Employment Agreement provides for an indefinite term and is terminable at will by us or Mr. Ban, provided that one month's advance notice must be provided by us in the event of a termination of employment without "Cause" and two weeks' advance notice must be provided by Mr. Ban in the event of a resignation for any reason.

The Ban Employment Agreement provides for Mr. Ban's eligibility to receive discretionary annual bonuses and/or long term incentive compensation with an initial target of 25% of Mr. Ban's annual base salary, based upon achievement of annual performance targets (Mr. Ban currently participates in a commission program in lieu of the foregoing). Pursuant to the Ban Employment Agreement, upon termination of employment by us without Cause or following a "Change of Control" if Mr. Ban does not receive an offer of employment with the new controlling entity under an agreement that provides him with the same base pay and comparable incentives, benefits and terms, Mr. Ban will receive the sum of two months of his then current annual base salary and an additional one month of his then current base salary for each full year of Mr. Ban's employment with us beyond his second year of employment, with such amount payable in a lump sum, as well as subsidized COBRA premiums for a number months following his termination of employment corresponding to the number of months of his then current base salary to which he would be entitled as severance. Mr. Ban will be required to execute a release of claims in favor of us in order to receive his severance benefits.

For purposes of the Ban Employment Agreement, "Change of Control" has the same meaning as used in the Herbert Employment Agreement.

"Cause" is defined in the Ban Employment Agreement as (i) Mr. Ban's breach of his obligations under the Ban Employment Agreement, or his repeated failure or refusal to perform or observe his duties, responsibilities and obligations as an executive, for reasons other than disability; (ii) any material dishonesty or other breach of the duty of loyalty affecting us or any of our customers, vendors or employees; (iii) use of alcohol or other drugs in a manner which affects the performance of Mr. Ban's duties, responsibilities and obligations as an employee; (iv) conviction of, or a plea of guilty or *nolo contendre* to, a charge of commission of a felony or of any crime involving misrepresentation, moral turpitude or fraud; (v) commission by Mr. Ban of any other willful or intentional act which injures our reputation, business or business relationships; or (vi) the existence of any court order or settlement agreement prohibiting Mr. Ban's continued employment with us.

The Ban Employment Agreement contains non-competition and employee non-solicitation covenants that apply through one year following termination of employment.

Richard Buchholz

We entered into an employment agreement with Mr. Buchholz, dated June 1, 2014, or the Buchholz Employment Agreement, providing for his position as Chief Financial Officer and an initial annual base salary of $235,000 (which has been increased to $282,346 for 2018 and, effective April 9, 2018, was further increased to $322,100). The Buchholz Employment Agreement provides for an indefinite term and is terminable at will by us or Mr. Buchholz, provided that one month's advance notice must be provided by us in the event of a termination of employment without "Cause" and two weeks' advance notice must be provided by Mr. Buchholz in the event of a resignation for any reason.

The Buchholz Employment Agreement provides for Mr. Buchholz's eligibility to receive discretionary annual bonuses and/or long term incentive compensation with an initial target of 25% of Mr. Buchholz's annual base salary (which has been increased to 40% for 2018 and, effective April 9, 2018, was further increased to 45%), based upon achievement of annual performance targets. Pursuant to the Buchholz Employment Agreement, upon termination of employment by us without Cause or following a "Change of Control" if Mr. Buchholz does not receive an offer of employment with the new controlling entity under an agreement that provides him with the same base pay and comparable incentives, benefits and terms, Mr. Buchholz will receive the sum of six months of his then current annual base salary and an additional one month of his then current base salary for each full year of Mr. Buchholz's employment with us beyond his second year of employment, with such amount payable in a lump sum, as well as subsidized COBRA premiums for a number months following his termination of employment corresponding to the number of months of his then current base salary to which he would be entitled as severance. Mr. Buchholz will be required to execute a release of claims in favor of us in order to receive his severance benefits.

For purposes of the Buchholz Employment Agreement, "Change of Control" has the same meaning as used in the Herbert Employment Agreement.

"Cause" is defined in the Buchholz Employment Agreement as (i) Mr. Buchholz's breach of his obligations under the Buchholz Employment Agreement, or his repeated failure or refusal to perform or observe his duties, responsibilities and obligations as an executive, for reasons other than disability; (ii) any material dishonesty or other breach of the duty of loyalty affecting us or any of our customers, vendors or employees; (iii) use of alcohol or other drugs in a manner which affects the performance of Mr. Buchholz's duties, responsibilities and obligations as an employee; (iv) conviction of, or a plea of guilty or *nolo contendre* to, a

charge of commission of a felony or of any crime involving misrepresentation, moral turpitude or fraud; (v) commission by Mr. Buchholz of any other willful or intentional act which materially injures our reputation, business or business relationships; or (vi) the existence of any court order or settlement agreement prohibiting Mr. Buchholz's continued employment with us.

The Buchholz Employment Agreement contains non-competition and employee non-solicitation covenants that apply through one year following termination of employment.

Amendment and Restatement Effective as of April 9, 2018, we entered into amended and restated employment agreements with each of our named executive officers, which modified existing severance provisions (as described below) under each named executive officer's existing employment agreement, but were otherwise substantially similar in all other respects.

Mr. Herbert's amended and restated employment agreement provides for severance equal to (i) in the event of a severance-eligible termination of employment that occurs on or within the twelve-month period following a Change of Control, (A) the sum of (x) eighteen months of his then current base salary and (y) annual target bonus, payable in substantially equal installments for eighteen months following his termination of employment (B) subsidized COBRA premiums for eighteen months following his termination of employment and (C) acceleration in full of the vesting of his outstanding equity awards, and (ii) in the event of a severance-eligible termination of employment that does not occur on or within the twelve-month period following a Change of Control, (A) the sum of (x) twelve months of his then current base salary and (y) a prorated portion of his annual bonus, payable in substantially equal installments for twelve months following his termination of employment, and (B) subsidized COBRA premiums for twelve months following his termination of employment.

The amended and restated employment agreements for each of Messrs. Ban and Buchholz provide for severance equal to (i) in the event of a severance-eligible termination of employment that occurs on or within the twelve-month period following a Change of Control, (A) the sum of (x) twelve months of his then current base salary and (y) annual target bonus or commission amount, payable in substantially equal installments for twelve months following his termination of employment (less, with respect to Mr. Ban, any quarterly commissions already earned and paid during the calendar year in which the date of termination occurs), (B) subsidized COBRA premiums for twelve months following his termination of employment and (C) acceleration in full of the vesting of any outstanding equity awards that are granted by us on or following April 9, 2018, and (ii) in the event of a severance-eligible termination of employment that does not occur on or within the twelve-month period following a Change of Control, (A) the sum of (x) nine months of his then current base salary and (y) a prorated portion of his annual target bonus or commission amount, payable in substantially equal installments for nine months following his termination of employment (less, with respect to Mr. Ban, any quarterly commissions already earned and paid during the calendar year in which the date of termination occurs), and (B) subsidized COBRA premiums for nine months following his termination of employment.

Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2017.

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Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable(2)		Number of Securities Underlying Unexercised Options (#) Unexercisable(2)	Option Exercise Price ($)(2)	Option Expiration Date
Timothy P. Herbert	8/15/2009	30,075		–	3.26	8/14/2019
	5/1/2012	167,067		–	1.47	4/30/2022
	9/12/2013	134,586		–	1.14	9/11/2023
	3/31/2014	165,648		11,043	2.07	3/30/2024
	1/1/2017	–		57,894	0.94	12/31/2026
	4/1/2017	–		152,180	0.94	3/31/2027
Randy A. Ban	8/15/2009	28,270	(3)	–	3.26	8/14/2019
	5/1/2012	56,390		–	1.47	4/30/2022
	9/12/2013	75,187		–	1.14	9/11/2023
	3/31/2014	25,375		1,691	2.07	3/30/2024
	1/1/2017	–		13,533	0.94	12/31/2026
	4/1/2017	–		36,090	0.94	3/31/2027

Richard J. Buchholz	6/1/2014	72,368	10,338	2.07	5/31/2024
	1/1/2017	—	6,015	0.94	12/31/2026
	4/1/2017	—	15,789	0.94	3/31/2027

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(1) Each stock option award has the same vesting schedule, which provides for 25% of the award to vest on the first anniversary of the grant date and the remaining 75% of the award to vest in 36 equal monthly installments thereafter (such that the award would fully vest on the fourth anniversary of the grant date), subject to the recipient's continuous employment with us through the relevant vesting dates; provided that a stock option award will fully accelerate in vesting in the event of a termination of the recipient's employment by us without "Cause" (as defined in the named executive officer's employment agreement) within one year following a "Change in Control". For additional details, please refer to the section titled "Narrative to Summary Compensation Table—Equity Compensation" above.

(2) Pursuant to provisions in the 2007 Plan and 2017 Plan, the exercise price and number of shares subject to these options were adjusted in connection with the 1-for-6.650 reverse stock split of our common stock effected on April 20, 2018. Accordingly, the share totals and exercise prices shown in the table above (and in the corresponding footnotes) reflect our named executive officers' post reverse stock split holdings.

(3) Mr. Ban's stock option award initially corresponded to 30,075 underlying shares of our common stock. Prior to December 31, 2017, however, Mr. Ban chose to exercise a portion of his vested stock option award with respect to 1,804 underlying shares of our common stock.

Director Compensation

Other than Dr. Griffin, Mr. McCormick and Ms. Nelson, none of our directors received compensation as a director for the year ended December 31, 2017. The only compensation that Dr. Griffin, Mr. McCormick and Ms. Nelson received as a director for the year ended December 31, 2017 was in the form of stock option awards, as indicated in the table below.

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Name	Option Awards ($)(1)(2)	Total ($)
Jerry Griffin, M.D.	4,308	4,308
Shawn T McCormick	8,615	8,615
Marilyn Carlson Nelson	8,615	8,615

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(1) Amounts reflect the full grant-date fair value of stock options granted during 2017 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of all stock option awards made to our directors in Note 8 to our audited financial statements included elsewhere in this prospectus.

(2) The table below shows the aggregate numbers of stock option awards (exercisable and unexercisable) held as of December 31, 2017 by each director who was serving as of December 31, 2017. No directors other than Dr. Griffin, Mr. McCormick or Ms. Nelson held outstanding stock option awards as of December 31, 2017.

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Name	Number of Shares of Common Stock Underlying Options Outstanding at Fiscal Year End
Jerry Griffin, M.D.	11,278
Shawn T McCormick	22,556
Marilyn Carlson Nelson	22,556

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IPO Grants to Non-Employee Directors under the 2018 Plan

In connection with the IPO, on May 2, 2018, we granted to each of our non-employee directors an award of a stock option to purchase 17,296 shares of our common stock under the 2018 Plan, at an exercise price per share equal to $16.00, the IPO price of our common stock. Each such stock option will vest in full on the earlier to occur of a Change in Control and the first anniversary of the date of grant, subject to the non-employee director's continued service through the applicable vesting date, and will expire upon the tenth anniversary of the date of grant.

Non-Employee Director Compensation Policy

In connection with the IPO, we adopted, and our shareholders approved, a compensation policy for our non-employee directors that consists of annual retainer fees and long-term equity awards.

Pursuant to this policy, each eligible non-employee director receives an annual cash retainer of $40,000. The chairperson of the board of directors receives an additional annual cash retainer of $35,000. Further, the chairperson of the audit committee receives an additional annual cash retainer of $20,000 and each other member of the audit committee receives an additional annual cash retainer of $10,000, the chairperson of the compensation committee receives an additional annual cash retainer of $15,000 and each other member of the compensation committee receives an additional annual cash retainer of $7,500, and the chairperson of the nominating and governance committee receives an additional annual cash retainer of $10,000 and each other member of the nominating and governance committee receives an additional annual cash retainer of $5,000. Each annual cash retainer will be paid quarterly in arrears. The board of directors may, in its discretion, permit a non-employee director to elect to receive any portion of the annual cash retainer in the form of fully vested and unrestricted shares of common stock in lieu of cash. Also, pursuant to this policy, on the date of any annual meeting of our stockholders, we intend to grant each eligible non-employee director an award of an option to purchase a number of shares of our common stock (at a per-share exercise price equal to the closing price per share of the common stock on the date of such annual meeting (or on the last preceding trading day)) that has a grant date fair value of $110,000. The terms of each such award will be set forth in a written award agreement between each non-employee director and us, which will generally provide for vesting after one year of continued service as a director. Each such award will vest in full immediately prior to the occurrence of a Change in Control (as defined in the 2018 Plan).

Also, pursuant to this policy, we intend to grant any eligible non-employee director who is elected or appointed mid-year an award of an option to purchase a number of shares of our common stock (at a per-share exercise price equal to the closing price per share of the common stock on the date of such director's election or appointment (or on the last preceding trading day)) that has a grant date fair value of $165,000. The terms of each such award will be set forth in a written award agreement between the non-employee director and us, which will generally provide for vesting in three equal installments following the date of grant (such that such award will vest in full on the third anniversary of the date of grant). Each such award will vest in full immediately prior to the occurrence of a Change in Control.

All cash and equity awards granted under the non-employee director compensation policy will be granted under, and subject to the limits of, the 2018 Plan.

Equity Incentive Plans

2007 Stock Incentive Plan and 2017 Stock Incentive Plan

We maintain the 2007 Plan (as described above), which terminated in accordance with its terms on November 28, 2017, and the 2017 Plan (as described above). No further grants are permitted to be made under the 2017 Plan.

2018 Incentive Award Plan

In connection with the IPO, we adopted, and our shareholders approved, the 2018 Plan, under which we may grant cash and equity incentive awards to eligible employees, consultants and directors in order to attract, motivate and retain the talent for which we compete. The material terms of the 2018 Plan are summarized below.

Eligibility and Administration. Our employees, consultants and directors, and employees, consultants and directors of our subsidiaries are eligible to receive awards under the 2018 Plan. The 2018 Plan is administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under Section 16 of the Exchange Act and/or stock exchange rules, as applicable. The plan administrator has the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2018 Plan, subject to its express terms and conditions. The plan administrator also sets the terms and conditions of all awards under the 2018 Plan, including any vesting and vesting acceleration conditions.

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Limitation on Awards and Shares Available. The aggregate number of shares of our common stock that are available for issuance under awards granted pursuant to the 2018 Plan, which shares may be authorized but unissued shares, or shares purchased in the open market, is equal to the sum of (i) 1,386,809 shares and (ii) an annual increase on the first day of each year beginning in 2019 and ending in 2028, equal to the lesser of (A) 739,631 shares, (B) 4% of the shares outstanding (on an as-converted basis) on the last day of the immediately preceding fiscal year and (C) such smaller number of shares as determined by our board of directors. If an award under the 2018 Plan is forfeited, expires, is converted to shares of another entity in connection with a spin-off or other similar event or is settled for cash, any shares subject to such award may, to the extent of such forfeiture, expiration, conversion or cash settlement, be used again for new grants under the 2018 Plan. However, the following shares may not be used again for grant under the 2018 Plan: (1) shares tendered or withheld to satisfy grant or exercise price or tax withholding obligations associated with an award; (2) shares subject to a stock appreciation right, or SAR, that are not issued in connection with the stock settlement of the SAR on its exercise; and (3) shares purchased on the open market with the cash proceeds from the exercise of options. Awards granted under the 2018 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2018 Plan. The sum of the grant date fair value of equity-based awards and the amount of any cash compensation granted to a non-employee director during (i) the first calendar year of such non-employee director's service will not exceed $1,000,000 and (ii) each subsequent calendar year of such non-employee director's service will not exceed $500,000.

Awards. The 2018 Plan provides for the grant of stock options, including incentive stock options, or ISOs, and nonqualified stock options, or NSOs, stock appreciation rights, or SARS, restricted stock, restricted stock units, or RSUs, other stock or cash based awards and dividend equivalents. Certain awards under the 2018 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2018 Plan are set forth in award agreements, which detail all terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards other than cash awards are generally settled in shares of our common stock, but the plan administrator may provide for cash settlement of any award. A brief description of each award type follows.

- *Stock Options.* Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. The exercise price of a stock option may not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance and/or other conditions.

- *SARs.* SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR may not be less than 100% of the fair market value of the underlying share on the date of grant (except with respect to certain substitute SARs granted in connection with a corporate transaction) and the term of a SAR may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to SARs and may include continued service, performance and/or other conditions.

- *Restricted Stock and RSUs.* Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met. Delivery of the shares underlying RSUs may be deferred under the terms of the award or at the election of the participant, if the plan administrator permits such a deferral. Conditions applicable to restricted stock and RSUs may be based on continuing service, the attainment of performance goals and/or such other conditions as the plan administrator may determine.

- *Other Stock or Cash Based Awards.* Other stock or cash awards are cash payments, cash bonus awards, stock payments, stock bonus awards or incentive awards paid in cash, shares of our common stock or a combination of both, and may include deferred stock, deferred stock units, retainers, committee fees and meeting based fees.

- *Dividend Equivalents.* Dividend equivalents represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards other than stock options or SARs. Dividend equivalents are credited as of dividend record dates during the period between the date an award is granted and the date such award vests, is exercised, is distributed or expires, as determined by the plan administrator. Dividend equivalents may not be paid on awards granted under the 2018 Plan unless and until such awards have vested.

Section 162(m) of the Code imposes a $1 million cap on the compensation deduction that a public company may take in respect of compensation paid to its "covered employees". Under current tax law, we do not expect Section 162(m) of the Code to apply to certain awards under the 2018 Plan until the earliest to occur of (1) our annual stockholders' meeting at which members of our board of directors are to be elected in 2022; (2) a material modification of the 2018 Plan; (3) an exhaustion of the share supply under the 2018 Plan; or (4) the expiration of the 2018 Plan.

Certain Transactions. The plan administrator has broad discretion to take action under the 2018 Plan, as well as make adjustments to the terms and conditions of existing and future awards, to prevent the dilution or enlargement of intended benefits and facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations and other corporate transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders known as "equity restructurings," the plan administrator may make equitable adjustments to the 2018 Plan and outstanding awards. In the event of a change in control of our company (as defined in the 2018 Plan), to the extent that the surviving entity declines to continue, convert, assume or replace outstanding awards, all such awards will become fully vested and exercisable in connection with the transaction. Upon or in anticipation of a change of control, the plan administrator may cause any outstanding awards to terminate at a specified time in the future and give the participant the right to exercise such awards during a period of time determined by the plan administrator in its sole discretion. Individual award agreements may provide for additional accelerated vesting and payment provisions.

Foreign Participants, Claw-Back Provisions, Transferability, and Participant Payments. The plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above, in order to facilitate grants of awards subject to the laws and/or stock exchange rules of countries outside of the United States. All awards are subject to the provisions of any claw-back policy implemented by our company to the extent set forth in such claw-back policy and/or in the applicable award agreement. With limited exceptions for estate planning, domestic relations orders, certain beneficiary designations and the laws of descent and distribution, awards under the 2018 Plan are generally non-transferable prior to vesting, and are exercisable only by the participant. With regard to tax withholding, exercise price and purchase price

obligations arising in connection with awards under the 2018 Plan, the plan administrator may, in its discretion, accept cash or check, shares of our common stock that meet specified conditions, a "market sell order" or such other consideration as it deems suitable.

Plan Amendment and Termination. Our board of directors may amend or terminate the 2018 Plan at any time; however, except in connection with certain changes in our capital structure, stockholder approval will be required for any amendment that increases the number of shares available under the 2018 Plan, "reprices" any stock option or SAR, or cancels any stock option or SAR in exchange for cash or another award when the option or SAR price per share exceeds the fair market value of the underlying shares. No award may be granted pursuant to the 2018 Plan after the tenth anniversary of the date on which our board of directors adopted the 2018 Plan.

2018 Employee Stock Purchase Plan

In connection with the IPO, we adopted, and our shareholders approved, the ESPP. Our executive officers and all of our other employees are allowed to participate in our ESPP, subject to the eligibility requirements described below. The material terms of the ESPP are summarized below.

The aggregate number of shares of our common stock that are reserved for issuance under our ESPP is equal to the sum of (i) 277,362 shares and (ii) an annual increase on the first day of each year beginning in 2019 and ending in 2028, equal to the lesser of (A) 184,908 shares, (B) 1% of the shares outstanding (on an as-converted basis) on the last day of the immediately preceding fiscal year and (C) such smaller number of shares as determined by our board of directors. Our board of directors or its committee has full and exclusive authority to interpret the terms of the ESPP and determine eligibility. Our compensation committee is the initial administrator of the ESPP.

Our employees and the employees of our subsidiaries are eligible to participate in the ESPP if they are customarily employed by us or any participating subsidiary for at least 20 hours per week and more than five months in any calendar year. However, an employee may not be granted rights to purchase stock under our ESPP if such employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common stock.

Our ESPP is intended to qualify under Section 423 of the Code and stock will be offered under the ESPP during offering periods. The length of the offering periods under the ESPP will be determined by our compensation committee and may be up to 27 months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The purchase dates will be determined by the compensation committee for each offering period, but will generally be the last day in each offering period. Offering periods under the ESPP will commence when determined by our compensation committee. The compensation committee may, in its discretion, modify the terms of future offering periods.

Our ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation, which includes a participant's gross base compensation for services to the company, excluding overtime payments, sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments. A participant is permitted to purchase a maximum of 100,000 shares of common stock during each offering period. In addition, no employee is permitted to accrue the right to purchase stock under the ESPP at a rate in excess of $25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant will be automatically granted an option to purchase shares of our common stock. The option will expire at the end of the offering period or upon termination of employment, whichever is earlier, but is exercised at the end of each purchase period to the extent of the payroll deductions accumulated during such purchase period. The purchase price of the shares will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the applicable purchase date. Participants may end their participation at any time during an offering period, and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation will end automatically upon termination of employment with us.

A participant may not transfer rights granted under the ESPP other than by will, the laws of descent and distribution or as otherwise provided under the ESPP.

In the event of certain significant transactions or a "Change in Control" (as defined in the ESPP), the compensation committee may provide for (i) either the replacement or termination of outstanding rights in exchange for cash, (ii) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (iii) the adjustment in the number and type of shares of stock subject to outstanding rights, (iv) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next purchase date and termination of any rights under ongoing offering periods or (v) the termination of all outstanding rights.

The compensation committee may amend, suspend or terminate the ESPP. However, stockholder approval of any amendment to the ESPP will be obtained for any amendment which changes the aggregate number or type of shares that may be sold pursuant to rights under the ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the ESPP or changes the ESPP in any manner that would cause the ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Code.

Federal Income Taxes. The material federal income tax consequences of the ESPP under current federal income tax law are summarized in the following discussion, which deals with the general tax principles applicable to the ESPP. The following discussion is based upon laws, regulations, rulings and decisions now in effect, all of which are subject to change. Foreign, state and local tax laws, and employment, estate and gift tax considerations are not discussed due to the fact that they may vary depending on individual circumstances and from locality to locality.

The ESPP, and the right of participants to make purchases thereunder, are intended to qualify under the provisions of Section 423 of the Code. Under the applicable Code provisions, no income will be taxable to a participant until the sale or other disposition of the shares purchased under the ESPP. This means that an eligible employee will not recognize taxable income on the date the employee is granted an option under the ESPP (*i.e.*, the first day of the offering period). In addition, the employee will not recognize taxable income upon the purchase of shares. Upon such sale or disposition, the participant will generally be subject to tax in an amount that depends upon the length of time such shares are held by the participant prior to disposing of them. If the shares are sold or disposed of more than two years from the first day of the offering period during which the shares were purchased and more than one year from the date of purchase, or if the participant dies while holding the shares, the participant (or his or her estate) will recognize ordinary income measured as the lesser of (1) the excess of the fair market value of the shares at the time of such sale or disposition over the purchase price or (2) an amount equal to 85% of the fair market value of the shares as of the first day of the offering period. Any additional gain will be treated as long-term capital gain. If the shares are held for the holding periods described above but are sold for a price that is less than the purchase price, there will be no ordinary income and the participating employee has a long-term capital loss for the difference between the sale price and the purchase price.

If the shares are sold or otherwise disposed of before the expiration of the holding periods described above, the participant will recognize ordinary income generally measured as the excess of the fair market value of the shares on the date the shares are purchased over the purchase price and we will be entitled to a tax deduction for compensation expense in the amount of ordinary income recognized by the employee. Any additional gain or loss on such sale or disposition will be long-term or short-term capital gain or loss, depending on how long the shares were held following the date they were purchased by the participant prior to disposing of them. If the shares are sold or otherwise disposed of before the expiration of the holding periods described above but are sold for a price that is less than the purchase price, the participant will recognize ordinary income equal to the excess of the fair market value of the shares on the date of purchase over the purchase price (and we will be entitled to a corresponding deduction), but the participant generally will be able to report a capital loss equal to the difference between the sales price of the shares and the fair market value of the shares on the date of purchase.

Certain Relationships and Related Party Transactions

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2015, to which we have been a party in which the amount involved exceeded or will exceed $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock at the time of such transaction, or any member of the immediate family of any of the foregoing persons, had or will have a direct or indirect material interest, other than equity and other compensation, termination,

change in control and other arrangements, which are described under "Executive and Director Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

Participation in our Initial Public Offering

In connection with our IPO, certain of our existing stockholders and members of our board of directors purchased shares of our common stock from the underwriters at the initial public offering price of $16.00 per share, and on the same terms as other investors in our IPO. The following table summarizes purchases of shares of our common stock in our IPO by holders of more than 5% of our capital stock, certain members of our board of directors and an entity affiliated with a member of our board of directors.

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Participants	Shares Purchased	Aggregate Purchase Price
		(in thousands)
Greater than 5% Stockholders(1)		
Orbimed Private Investments V, L.P.(2)	312,500	$5,000
Amzak Health Investors, LLC(3)	125,000	$2,000
Directors and Affiliates		
GDN Holdings, LLC(4)	62,500	$1,000
Dana G. Mead, Jr.	20,000	$320
Casey Tansey	187,500	$3,000

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(1) Additional details regarding these stockholders and their equity holdings are provided in this prospectus under the caption "Principal and Selling Stockholders."

(2) Mr. Chau Khuong, a member of our board of directors, is affiliated with OrbiMed Private Investments V, L.P.

(3) Ms. Joyce Erony, a member of our board of directors, is affiliated with Amzak Health Investors, LLC.

(4) Ms. Marilyn Carlson Nelson, a member of our board of directors, is the managing member of GDN Holdings, LLC.

Sale of Series F Convertible Preferred Stock

In February 2017, we completed the sale of an aggregate of 27,372,261 shares of our Series F convertible preferred stock at a purchase price of $1.37 per share for an aggregate purchase price of $37.5 million. The shares were issued in two tranches, with the first tranche of 9,124,084 shares closing in October 2016 and the second tranche of 18,248,177 shares closing in February 2017. Each share of our Series F convertible preferred stock converted into shares of our common stock immediately prior to the closing of our IPO in accordance with our certificate of incorporation, including adjustments in connection with the 1-for-6.650 reverse stock split of our common stock effected on April 20, 2018. The following table summarizes purchases of shares of our Series F convertible preferred stock by holders of more than 5% of our capital stock, a member of our board of directors and an entity affiliated with a member of our board of directors.

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	Initial Closing(1)	Second Closing

Participants	Shares of Series F Convertible Preferred Stock	Aggregate Purchase Price	Shares of Series F Convertible Preferred Stock	Aggregate Purchase Price	Total Shares Purchased	Aggregate Purchase Price
		(in thousands)		(in thousands)		(in thousands)
Greater than 5% Stockholders(2)						
U.S. Venture Partners IX, L.P.(3)	1,265,207	$1,733	2,530,414	$3,467	3,795,621	$5,200
Orbimed Private Investments V, L.P.(4)	1,216,545	$1,667	2,433,090	$3,333	3,649,635	$5,000
Synergy Life Science Partners, LP(5)	1,034,063	$1,417	2,068,127	$2,833	3,102,190	$4,250
KPCB Holdings, Inc.(6)	753,133	$1,032	1,506,266	$2,064	2,259,399	$3,095
Amzak Health Investors, LLC(7)	3,041,363	$4,167	6,082,725	$8,333	9,124,088	$12,500
Medtronic	141,846	$194	283,693	$389	425,539	$583
Directors and Affiliates						
GDN Holdings, LLC(8)	166,954	$229	333,909	$457	500,863	$686
Jerry Griffin, M.D.	17,845	$24	35,690	$49	53,535	$73

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(1) A portion of the consideration paid for the shares of Series F convertible preferred stock issued in the initial closing was funded through the conversion of the aggregate principal amount and accrued interest under the Bridge Notes (as defined below). See "—Convertible Bridge Notes."

(2) Additional details regarding certain of these stockholders and their equity holdings are provided in this prospectus under the caption "Principal and Selling Stockholders."

(3) Mr. Casey Tansey, a member of our board of directors, is affiliated with U.S. Venture Partners IX, L.P.

(4) Mr. Chau Khuong, a member of our board of directors, is affiliated with OrbiMed Private Investments V, L.P.

(5) Mr. Mudit K. Jain, a member of our board of directors, was affiliated with Synergy Life Science Partners, LP at the time of this transaction.

(6) Mr. Dana G. Mead, Jr. a member of our board of directors, was affiliated with KPCB Holdings, Inc. at the time of this transaction.

(7) Ms. Joyce Erony, a member of our board of directors, is affiliated with Amzak Health Investors, LLC.

(8) Ms. Marilyn Carlson Nelson, a member of our board of directors, is the managing member of GDN Holdings, LLC.

Convertible Bridge Notes

In July 2016, we entered into a bridge note purchase agreement pursuant to which we issued $4 million in aggregate principal amount of convertible bridge notes, which we refer to as the Bridge Notes. The Bridge Notes matured on December 30, 2016, and accrued interest at a rate of 10% per year, payable in cash or in kind upon repayment. The aggregate principal amount and

accrued interest on the Bridge Notes automatically converted into shares of our Series F convertible preferred stock at a conversion price of $1.37 per share upon the closing of the initial tranche of our Series F convertible preferred stock financing in October 2016. The following table summarizes the Bridge Notes purchased by holders of more than 5% of our capital stock, a member of our board of directors and an entity affiliated with a member of our board of directors, and the conversion of such Bridge Notes and accrued interest thereon into shares of our Series F convertible preferred stock.

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	Bridge Notes		
Participants	Principal Amount(1)	Interest(2)	Shares of Series F Convertible Preferred Stock
	(in thousands)	(in thousands)	
Greater than 5% Stockholders(3)			
U.S. Venture Partners IX, L.P.(4)	$844	$18	629,658
Orbimed Private Investments V, L.P.(5)	$743	$16	554,316
Synergy Life Science Partners, LP(6)	$848	$18	632,597
KPCB Holdings, Inc.(7)	$844	$18	629,658
Medtronic	$159	$3	118,591
Directors and Affiliates			
GDN Holdings, LLC(8)	$199	$4	148,468
Jerry Griffin, M.D.	$4	$*	3,112

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*
Amount less than $500.

(1)
Also represents the largest principal amount outstanding and the amount of principal repaid subsequent to January 1, 2015.

(2)
Represents interest accrued during the year ended December 31, 2016 and converted into shares of Series F convertible preferred stock.

(3)
Additional details regarding these stockholders and their equity holdings are provided in this prospectus under the caption "Principal and Selling Stockholders."

(4)
Mr. Casey Tansey, a member of our board of directors, is affiliated with U.S. Venture Partners IX, L.P.

(5)
Mr. Chau Khuong, a member of our board of directors, is affiliated with OrbiMed Private Investments V, L.P.

(6)
Mr. Mudit K. Jain, a member of our board of directors, was affiliated with Synergy Life Science Partners, LP at the time of this transaction.

(7)
Mr. Dana G. Mead, Jr. a member of our board of directors, was affiliated with KPCB Holdings, Inc. at the time of this transaction.

(8)
Ms. Marilyn Carlson Nelson, a member of our board of directors, is the managing member of GDN Holdings, LLC.

Convertible Promissory Notes and Warrants to Purchase Shares of Series C Convertible Preferred Stock

In 2011 and 2012, we issued $3.0 million in aggregate principal amount of convertible promissory notes to certain holders of more than 5% of our capital stock. The convertible promissory notes had a maturity of one year and accrued interest at a rate of 8% per year. We repaid the convertible promissory notes in full in January 2012.

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In connection with the issuance of the convertible promissory notes, we also issued to the holders thereof warrants to purchase an aggregate of 278,507 shares of our Series C convertible preferred stock at an exercise price of $1.07 per share. Warrants to purchase 19,627 shares of our Series C convertible preferred stock were exercised in 2014, and warrants to purchase the remaining 258,880 shares of Series C convertible preferred stock were exercised in 2016. Warrants to purchase shares of our Series C convertible preferred stock converted into warrants to purchase shares of our common stock immediately prior to the closing of our IPO in accordance with their terms, including adjustments in connection with the 1-for-6.650 reverse stock split of our common stock effected on April 20, 2018.

The following table summarizes the issuance and repayment of the convertible promissory notes and the issuance of the related warrants to holders of more than 5% of our capital stock and an entity affiliated with a member of our board of directors.

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	Convertible Promissory Notes		
Participants	Principal Amount(2)	Interest Paid(3)	Series C Convertible Preferred Stock Warrants
	(in thousands)	(in thousands)	
Greater than 5% Stockholders(1)			
U.S. Venture Partners IX, L.P.(4)	$959	$9	89,639
Synergy Life Science Partners, LP(5)	$851	$8	79,602
KPCB Holdings, Inc.(6)	$959	$9	89,639
Director Affiliates			
GDN Holdings, LLC(7)	$210	$2	19,627

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(1) Additional details regarding these stockholders and their equity holdings are provided in this prospectus under the caption "Principal and Selling Stockholders."

(2) Also represents the largest principal amount outstanding and the amount of principal repaid subsequent to January 1, 2015.

(3) Represents interest paid during the year ended December 31, 2015.

(4) Mr. Casey Tansey, a member of our board of directors, is affiliated with U.S. Venture Partners IX, L.P.

(5) Mr. Mudit K. Jain, a member of our board of directors, was affiliated with Synergy Life Science Partners, LP at the time of this transaction.

(6) Mr. Dana G. Mead, Jr. a member of our board of directors, was affiliated with KPCB Holdings, Inc. at the time of this transaction.

(7) Ms. Marilyn Carlson Nelson, a member of our board of directors, is the managing member of GDN Holdings, LLC.

Transactions with Medtronic

In November 2007, we entered into an investment agreement with Medtronic, pursuant to which, among other things:

- we issued to Medtronic a convertible promissory note in the principal amount of $1.0 million;
- Medtronic agreed, subject to certain conditions and our achievement of certain funding milestones, to lend us an additional $1.0 million in exchange for an additional convertible promissory note, which we issued to Medtronic in May 2009;
- we granted to Medtronic the option, subject to our achievement of certain funding milestones, to purchase up to $4.5 million of shares of our convertible preferred stock at the applicable offering price for such shares, which option was exercised by Medtronic in January 2012 for 1,261,949 shares of our Series C convertible preferred stock;
- we issued to Medtronic 864,000 shares of our common stock as consideration for Medtronic's assignment and license, as applicable, of certain patents and other intellectual property rights to us pursuant to the Assignment and License Agreement, and agreed to issue to Medtronic additional shares of our common stock subject to our achievement of certain funding milestones, pursuant to which we issued to Medtronic 997,000 shares of our common stock in May, 2009, and 859,960 shares of our common stock in January 2012; and
- we and Medtronic entered into a development agreement, which established a joint development program to develop and build our Inspire II neurostimulator and the pressure sensor used in our original pressure sensing lead, which we refer to below as the Products, and a supply agreement, pursuant to which Medtronic agreed to supply, and we agreed to purchase from Medtronic, all of our commercial and clinical requirements of the Products.

The convertible promissory notes described above, which we refer to as the Medtronic Promissory Notes, had a maturity of seven years, accrued interest at a rate of prime plus 0.5% per year, and were secured by all of our assets. The largest aggregate principal amount outstanding under the Medtronic Promissory Notes subsequent to January 1, 2015 was $1.0 million, which amount was repaid in full in April 2015. We paid $0.2 million in interest on the Medtronic Promissory Notes during the year ended December 31, 2015.

The development agreement expired in 2015 after development of the Products was complete. Pursuant to the development agreement, we agreed to reimburse Medtronic for non-recurring engineering costs and expenses incurred by it in connection with the development of the Products. During the year ended December 31, 2015, we reimbursed Medtronic for $0.1 million of costs and expenses pursuant to the development agreement. We did not reimburse Medtronic for any costs and expenses during the years ended December 31, 2016 and 2017.

The initial term of the supply agreement expired in June 2017 and was extended to allow Medtronic to complete the final build of the current pressure sensor, which will not be a component of our newly designed pressure sensing lead. The final build of the Inspire II neurostimulator was completed in December 2016, and the final build of the pressure sensor was completed in the first half of 2018. During the years ended December 31, 2015, 2016 and 2017, we purchased $0.9 million, $0.8 million and $1.1 million in inventory from Medtronic pursuant to the supply agreement. As of December 31, 2017, we had $0.4 million of outstanding purchase commitments to Medtronic.

For a description of the Assignment and License Agreement, see "Business—License Agreement with Medtronic."

Investor Rights Agreement

We are party to a fifth amended and restated investor rights agreement, or the Investor Rights Agreement, with each holder of our formerly outstanding convertible preferred stock, including each holder of more than 5% of our common stock and certain of our directors (or, in some cases, entities affiliated therewith). The Investor Rights Agreement imposes certain affirmative obligations on us, and also grants certain rights to the holders, including certain registration rights with respect to the registrable securities

held by them. See "Description of Capital Stock—Registration Rights" for additional information. In connection with our IPO, we entered into an amendment to the Investor Rights Agreement which provided for the termination of all rights and covenants thereunder, other than the registration rights described above, immediately prior to the consummation of our IPO.

Employment Agreements

We have entered into employment agreements with each of our executive officers. See "Executive and Director Compensation—Narrative to Summary Compensation Table—Employment Agreements" for a further discussion of these arrangements.

Voting Agreement

We were party to that certain fifth amended and restated voting agreement, as amended, or the Voting Agreement, pursuant to which each of U.S. Venture Partners IX, L.P., Kleiner Perkins Caufield & Byers, Synergy Life Science Partners, LP, OrbiMed Private Investments V, L.P. and Amzak Health Investors, LLC had the right to designate one member to be elected to our board of directors. See "Management—Board Composition and Election of Directors." The Voting Agreement terminated by its terms in connection with the closing of our IPO and none of our stockholders currently have any continuing rights regarding the election or designation of members of our board of directors.

Right of First Refusal and Co-Sale Agreement

We were party to a fifth amended and restated right of first refusal and co-sale agreement with the Timothy P. Herbert 2013 Family Irrevocable GST Trust U/A/D November 27, 2013 and each holder of our convertible preferred stock, which included each holder of more than 5% of our capital stock and certain of our directors (or, in some cases, entities affiliated therewith), pursuant to which we had a right of first refusal in respect of certain sales of securities by the Timothy P. Herbert 2013 Family Irrevocable GST Trust U/A/D November 27, 2013. The right of first refusal and co-sale agreement terminated in connection with the closing of our IPO.

Director and Officer Indemnification and Insurance

We have agreed to indemnify each of our directors and executive officers against certain liabilities, costs and expenses, and have purchased directors' and officers' liability insurance. See "Description of Capital Stock—Limitations on Liability and Indemnification Matters."

Stock Option Grants to Executive Officers and Directors

We have granted options to our executive officers and our directors as more fully described in the section entitled "Executive and Director Compensation."

Policies and Procedures for Related Party Transactions

Our board of directors has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds $120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction.

Principal and Selling Stockholders

PRINCIPAL AND SELLING STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock, as of September 30, 2018, and as adjusted to reflect the sale of common stock in this offering, for:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each of the other selling stockholders.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, a person is deemed to be a "beneficial" owner of a security if that person has or shares voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the individuals and entities named in the table below have sole voting and investment power with respect to all shares of common stock beneficially owned by them, subject to any applicable community property laws.

Percentage ownership of our common stock before this offering is based on 21,391,590 shares of our common stock outstanding as of September 30, 2018. Percentage ownership of our common stock after this offering without giving effect to the exercise of the underwriters' option to purchase additional shares is based on 22,891,590 shares of our common stock outstanding as of September 30, 2018, after giving effect to our issuance of 1,500,000 shares of our common stock in this offering and the sale of 1,000,000 shares of our common stock by the selling stockholders in this offering. Percentage ownership of our common stock after this offering and after giving effect to the exercise in full of the underwriters' option to purchase additional shares is based on 23,266,590 shares of our common stock outstanding as of September 30, 2018, after giving effect to our issuance of 1,875,000 shares of common stock in this offering and the sale of 1,000,000 shares of common stock by the selling stockholders in this offering. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or that will become exercisable within 60 days of September 30, 2018 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is 9700 63rd Ave. N., Suite 200, Maple Grove, Minnesota 55369.

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			Common stock to be sold in this offering		Common stock beneficially owned after this offering			
	Common stock beneficially owned before this offering		No exercise of option	Full exercise of option	No exercise of option		Full exercise of option	
	Number	%	Number	Number	Number	%	Number	%
Name of beneficial owner								
5% stockholders:								
OrbiMed Private Investments V, L.P.(1)	2,444,221	11.4%	614,772	614,772	1,829,449	8.0%	1,829,449	7.9%
U.S. Venture Partners IX, L.P.(2)	2,168,254	10.1	—	—	2,168,254	9.5	2,168,254	9.3
Synergy Life Science Partners, LP(3)	2,095,507	9.8	—	—	2,095,507	9.2	2,095,507	9.0
KPCB Holdings, Inc.(4)	1,937,244	9.1	—	—	1,937,244	8.5	1,937,244	8.3
Amzak Health Investors, LLC(5)	1,497,043	7.0	—	—	1,497,043	6.5	1,497,043	6.4

Named executive officers and directors:								
Timothy Herbert(6)	885,166	4.1	—	—	885,166	3.9	885,166	3.8
Randy Ban(7)	210,106	1.0	—	—	210,106	*	210,106	*
Richard Buchholz(8)	96,461	*	—	—	96,461	*	96,461	*
Marilyn Carlson Nelson(9)	643,502	3.0	—	—	643,502	2.8	643,502	2.8
Joyce Erony(10)	1,497,043	7.0	—	—	1,497,043	6.5	1,497,043	6.4
Jerry Griffin, M.D.(11)	62,050	*	1,300	1,300	60,750	*	60,750	*
Mudit K. Jain(12)	495	*	—	—	495	*	495	*
Chau Khuong(13)	471	*	—	—	471	*	471	*
Dana G. Mead, Jr.	20,000	*	—	—	20,000	*	20,000	*
Shawn T McCormick(14)	14,277	*	—	—	14,277	*	14,277	*
Casey Tansey(15)	2,356,299	11.0	—	—	2,356,299	10.3	2,356,299	10.1
All executive officers and directors as a group (12 individuals)(16)	5,796,691	26.0	1,300	1,300	5,795,391	25.3	5,795,391	24.9
Other Selling Stockholders:								
Medtronic(17)	767,856	3.6	383,928	383,928	383,928	1.7	383,928	1.7

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*

Less than 1%.

(1)

OrbiMed Capital GP V LLC, or OrbiMed GP V, is the general partner of OrbiMed Private Investment V, LP, or OPI V. OrbiMed Advisors LLC, or OrbiMed Advisors, is the managing member of OrbiMed GP V. OrbiMed Advisors exercises this investment and voting power through a management committee comprised of Carl L. Gordon, Ph.D., Sven H. Borho and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by OPI V. Chau Khuong is an employee of OrbiMed Advisors and its designee to our board of directors pursuant to our amended and restated voting agreement. Each of OrbiMed GP, OrbiMed Advisors, Dr. Gordon, Mr. Borho, Mr. Silverstein and Mr. Khuong disclaims beneficial ownership of the shares held by OPI V, except to the extent of its or his proportionate pecuniary interest therein, if any. The mailing address of OrbiMed Advisors, OrbiMed GVP and OPI V is 601 Lexington Avenue, 54th Floor, New York, New York 10022.

(2)

Does not reflect the distribution by U.S. Venture Partners IX, L.P., or USVP IX, of 1,084,127 shares of common stock to its partners in November 2018. Presidio Management Group IX, L.L.C., or PMG IX, is the general partner of USVP IX and has voting and dispositive power over the shares held by USVP IX. Casey M. Tansey, a member of our board of directors, Irwin Federman, Steven Krausz, David Liddle, Paul Matteucci, Jonathan D. Root and Philip M. Young are the managing members of PMG IX and, as a result, may be deemed to share voting and dispositive power over the shares held by USVP IX. Each of the managing members of PMG IX disclaims beneficial ownership of such holdings. The mailing address of PMG IX and USVP IX is 1460 El Camino Real, Suite 100, Menlo Park, California 94025.

(3)

Synergy Venture Partners, LLC, or Synergy Venture Partners, is the general partner of Synergy Life Science Partners, LP, or Synergy Life Science Partners, and has voting and dispositive power over the shares held by Synergy Life Science Partners. William N. Starling, Jr. and Richard S. Stack, M.D. are the managing members of Synergy Venture Partners and share voting and dispositive power over the securities held by Synergy Life Science Partners. The mailing address of Synergy Venture Partners and Synergy Life Science Partners is 1350 Bayshore Highway, Suite 920, Burlingame, California 94010.

(4)

Consists of shares of our common stock beneficially owned by Kleiner Perkins Caufield & Byers XII, LLC, or KPCB XII, KPCB XII Founders Fund, LLC, or KPCB XII FF, and individuals and entities associated with Kleiner Perkins Caufield & Byers. All shares are held in the name of "KPCB Holdings, Inc., as nominee" for the accounts of such individuals and entities who each exercise their own voting and dispositive power over such shares. KPCB XII Associates, LLC, or KPCB XII Associates, is the managing member of KPCB XII and KPCB XII FF. Brook H. Byers, L. John Doerr, Raymond J. Lane and Theodore E. Schlein, the managers of KPCB XII Associates, exercise shared voting and dispositive power over the shares directly owned by KPCB XII and KPCB XII FF. KPCB XII Associates and each of its managers disclaim beneficial ownership of these shares. The mailing address of KPCB XII Associates, KPCB XII and KPCB XII FF is 2750 Sand Hill Road, Menlo Park, California 94025.

(5)

Joyce Erony, a member of our board of directors, Michael D. Kazma and Anders Hove, are managers of Amzak Health Investors, LLC, or Amzak Health and, as a result, have shared voting and dispositive power over the shares held by Amzak Health. Ms. Erony disclaims beneficial ownership of the shares held by Amzak Health. The mailing address of Amzak Health is 980 North Federal Highway, Suite 315, Boca Raton, Florida 33432.

(6)

Includes (i) 289,624 shares of common stock held by the Timothy P. Herbert 2013 Family Irrevocable GST Trust U/A/D November 27, 2013, or the Herbert Trust, and (ii) 595,192 shares of common stock underlying options exercisable within 60 days of September 30, 2018. Mr. Herbert is a trustee of the Herbert Trust and, as a result, has shared voting and dispositive power over the shares held by it. Does not give effect to the sale of 15,000 shares pursuant to a Rule 10b5-1 trading plan in November 2018.

(7)

Includes 179,132 shares of common stock underlying stock options exercisable within 60 days of September 30, 2018. Does not give effect to the sale of 10,000 shares acquired upon the exercise of options in November 2018 pursuant to Mr. Ban's Rule 10b5-1 trading plan.

(8)

Includes 91,711 shares of common stock underlying stock options exercisable within 60 days of September 30, 2018.

(9)

Includes (i) 631,451 shares of common stock held by GDN Holdings, LLC, or GDN, (ii) 11,277 shares of common stock underlying stock options exercisable within 60 days of September 30, 2018, and (iii) 492 shares of common stock issuable to Ms. Nelson as of September 30, 2018 pursuant to our Non-Employee Director Compensation Policy (which shares were subsequently issued in October 2018). Ms. Nelson is the managing member of GDN and, as a result, has sole voting and dispositive power over the shares held by GDN.

(10)

Consists of 1,497,043 shares of common stock held by Amzak Health, which Ms. Erony may be deemed to beneficially own. See footnote (5) above. Ms. Erony disclaims beneficial ownership of such shares.

(11)

Includes 5,638 shares of common stock underlying stock options exercisable within 60 days of September 30, 2018.

(12)

Includes 307 shares of common stock issuable to Mr. Jain as of September 30, 2018 pursuant to our Non-Employee Director Compensation Policy (which shares were subsequently issued in October 2018).

(13)

Includes 292 shares of common stock issuable to Mr. Khuong as of September 30, 2018 in lieu of cash compensation under our Non-Employee Director Compensation Policy (which shares were subsequently issued in October 2018).

(14)

Includes 3,759 shares of common stock underlying stock options exercisable within 60 days of September 30, 2018.

(15)

Includes (i) 2,168,254 shares of common stock held by USVP IX, which Mr. Tansey may be deemed to beneficially own (which amount does not reflect the distribution by USVP IX of 1,084,127 shares of common stock to its partners in November 2018 (see footnote (2) above)), and (ii) 338 shares of common stock issuable to Mr. Tansey as of September 30,

2018 pursuant to our Non-Employee Director Compensation Policy (which shares were subsequently issued in October 2018). Mr. Tansey disclaims beneficial ownership of the shares held by USVP IX.

(16) Includes (i) 895,480 shares of common stock underlying stock options exercisable within 60 days of September 30, 2018, and (ii) an aggregate of 1,429 shares of common stock issuable to certain directors as of September 30, 2018 pursuant to our Non-Employee Director Compensation Policy (which shares were subsequently issued in October 2018). Does not give effect to the sale of an aggregate of 25,000 shares pursuant to Rule 10b5-1 trading plans in November 2018. See footnotes (6) and (7) above.

(17) Medtronic plc may be deemed to beneficially own the shares of our common stock held by Medtronic. The mailing address for Medtronic and Medtronic plc is 20 On Hatch, Lower Hatch Street, Dublin 2, Ireland.

THIS IS THE END OF A COMPOSITION COMPONENT TOC_END

Description of Capital Stock

DESCRIPTION OF CAPITAL STOCK

`Capital Structure`

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified in their entirety by reference to the full text of our amended and restated certificate of incorporation and amended and restated bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part. We urge you to read these documents before making any decision to purchase shares of our common stock in this offering.

`General`

Our authorized capital stock consists of 210,000,000 shares, all with a par value of $0.001 per share, of which:

- 200,000,000 shares are designated as common stock; and
- 10,000,000 shares are designated as preferred stock.

`Common Stock`

As of September 30, 2018, we had outstanding 21,391,590 shares of common stock held of record by 50 stockholders. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

As of September 30, 2018, there were no shares of preferred stock outstanding. Under the terms of our amended and restated certificate of incorporation, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock.

Warrants

As of September 30, 2018, we had warrants to purchase an aggregate of 80,884 shares of our common stock outstanding with a weighted average exercise price of $9.61 per share. These warrants may be exercised at any time and from time to time, in whole or in part. In November 2018, we issued 31,270 shares of common stock upon the net exercise of warrants to purchase an aggregate of 39,165 shares of common stock. Unless earlier exercised, warrants to purchase 6,595 shares of our common stock will expire on June 27, 2024, and warrants to purchase 35,124 shares of our common stock will expire on February 7, 2028.

Options

As of September 30, 2018, options to purchase 2,198,130 shares of our common stock were outstanding under our equity incentive plans, of which 1,307,821 options were vested as of that date.

Registration Rights

The Investor Rights Agreement grants the parties thereto certain registration rights in respect of the "registrable securities" held by them, which securities include (1) the shares of our common stock issued upon the conversion of shares of our convertible preferred stock, (2) the shares of our common stock issued to Medtronic pursuant to the Investment Agreement, and (3) any shares of our common stock issued as a dividend or other distribution with respect to the shares described in the foregoing clauses (1) and (2). The registration of shares of our common stock pursuant to the exercise of these registration rights would enable the holders thereof to sell such shares without restriction under the Securities Act when the applicable registration statement is declared effective. Under the Investor Rights Agreement, we will pay all expenses relating to such registrations, including the reasonable fees of one special counsel for the participating holders, and the holders will pay all underwriting discounts and commissions relating to the sale of their shares. The Investor Rights Agreement also includes customary indemnification and procedural terms.

Holders of 7,761,811 shares of our common stock are entitled to such registration rights pursuant to the Investor Rights Agreement. These registration rights will expire on the earlier of (1) the date that is three years after the closing of our IPO or (2) with respect to each stockholder following the closing of our IPO, at such time as such stockholder can sell all of its registrable securities pursuant to Rule 144 of the Securities Act during any three month period.

Demand Registration Rights

The Investor Rights Agreement provides that holders of not less than 30% of the registrable securities then outstanding may, on not more than two occasions, request that we prepare, file and maintain a registration statement on Form S-1 to register at least 20% of their registrable securities, or any lesser percentage of their registrable securities if the aggregate offering price, net of underwriting discounts and commissions, would exceed $10 million. Once we are eligible to use a registration statement on Form S-3, the stockholders party to the Investor Rights Agreement may, on not more than two occasions in any 12-month period, request that we prepare, file and maintain a registration statement on Form S-3 covering the sale of their registrable securities, but only if the anticipated offering price, net of underwriting discounts and commissions, would exceed $1 million.

Piggyback Registration Rights

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the stockholders party to the Investor Rights Agreement will be entitled to certain "piggyback" registration rights allowing them to include their registrable securities in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act other than with respect to a demand registration or a registration statement on Form S-4 or S-8, these holders will be entitled to notice of the registration and will have the right to include their registrable securities in the registration subject to certain limitations.

Anti-Takeover Provisions

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the voting power of our shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation and amended and restated bylaws provide that all stockholder actions must be effected at a duly called meeting of stockholders and not by consent in writing. A special meeting of stockholders may be called only by a majority of our board of directors, the chair of our board of directors, or our chief executive officer.

Our amended and restated certificate of incorporation further provides that the affirmative vote of holders of at least sixty-six and two-thirds percent ($66^2/3\%$) of the voting power of all of the then outstanding shares of voting stock, voting as a single class, is required to amend certain provisions of our certificate of incorporation, including provisions relating to the size of the board, removal of directors, special meetings, actions by written consent and cumulative voting. The affirmative vote of holders of at least sixty-six and two-thirds percent ($66^2/3\%$) of the voting power of all of the then outstanding shares of voting stock, voting as a single class, is required to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors.

Our amended and restated certificate of incorporation further provides that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms, and gives our board of directors 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.

Finally, our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of us; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees or agents to us or our stockholders; (iii) any action asserting a claim against us 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 against us governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action.

The foregoing provisions may make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions may also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change the control of our company.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of our company. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, these provisions may have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in control of our company or our management. As a consequence, these provisions also may inhibit fluctuations in the market price of our common stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon closing of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (1) persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by our board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least $66^{2}/_{3}\%$ of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Limitations on Liability and Indemnification Matters

Our amended and restated bylaws provide that we will indemnify each of our directors and executive officers to the fullest extent permitted by the DGCL. In connection with our IPO, we entered into indemnification agreements with each of our directors and executive officers that may, in some cases, be broader than the specific indemnification provisions contained under Delaware law. Further, we agreed to indemnify each of our directors and executive officers against certain liabilities, costs and expenses, and we have purchased a policy of directors' and officers' liability insurance that insures our directors and executive officers against the cost of defense, settlement or payment of a judgment under certain circumstances. In addition, as permitted by Delaware law, our amended and restated certificate of incorporation includes provisions that eliminate the personal liability of our directors for monetary damages resulting from breaches of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director for breach of fiduciary duties as a director.

These provisions may be held not to be enforceable for violations of the federal securities laws of the United States.

Listing

Our common stock is listed on the NYSE under the symbol "INSP."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

Material U.S. Federal Income Tax Consequences to Non-U.S. Holders

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

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

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

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
-

persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;

- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

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

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

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

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "—Sale or Other Taxable Disposition."

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

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

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

Sale or Other Taxable Disposition

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

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

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

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

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

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

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable

disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

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

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

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States-owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock, and will apply to payments of gross proceeds from the sale or other disposition of such stock on or after January 1, 2019.

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

THIS IS THE END OF A COMPOSITION COMPONENT TOC_END

Underwriting

UNDERWRITING

Merrill Lynch, Pierce, Fenner & Smith Incorporated, Leerink Partners LLC and Wells Fargo Securities, LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us, the selling stockholders and the underwriters, we and the selling stockholders have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us and the selling stockholders, the number of shares of common stock set forth opposite its name below.

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Underwriter	Number of Shares
Merrill Lynch, Pierce, Fenner & Smith Incorporated	
Leerink Partners LLC	
Wells Fargo Securities, LLC	

Guggenheim Securities, LLC	
Stifel, Nicolaus & Company, Incorporated	
Total	2,500,000

end of user-specified TAGGED TABLE

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We and the selling stockholders have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us and the selling stockholders that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount and proceeds before expenses to us and the selling stockholders. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

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	Per Share	Without Option	With Option
Public offering price		$ $	$
Underwriting discount		$ $	$
Proceeds, before expenses, to us		$ $	$
Proceeds, before expenses, to the selling stockholders		$ $	$

end of user-specified TAGGED TABLE

The expenses of the offering, not including the underwriting discount, are estimated at $700,000 and are payable by us. We have also agreed to reimburse the underwriters for their expenses relating to clearance of this offering with the Financial Industry Regulatory Authority in an amount up to $30,000.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 375,000 additional shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, the selling stockholders, our executive officers, directors and certain of our affiliates have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 90 days after the date of this prospectus without first obtaining the written consent of Merrill Lynch, Pierce, Fenner & Smith Incorporated. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant to purchase any common stock,
- otherwise dispose of or transfer any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock, or
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

Merrill Lynch, Pierce, Fenner & Smith Incorporated, in its sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice. In addition, in the event that any stockholder is granted an early release from the lock-up restrictions with respect to our securities in an aggregate amount in excess of 1% of our issued and outstanding shares (whether in one or multiple releases), then, subject to certain other conditions, each stockholder holding in excess of 5% of our outstanding shares, to the extent it has entered into a lock-up agreement, automatically will be granted an equivalent early release from its obligations under the lock-up agreement on a pro-rata basis. Such release shall not be applicable in the event of an underwritten primary or secondary public offering or sale of our common stock during the period ending 90 days after the date of this prospectus.

New York Stock Exchange Listing

The shares are listed on the New York Stock Exchange under the symbol "INSP."

Price Stabilization, Short Positions

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in

excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the New York Stock Exchange, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area

In relation to each member state of the European Economic Area, no offer of shares which are the subject of the offering has been, or will be made to the public in that Member State, other than under the following exemptions under the Prospectus Directive:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of shares referred to in (a) to (c) above shall result in a requirement for the Company or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Directive, or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person located in a Member State to whom any offer of shares is made or who receives any communication in respect of an offer of shares, or who initially acquires any shares will be deemed to have represented, warranted, acknowledged and agreed to and with each representative and the Company that (1) it is a "qualified investor" within the meaning of the law in that Member State implementing Article 2(1)(e) of the Prospectus Directive; and (2) in the case of any shares acquired by it as a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, the shares acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in circumstances in which the prior consent of the representatives has been given to the offer or resale; or where shares have been acquired by it on behalf of persons in any Member State other than qualified investors, the offer of those shares to it is not treated under the Prospectus Directive as having been made to such persons.

The Company, the representatives and their respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgments and agreements.

This prospectus has been prepared on the basis that any offer of shares in any Member State will be made pursuant to an exemption under the Prospectus Directive from the requirement to publish a prospectus for offers of shares. Accordingly any person making or intending to make an offer in that Member State of shares which are the subject of the offering contemplated in this prospectus may only do so in circumstances in which no obligation arises for the Company or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Directive in relation to such offer. Neither the Company nor the representatives have authorized, nor do they authorize, the making of any offer of shares in circumstances in which an obligation arises for the Company or the representatives to publish a prospectus for such offer.

For the purposes of this provision, the expression an "offer of shares to the public" in relation to any shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (as amended) and includes any relevant implementing measure in each Member State.

The above selling restriction is in addition to any other selling restrictions set out below.

Notice to Prospective Investors in the United Kingdom

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the Prospectus Directive) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

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

Notice to Prospective Investors in the Dubai International Financial Centre

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

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or Exempt Investors, who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

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

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

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

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

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

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

(a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

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

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

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

(e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Notice to Prospective Investors in Canada

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

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

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Legal Matters

LEGAL MATTERS

The validity of the shares of our common stock offered hereby will be passed upon for us by Latham & Watkins LLP. Certain legal matters will be passed upon for the underwriters by Shearman & Sterling LLP, New York, New York.

Experts

EXPERTS

Our financial statements as of December 31, 2016 and 2017, and for the years ended December 31, 2015, 2016 and 2017, appearing in this prospectus and the registration statement of which it forms a part have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance on such report given on the authority of such firm as experts in accounting and auditing.

Where You Can Find More Information

WHERE YOU CAN FIND MORE INFORMATION

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

We are subject to the informational requirements of the Exchange Act, and, in accordance with the Exchange Act, are required to file annual, quarterly and current reports, proxy and information statements and other information with the SEC. Such annual, quarterly and current reports, proxy and information statements and other information can be inspected and copied at the locations set forth above. Such information is also available on the investor relations section of our website, which is located at *www.inspiresleep.com*. Information on, or accessible through, our website is not part of this prospectus.

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Inspire Medical Systems, Inc. Index to Financial Statements

INSPIRE MEDICAL SYSTEMS, INC.
INDEX TO FINANCIAL STATEMENTS

As of December 31, 2016 and 2017 and for the Years Ended December 31, 2015, 2016 and 2017

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As of September 30, 2018 and December 31, 2017 and
for the Nine Months Ended September 30, 2017 and 2018 (Unaudited)

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Report of Independent Registered Public Accounting Firm

Report of Independent Registered Public Accounting Firm To the Stockholders and the Board of Directors
Inspire Medical Systems, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Inspire Medical Systems, Inc. (the Company) as of December 31, 2016 and 2017, the related statements of operations and comprehensive loss, stockholders' (deficit) equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2016 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting

principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP We have served as the Company's auditor since 2015.
Minneapolis, Minnesota February 14, 2018, except for the effect of the reverse stock split discussed in the third paragraph of Note 13 to the financial statements, as to which the date is April 23, 2018

Balance Sheets

INSPIRE MEDICAL SYSTEMS, INC.

THIS IS THE END OF A COMPOSITION COMPONENT

Balance Sheets

(in thousands, except share amounts)

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	December 31	
	2016	**2017**
Assets		
Current assets:		
Cash and cash equivalents	$6,685	$8,955
Short-term investments	—	7,188
Accounts receivable, net of allowances of $44 and $47, respectively	2,091	3,858
Inventories	3,355	3,670
Prepaid expenses and other assets	118	426
Total current assets	12,249	24,097
Property and equipment, cost	1,548	1,804
Less: accumulated depreciation	(681)	(810)
Property and equipment, net	867	994
Total assets	$13,116	$25,091
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$1,173	$2,998
Accrued expenses	2,704	4,032
Accrued interest	103	117
Current portion of notes payable	3,310	—

Total current liabilities	7,290	7,147
Notes payable	12,381	16,460
Preferred stock warrants	53	157
Total long-term liabilities	12,434	16,617
Stockholders' (deficit) equity		
Preferred Stock, $0.001 par value per share, 58,354,472 and 76,894,620 shares authorized at December 31, 2016 and 2017, respectively and 57,986,873 and 76,235,050 shares issued and outstanding at December 31, 2016 and 2017, respectively	94,138	119,106
Common Stock, $0.001 par value per share; 85,000,000 and 110,000,000 shares authorized at December 31, 2016 and 2017, respectively; 1,145,238 and 1,272,360 issued and outstanding at December 31, 2016 and 2017, respectively	1	1
Additional paid in capital	6,827	7,305
Accumulated other comprehensive loss	—	—
Accumulated deficit	(107,574)	(125,085)
Total stockholders' (deficit) equity	(6,608)	1,327
Total liabilities and stockholders' (deficit) equity	$13,116	$25,091

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

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Statements of Operations and Comprehensive Loss

INSPIRE MEDICAL SYSTEMS, INC.

Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

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	Year Ended December 31		
	2015	**2016**	**2017**
Revenue	$8,012	$16,427	$28,567
Cost of goods sold	2,809	3,905	6,018
Gross profit	5,203	12,522	22,549
Operating expenses:			
Selling and marketing	15,291	20,019	28,552
Research and development	7,079	7,091	6,194

General and administrative	2,631	2,665	3,806
Total operating expenses	25,001	29,775	38,552
Operating loss	(19,798)	(17,253)	(16,003)
Other expense (income):			
Interest income	(66)	(57)	(203)
Interest expense	1,564	1,303	1,753
Other expense (income), net	41	29	(42)
Loss before income taxes	(21,337)	(18,528)	(17,511)
Income taxes	—	—	—
Net loss	(21,337)	(18,528)	(17,511)
Other comprehensive loss:			
Unrealized gains on short-term investments	14	—	—
Total comprehensive loss	$(21,323)	$(18,528)	$(17,511)
Net loss per share, basic and diluted	$(20.74)	$(16.90)	$(14.88)
Weighted average common shares used to compute net loss per share, basic and diluted	1,027,925	1,096,013	1,176,650

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

THIS IS THE END OF A COMPOSITION COMPONENT

Statements of Stockholders' (Deficit) Equity

INSPIRE MEDICAL SYSTEMS, INC.

Statements of Stockholders' (Deficit) Equity

(in thousands, except share amounts)
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	Common Stock		Additional paid-in capital	Convertible Preferred Stock		Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount		Shares	Amount			

Balance at December 31, 2014	1,014,614	$1	$6,043	48,603,909	$81,513	$(14)	$(67,709)	$19,834
Stock options exercised	21,545	—	42	—	—	—	—	42
Stock-based compensation expense	—	—	305	—	—	—	—	305
Unrealized gains on investments	—	—	—	—	—	14	—	14
Net loss	—	—	—	—	—	—	(21,337)	(21,337)
Balance at December 31, 2015	1,036,159	1	6,390	48,603,909	81,513	—	(89,046)	$(1,142)
Stock options exercised	109,079	—	189	—	—	—	—	189
Exercise of Series C preferred stock warrants	—	—	—	258,880	277	—	—	277
Sale of Series F convertible preferred stock, net issuance costs of $152	—	—	—	9,124,084	12,348	—	—	12,348
Stock-based compensation expense	—	—	248	—	—	—	—	248
Net loss	—	—	—	—	—	—	(18,528)	(18,528)
Balance at December 31, 2016	1,145,238	1	6,827	57,986,873	94,138	—	(107,574)	$(6,608)
Stock options exercised	127,122	—	235	—	—	—	—	235
Sale of Series F convertible preferred stock, net issuance costs of $32	—	—	—	18,248,177	24,968	—	—	24,968
Stock-based compensation expense	—	—	243	—	—	—	—	243
Net loss	—	—	—	—	—	—	(17,511)	(17,511)
Balance at December 31, 2017	1,272,360	$1	$7,305	76,235,050	$119,106	$—	$(125,085)	$1,327

end of user-specified TAGGED TABLE
The accompanying notes are an integral part of these financial statements.

THIS IS THE END OF A COMPOSITION COMPONENT

Statements of Cash Flows

INSPIRE MEDICAL SYSTEMS, INC.

Statements of Cash Flows

(in thousands)

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	Year Ended December 31		
	2015	**2016**	**2017**
Operating activities			
Net loss	$(21,337)	$(18,528)	$(17,511)
Adjustments to reconcile net loss:			
Depreciation and amortization	120	103	285
Accretion of debt discount	50	180	315
Stock-based compensation expense	305	248	243
Change in the fair value of preferred stock warrants	12	(195)	100
Changes in operating assets and liabilities:			
Accounts receivable	(261)	(760)	(1,767)
Inventories	(1,514)	612	(315)
Prepaid expenses and other assets	(118)	88	(308)
Accounts payable	418	(480)	1,825
Accrued expenses	71	783	1,342
Net cash used in operating activities	(22,254)	(17,949)	(15,791)
Investing activities			
Purchases of property and equipment	(346)	(306)	(412)
Purchases of short-term investments	—	—	(8,969)
Proceeds from sales or maturities of short-term investments	23,910	—	1,781
Net cash provided by (used in) investing activities	23,564	(306)	(7,600)
Financing activities			
Payments of notes payable	(7,000)	—	—

Proceeds from issuance of notes payable	9,500	—	458
Proceeds from the exercise of stock options	42	189	235
Proceeds from the exercise of preferred stock warrants	—	277	—
Proceeds from sale of preferred stock	—	12,348	24,968
Net cash provided by financing activities	2,542	12,814	25,661
Increase (decrease) in cash and cash equivalents	3,852	(5,441)	2,270
Cash and cash equivalents at beginning of year	8,274	12,126	6,685
Cash and cash equivalents at end of year	$12,126	$6,685	$8,955
Supplemental cash flow information			
Debt issuance costs	$72	$—	$—
Cash paid for interest	1,192	1,232	1,323
Issuance of preferred stock warrants	33	—	4

end of user-specified TAGGED TABLE
The accompanying notes are an integral part of these financial statements.

THIS IS THE END OF A COMPOSITION COMPONENT

Notes to Financial Statements

INSPIRE MEDICAL SYSTEMS, INC.

Notes to Financial Statements

(in thousands, except share and per share amounts)

1. Organization

Description of Business

Inspire Medical Systems, Inc. (the Company) is a medical technology company focused on the development and commercialization of innovative and minimally invasive solutions for patients with obstructive sleep apnea. The Company's proprietary Inspire system is the first and only FDA-approved neurostimulation technology that provides a safe and effective treatment for moderate to severe obstructive sleep apnea. The Company has 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 received premarket approval, or PMA, from the U.S. Food and Drug Administration, or FDA, in April 2014 and has been commercially available in certain European markets since November 2011.

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP).

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 financial statements. Management uses significant judgment when making estimates related to its allowance for doubtful accounts, inventory reserves and the valuations of its common stock, share-based awards, and certain of its outstanding preferred stock warrants. Management bases its 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.

JOBS Act Accounting Election

As an emerging growth company under the Jumpstart Our Business Startups Act, the Company is eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. The Company has elected to take advantage of the extended transition period for adopting new or revised accounting standards that have different effective dates for public and private companies until such time as those standards apply to private companies.

Cash and Cash Equivalents

The Company considers all highly liquid securities, readily convertible to cash, that mature within 90 days or less from the date of purchase to be cash equivalents. The carrying amount reported in the balance sheets for cash is cost, which approximates fair value.

Short-term Investments

The Company had no short-term investments at December 31, 2016. At December 31, 2017, the Company's short-term investments consisted of commercial paper and corporate bonds which are classified as available-for-sale and had maturities less than one year. Short-term investments are reported at their estimated fair market value which approximates cost at December 31, 2017. Any with unrealized gains and losses are reported in accumulated other comprehensive loss.

Fair Value of Financial Instruments

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents and certain of its outstanding preferred stock warrants. 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—Other inputs that are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuation techniques for which all significant inputs are observable in the market or can be derived from observable market data. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs, including interest rate curves, foreign exchange rates, and credit ratings.

Level 3—Unobservable inputs that are supported by little or no market activities, which would require the Company to develop its own assumptions.

The Company uses the methods and assumptions described below in determining the fair value of its financial instruments.

Money market funds: Fair values of money market funds are based on quoted market prices in active markets.

Commercial paper: Short-term, highly liquid investments are included as a Level 2 measurement in the tables below.

Corporate bonds: Consists of U.S. Government treasury bills, notes, and bonds with original maturities of less than one year and various yields. These are included as a Level 2 measurement in the tables below.

The following tables sets forth by level within the fair value hierarchy the Company's assets and liabilities that are reported at fair value as of December 31, 2016 and 2017. As required by Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 820, *Fair Value Measurement*, assets and liabilities are classified in their entirety based on the lowest level of input that

is significant to the fair value measurement. The following tables summarize certain information for assets and liabilities measured at fair value on a recurring basis:

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		Fair Value Measurements as of December 31, 2016		
	Estimated Fair Value	Level 1	Level 2	Level 3
Assets				
Money market funds	$5,084	$5,084	$—	$—
Liabilities				
Preferred stock warrants	$53	$—	$—	$53

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		Fair Value Measurements as of December 31, 2017		
	Estimated Fair Value	Level 1	Level 2	Level 3
Assets				
Cash equivalents:				
Money market funds	$6,446	$6,446	$—	$—
Commercial paper	1,099	—	1,099	—
Total cash equivalents	7,545	6,446	1,099	—
Short-term investments:				

Commercial paper	$5,384	$—	$5,384	—
Corporate bonds	1,804	—	1,804	—
Total short-term investments	7,188	—	7,188	—
Total assets	$14,733	$6,446	$8,287	$—
Liabilities				
Preferred stock warrants	$157	$—	$—	$157

end of user-specified TAGGED TABLE

There were no transfers in and out of Level 1 and Level 2 fair value measurements during the years ended December 31, 2016 and 2017.

The recurring Level 3 fair value measurements of the Company's preferred stock warrant liabilities use the Black-Scholes option pricing model and value of the respective class of the Company's convertible preferred stock (see Note 7), which is unobservable. All other assumptions included in the model are observable Level 1 inputs.

2. Summary of Significant Accounting Policies (Continued)

The following table provides a reconciliation of the beginning and ending balances of the Company's preferred stock warrant liabilities:

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Balance as of December 31, 2014	$203
Initial fair value of preferred stock warrants issued	33
Change in fair value of preferred stock warrants	12
Balance as of December 31, 2015	248
Change in fair value of preferred stock warrants	(195)
Balance as of December 31, 2016	53
Initial fair value of preferred stock warrants issued	4
Change in fair value of preferred stock warrants	100
Balance as of December 31, 2017	$157

end of user-specified TAGGED TABLE
Changes in the fair value of the preferred stock warrant liability are recorded in other expenses on the statements of operations and comprehensive loss.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash equivalents and accounts receivable. The Company believes that the credit risk in its accounts receivable is mitigated by its credit evaluation process, relatively short collection terms, and dispersion of its customer base. The Company generally does not require collateral, and losses on accounts receivable have historically been within management's expectations.

The Company's 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. The Company places restrictions on maturities and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the issuers of these securities to the extent recorded on the balance sheets. However, as of December 31, 2016 and 2017, the Company has limited its credit risk associated with its cash equivalents by placing its investments with banks it believes are highly creditworthy.

Allowance for Doubtful Accounts

The Company records an allowance for doubtful accounts for accounts receivable deemed uncollectible. The Company evaluates the collectability of its accounts receivable based on known collection risks and historical experience. In circumstances where the Company is aware of a specific customer's inability to meet its financial obligations to the Company (e.g., bankruptcy filings, substantial downgrading of credit ratings), the Company records a specific allowance for bad debts against amounts due to reduce the carrying amount of accounts receivable to the amount it reasonably believes will be collected.

2. Summary of Significant Accounting Policies (Continued)

Inventories

Inventories are valued at the lower of cost or net realizable value, computed on a first-in, first out basis. The Company regularly reviews inventory quantities on-hand for excess and obsolete inventory and, when circumstances indicate, incurs charges to write down inventories to their net realizable value. The Company's review of inventory for excess and obsolete quantities is based primarily on the estimated forecast of future product demand, product life cycles, including expiration of inventory prior to sale, and introduction of new products. The reserve for excess and obsolete inventory was $191 and $518 as of December 31, 2016 and 2017, respectively.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is determined using the straight-line method over the estimated useful lives of the respective assets, generally three to seven years. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the term of the lease.

Impairment of Long-lived Assets

Long-lived assets consist primarily of property and equipment and 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, the Company compares 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, the Company determines the fair value of the asset and recognizes an impairment loss to the extent the carrying amount of the asset

exceeds its fair value. The Company determines fair value using the income approach based on the present value of expected future cash flows or other appropriate measures of estimated fair value. The Company's cash flow assumptions consider historical and forecasted revenue and operating costs and other relevant factors. The Company did not record any impairment charges on long-lived assets during the years ended December 31, 2015, 2016 and 2017.

Revenue Recognition

The Company recognizes revenue when persuasive evidence of an arrangement exists, product shipment has occurred, or there are no further obligations yet to be performed, pricing is fixed or determinable, and collection is reasonably assured. The Company makes reasonable assumptions regarding the future collectability of amounts receivable from customers to determine whether the revenue recognition criteria have been met. Taxes assessed by a governmental authority that are directly imposed on revenue-producing transactions between a seller and a customer are not recorded as revenue. In general, the Company's standard terms and conditions of sale do not allow for product returns. Sales returns have been limited to damaged product and have not been material. The Company expenses shipping and handling costs as incurred and includes them in the cost of goods sold. In those cases where shipping and handling costs are billed to customers, the Company classifies the amounts billed as a component of cost of goods sold.

2. Summary of Significant Accounting Policies (Continued)

Cost of Goods Sold

Cost of goods sold consists primarily of manufacturing overhead costs, material costs, and direct labor. Overhead costs include the cost of material procurement, inventory control, facilities, equipment, and operations supervision and management. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as shipping costs.

Research and Development

Research and development expenses consist primarily of product development, clinical and regulatory affairs, consulting services, and other costs associated with products and technologies in development. These expenses include employee compensation, stock-based compensation, supplies, travel, and facility costs. Clinical expenses include clinical trial design, clinical site reimbursement, data management, travel expenses, and the cost of manufacturing products for clinical trials.

Common Stock Valuation and Stock-Based Compensation

The Company maintains an equity incentive plan to provide long-term incentives for employees, consultants, and members of the board of directors. The plan allows for the issuance of non-statutory and incentive stock options to employees and non-statutory stock options to consultants and non-employee directors.

The Company recognizes equity-based compensation expense for awards of equity instruments to employees and non-employees based on the grant date fair value of those awards in accordance with FASB ASC Topic 718, *Stock Compensation* (ASC 718). ASC 718 requires all equity-based compensation awards to employees and nonemployee directors, including grants of restricted shares and stock options, to be recognized as expense in the statements of operations and comprehensive loss based on their grant date fair values. The Company estimates the fair value of stock options using the Black-Scholes option pricing model. The Company uses the value of its common stock to determine the fair value of restricted shares.

The Company accounts for restricted stock and common stock options issued to nonemployees under FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees* (ASC 505-50). As such, the value of such options is periodically remeasured and income or expense is recognized over their vesting terms. Compensation cost related to awards with service-based vesting schedules is recognized using the straight-line method. The Company determines the fair value of the restricted stock and common stock granted to nonemployees as either the fair value of the consideration received or the fair value of the equity instruments issued. The Company has not granted any share-based awards to its consultants.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (i) the expected share price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) the expected dividend yield. Due to the lack of a public market for the trading of the Company's common stock and a lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The group of representative companies have characteristics similar to the Company, including stage of product development and focus on the life

science industry. The Company uses the simplified method, which is the average of the final vesting tranche date and the contractual term, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to non-employees, the Company utilizes the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The Company uses an assumed dividend yield of zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

The Company expenses the fair value of its equity-based compensation awards granted to employees on a straight-line basis over the associated service period, which is generally the period in which the related services are received. The Company measures equity-based compensation awards granted to nonemployees at fair value as the awards vest and recognizes the resulting value as compensation expense at each financial reporting period. The Company accounts for award forfeitures as they occur.

Advertising Expenses

The Company expenses the costs of advertising, including promotional expenses, as incurred. Advertising expenses were $2.2 million, $3.4 million and $5.5 million during the years ended December 31, 2015, 2016, and 2017, respectively.

Income Taxes

The Company accounts 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 the Company has historically incurred operating losses, the Company has recorded a full valuation allowance against its net deferred tax assets, and there is no provision for income taxes. The Company's policy is to record interest and penalties expense related to uncertain tax positions as other expense in the statements of operations and comprehensive loss.

Comprehensive Loss

Comprehensive loss consists of net loss and changes in unrealized gains and losses on short-term investments classified as available-for-sale, if any. Accumulated other comprehensive loss is presented in the accompanying balance sheets as a component of stockholders' (deficit) 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 the Company has reported a net loss

for all periods presented, diluted net loss per share is the same as basic net loss per share for those periods as all potentially dilutive shares consisting of convertible preferred stock, stock options and warrants were antidilutive in those periods.

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09, *Revenue From Contracts With Customers* (ASU 2014-09), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In doing so, companies will need to use more judgment and make more estimates than under current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, and allocating the transaction price to each separate performance obligation. Under the original pronouncement, ASU 2014-09 would have been effective for the Company's annual reporting periods beginning January 1, 2018. In August 2015, the FASB issued ASU No. 2015-14, which formally defers the effective date of the new revenue standard by one year. As a result, the updated revenue guidance will be effective for the Company's annual reporting periods beginning January 1, 2019, and early adoption is permitted as of the original effective date contained within the original standard. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its financial statements and related disclosures.

In July 2015, the FASB issued ASU 2015-11 *Simplifying the Measurement of Inventory*, which is intended to narrow down the alternative methods available for valuing inventory. The new guidance does not apply to inventory currently measured using the last-in-first-out or the retail inventory valuation methods. Under the new guidance, inventory valued using other methods, including the first-in-first-out method, must be valued at the lower of cost or net realizable value. This guidance is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. This guidance was effective January 1, 2017 and did not have a material impact on the Company's financial position, results of operations and cash flows.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* (ASU 2015-17). ASU 2015-17 is intended to reduce complexity surrounding the presentation of deferred taxes within the balance sheet. Specifically, ASU 2015-17 requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as non-current on the balance sheet, effectively eliminating the requirement to allocate deferred taxes between current and non-current amounts. The new guidance does not permit companies to offset deferred tax liabilities from one jurisdiction against deferred tax assets of another jurisdiction. ASU 2015-17 will be effective for the Company's annual reporting periods beginning January 1, 2018, and can be applied on either a prospective or retrospective basis; early adoption is also permitted. The Company does not expect the ASU 2015-17 to significantly impact its financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02). ASU 2016-02 will require entities that lease assets to recognize the rights and obligations associated with those leases on their balance sheets. The guidance will be effective for the Company's annual reporting period

beginning January 1, 2020, with early adoption permitted. The Company is evaluating the impact this standard will have on its financial statements and related disclosures.

In March 2016, the FASB issued No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* (ASU 2016-09), which changes how companies will account for certain aspects of share-based payments to employees. As part of the new guidance, entities will be required to record the impact of income taxes arising from share-based compensation when awards vest or are

settled within earnings as part of income tax expense rather than recorded as part of additional paid-in capital (APIC) and will eliminate the requirement that excess tax benefits be realized prior to recognition. Additionally, the guidance requires entities to present excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. Additionally, companies will be required to make an accounting policy election at the time of adoption of the new guidance to either account for forfeitures of share-based awards in a manner similar to today's requirements (i.e., estimating the number of awards expected to be forfeited at the grant date and adjusting the estimate when awards are actually forfeited), or recognizing forfeitures as they occur with no estimate of forfeitures determined at the grant date. Companies will also be able to set a maximum statutory tax rate as it pertains to share-based awards it net settles on behalf of its employees. This will provide companies a greater ability to retain equity-award accounting treatment. Entities will apply the provisions of ASU 2016-09 using a modified retrospective transition approach, with a cumulative-effect adjustment booked to retained earnings as of the beginning of the period of adoption. The guidance will be effective for the Company's annual reporting periods beginning January 1, 2018, with early adoption permitted. The Company is evaluating the impact this standard will have on its financial statements and related disclosures.

The Company has reviewed and considered all other recent accounting pronouncements and believes there are none that could potentially have a material impact on its business practices, financial condition, results of operations, or disclosures.

3. Composition of Certain Financial Statement Items

Inventories

Inventory balances, net of reserves, consist of the following:

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	December 31	
	2016	**2017**
Raw materials	$738	$1,323
Finished goods	2,617	2,347
	$3,355	$3,670

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3. Composition of Certain Financial Statement Items (Continued)

Property and Equipment

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	December 31	
	2016	**2017**
Computer equipment and software	$75	$351
Furniture and office equipment	84	137
Manufacturing equipment	1,329	1,108
Research and development equipment	34	30
Leasehold improvements	26	178

	1,548	1,804
Less: accumulated depreciation and amortization	(681)	(810)
	$867	$994

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Depreciation and amortization expense was $120, $103 and $285 during the years ended December 31, 2015, 2016 and 2017, respectively.

Accrued Expenses

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	December 31	
	2016	**2017**
Payroll and commissions payable	$1,861	$2,871
Vacation	564	723
Other accrued expenses	279	438
	$2,704	$4,032

end of user-specified TAGGED TABLE

4. Long-Term Debt

Credit Facility

In August 2015, the Company entered into a loan and security agreement, which provided for a term A loan facility in the amount of $15.5 million, the proceeds of which were used to refinance the $12.0 million of borrowings outstanding under the Company's original credit facility, and a term B loan facility in an amount between $3.5 million and $10.0 million, subject to the Company's achievement of certain revenue milestones. Amounts outstanding under the credit facility bore interest at a fixed rate of 7.95% per annum. The Company had $15.5 million outstanding under the credit facility as of December 31, 2015.

In February 2017, the Company amended the loan and security agreement. Under the loan and security agreement, as amended, and subject to the limitation noted below, amounts outstanding under the credit facility bear interest at a floating interest rate equal to the greater of 7.95% or LIBOR plus 6.9% per annum. Upon execution of the amendment, the Company borrowed an additional $1.0 million under the term A loan portion of the credit facility, receiving net proceeds of $0.5 million, net of expenses, for a total of $16.5 million outstanding under the credit facility and reduced borrowings available under the term B loan facility to $9.0 million. All amounts borrowed under the credit facility

4. Long-Term Debt (Continued)

are interest-only through March 1, 2019, after which the Company will make monthly payments of principal and interest through February 2022; provided that the interest-only period will be extended to March 1, 2020 if the Company has revenue, measured on a trailing 12-month basis as of December 31, 2018, of at least $25.0 million. In connection with the execution of the

amendment to the loan and security agreement, the Company issued 29,197 ten-year warrants to purchase Series F preferred shares of stock at an exercise price of $1.37 per share.

In addition to the principal and interest payments, under the credit facility, the Company is required to pay a final payment fee of 5.0% on all amounts outstanding, which is being accreted using the effective interest rate method over the term of the loan and security agreement and shall be due at the earlier of maturity or prepayment. If the Company repays all the amounts borrowed under the term A loan facility on or prior to maturity, the Company will also be required to pay a prepayment fee equal to 2.5% if such borrowings are prepaid prior to February 24, 2018, 1.5% if such borrowings are prepaid on or after February 24, 2018 but prior to February 24, 2019, and 1.00% if such borrowings are prepaid on or after February 24, 2019. Borrowings under the term B loan facility are prepayable at the Company's option in whole, but not in part, together with all accrued and unpaid interest thereon and, if not previously made, the Final Payment, subject to a prepayment fee of 2.5% if the such borrowings are prepaid prior to February 7, 2019, 1.5% if such borrowings are prepaid on or after February 7, 2019 but prior to February 7, 2020 and 1.00% if such borrowings are on or after February 7, 2020.

The credit facility includes affirmative and restrictive covenants and events of default, including the following events of default: payment defaults, breaches of covenants, judgment defaults, cross defaults to certain other contracts, certain events with respect to governmental approvals if such events could cause a material adverse change, a material impairment in the perfection or priority of the lender's security interest or in the value of the collateral, a material adverse change in the business, operations, or condition of the Company or any of its subsidiaries, and a material impairment of the prospect of repayment of the loans. Upon the occurrence of an event of default, a default increase in the interest rate of an additional 5.00% could be applied to the outstanding loan balance and the lender could declare all outstanding obligations immediately due and payable and take such other actions as set forth in the loan and security agreement.

The Company's obligations under the credit facility are secured by a first priority security interest in substantially all of its assets, other than its intellectual property. There are no financial covenants contained in the loan and security agreement. The Company was in compliance with the affirmative and restrictive covenants as of December 31, 2016 and 2017.

The Company paid debt issuance costs of $72 in connection with its entry into the loan and security agreement in August 2015. The costs are being amortized over the term of the loan using the effective interest rate method. The Company also issued preferred stock warrants in connection with its borrowings under its credit facilities (see Note 7).

4. Long-Term Debt (Continued)

Expected future principal payments for the credit facility are as follows:

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Year ending December 31:	
2018	$—
2019	4,583
2020	5,500
2021	5,500
2022	917
	$16,500

end of user-specified TAGGED TABLE

5. Commitments

Operating Lease

The Company rents office space under an operating lease that expires on March 31, 2019. The lease allows the Company to terminate the lease any time after March 31, 2017 without a penalty.

Future minimum annual operating lease payments are as follows:

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Years ending December 31:	
2018	$190
2019	48
Total	$238

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Rent expense was $123, $127 and $184 during the years ended December 31, 2015, 2016 and 2017, respectively.

Purchase Commitments

As of December 31, 2016, and 2017, the Company had commitments to suppliers for inventory purchases totaling $6.1 million and $9.0 million, respectively, of which $0.6 million and $0.4 million, respectively, was committed to Medtronic, a related party.

6. Employee Retirement Plan

The Company sponsors an employee retirement plan covering all full-time employees of the Company. The plan allows for eligible employees to defer a portion of their eligible compensation up to the maximum allowed by IRS Regulations. The Company may elect to make a voluntary contribution to the plan. The Company did not make contributions for the years ended December 31, 2015, 2016 and 2017.

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7. Stockholders' (Deficit) Equity

Authorized Shares

The Company has authorized 186,894,620 shares of stock, of which 110,000,000 shares are designated as common stock and 76,894,620 shares are designated as Series A, B, C, D, E, and F preferred stock. All stock has a par value of $0.001.

Preferred Stock

A summary of the Company's preferred stock as of December 31, 2016 and 2017, is as follows:

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	2016

Series	Shares Authorized	Shares Issued and Outstanding	Carrying Value
A	5,375,507	5,375,507	$5,037
B	8,706,909	8,706,909	15,913
	14,091,589	13,829,906	14,949
D	5,683,292	5,683,292	6,043
E	15,373,091	15,267,175	39,848
F	9,124,084	9,124,084	12,348
	58,354,472	57,986,873	$94,138

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	2017		
Series	Shares Authorized	Shares Issued and Outstanding	Carrying Value
A	5,375,507	5,375,507	$5,037
B	8,706,909	8,706,909	15,913
	14,091,589	13,829,906	14,949
D	5,683,292	5,683,292	6,043
E	15,373,091	15,267,175	39,848
F	27,664,232	27,372,261	37,316
	76,894,620	76,235,050	$119,106

end of user-specified TAGGED TABLE

A summary of the Company's convertible preferred stock terms is as follows:

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Series	Liquidation Preference Per Share	8% Dividend Per Share	Conversion Price Per Share
A	$1.00	$0.08	$6.65
B	1.84	0.15	9.91
	1.07	0.09	7.12
D	1.07	0.09	7.12
E	2.62	0.21	15.16
F	1.37	0.11	9.11

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7. Stockholders' (Deficit) Equity (Continued)

The dividend per share on the convertible preferred stock is only payable when, as and if declared by the Board of Directors.

The Company has issued 5,375,507 shares of Preferred Stock, Series A, with an original issue price of $1.00 per share. Each share of Series A Preferred Stock may be converted into 0.1504 shares of common stock. The conversion price is subject to change for certain subdivisions, combinations of common stock, or other dilutive issuances of common stock. Each share of Series A Preferred Stock entitles the holder to vote on all matters submitted to holders of common stock, and each share of Series A Preferred Stock has the number of votes equal to the number of shares of common stock into which it may be converted.

The Company has issued 8,706,909 shares of Preferred Stock, Series B, with an original issue price of $1.84 per share. Each share of Series B Preferred Stock may be converted into 0.1855 shares of common stock. The conversion price is subject to change for certain subdivisions, combinations of common stock, or other dilutive issuances of common stock. Ownership of Series B Preferred Stock entitles the holder to vote on all matters submitted to holders of common stock. Each share of Series B Preferred Stock has the number of votes equal to the number of shares of common stock into which it may be converted.

The Company has issued 13,829,906 shares of Preferred Stock, Series C, with an original issue price of $1.07 per share. Each share of Series C Preferred Stock may be converted into 0.1504 shares of common stock. The conversion price is subject to change for certain subdivisions, combinations of common stock, or other dilutive issuances of common stock. Each share of Series C Preferred Stock entitles the holder to vote on all matters submitted to holders of common stock, and each share of Series C Preferred Stock has the number of votes equal to the number of shares of common stock into which it may be converted.

The Company has issued 5,683,292 shares of Preferred Stock, Series D, with an original issue price of $1.07 per share. Each share of Series D Preferred Stock may be converted into 0.1504 shares of common stock. The conversion price is subject to change for certain subdivisions, combinations of common stock, or other dilutive issuances of common stock. Each share of Series D Preferred Stock entitles the holder to vote on all matters submitted to holders of common stock, and each share of Series D Preferred Stock has the number of votes equal to the number of shares of common stock into which it may be converted.

In March 2014, the Company raised $39.8 million, net of stock issuance costs, through the issuance of 15,267,175 shares of Series E Preferred Stock, with an original issue price of $2.62 per share. Each share of Series E Preferred Stock may be converted into 0.1728 shares of common stock. The conversion price is subject to change for certain subdivisions, combinations of common stock, or other dilutive issuances of common stock. Each share of Series E Preferred Stock entitles the holder to vote on all matters submitted to holders of common stock, and each share of Series E Preferred Stock has the number of votes equal to the number of shares of common stock into which it may be converted.

In October 2016, the Company raised $12.3 million, net of stock issuance costs, through the issuance of 9,124,084 shares of Series F Preferred Stock, with an original issue price of $1.37 per share (Tranche 1). In February 2017, the Company raised $25.0 million, net of stock issuance costs, through

NOTES TO FINANCIAL STATEMENTS (Continued)

(in thousands, except share and per share amounts)

7. Stockholders' (Deficit) Equity (Continued)

the issuance of 18,248,177 shares of Series F Preferred Stock, with an original issue price of $1.37 per share (Tranche 2). Each share of Series F Preferred Stock may be converted into 0.1504 shares of common stock. The conversion price is subject to change for certain subdivisions, combinations of common stock, or other dilutive issuances of common stock. Each share of Series F Preferred Stock entitles the holder to vote on all matters submitted to holders of common stock, and each share of Series F Preferred Stock has the number of votes equal to the number of shares of common stock into which it may be converted.

Upon a liquidation, dissolution, or winding up of the Company, the holders of the Series F Preferred Stock shall be entitled to receive prior and in preference to any distribution of any of the assets of the Company to holders of Series A Preferred, Series B Preferred, Series C Preferred, Series D Preferred, Series E Preferred and common stock. If, upon a liquidation, the assets to be

distributed to the holders of the Series F Preferred are insufficient to permit the payment to such holders of the full amount payable, then the entire assets of the Company legally available for distribution shall be distributed pro rata to the holders of the Series F Preferred Stock in proportion to the full preferential amounts which each such holder would otherwise be entitled to receive.

Preferred Stock Warrants

In connection with certain convertible promissory notes issued by the Company during 2011 and 2012 and subsequently paid, the Company issued 278,506 five-year warrants to purchase Series C preferred shares of stock at an exercise price of $1.07 per share. Based on the Black-Scholes option pricing model, the value of each warrant was determined to be $0.34, for a total value of $94, and was fully expensed during the year ended December 31, 2012. As of December 31, 2015, the Company had a total of 258,880 outstanding warrants. In 2016, a total of 258,880 Series C preferred shares were issued upon exercise of the entire remaining warrants for proceeds of $277.

In connection with the execution of the Company's original credit facility entered into during 2012, the Company issued 186,916 ten-year warrants to purchase Series C preferred shares of stock at an exercise price of $1.07 per share. Based on the Black-Scholes option pricing model, the value of each warrant was determined to be $0.515, for a total value of $96 at the date of issuance and was fully expensed during the year ended December 31, 2012.

In connection with the added borrowings drawn upon the Company's original credit facility in 2013, the Company issued 74,768 ten-year warrants to purchase Series C preferred shares of stock at an exercise price of $1.07 per share. Based on the Black-Scholes option pricing model, the value of each warrant was determined to be $0.525, for a total value of $39 at the date of issuance and was fully expensed during the year ended December 31, 2013.

In connection with the execution of the Company's amended credit facility completed in June 2014, the Company also issued 76,334 ten-year warrants to purchase Series E preferred shares of stock at an exercise price of $2.62 per share. Based on the Black-Scholes option pricing model, the value of each warrant was determined to be $1.11, for a total value of $85 at the date of issuance and was fully expensed during the year ended December 31, 2014.

In connection with the execution of the Company's current credit facility completed in August 2015 (see Note 4), the Company issued 29,580 ten-year warrants to purchase Series E preferred shares

of stock at an exercise price of $2.62 per share. Based on the Black-Scholes option pricing model, the value of each warrant was determined to be $1.13, for a total value of $33 at the date of issuance and was fully expensed during the year ended December 31, 2015.

In connection with the execution of the amendment to the Company's current credit facility completed in February 2017 (see Note 4), the Company issued 29,197 ten-year warrants to purchase Series F preferred shares of stock at an exercise price of $1.37 per share. Based on the Black-Scholes option pricing model, the value of each warrant was determined to be $0.13, for a total value of $4 at the date of issuance and was fully expensed during the year ended December 31, 2017.

The preferred stock warrants issued in connection with the execution of the original credit facility and its subsequent amendments require re-measurement of the value of the preferred stock warrants each period, with changes in fair value recognized within other expenses on the statements of operations and comprehensive loss. The fair value of the preferred stock warrants was determined using the Black-Scholes option pricing model.

As of December 31, 2016 and 2017, the following preferred stock warrants issued under the Company's original credit facility and subsequent amendments were outstanding and exercisable:

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	Dates					
Issuance	Expiration	Series	Exercise Price	Warrants Outstanding at December 31, 2016	Initial Value	Fair Value at December 31, 2016
August 7, 2015	August 7, 2025	E	$2.62	29,580	$33	$4
June 27, 2014	June 27, 2024	E	2.62	76,334	85	10
August 5, 2013	August 5, 2023	C	1.07	74,768	39	11
November 16, 2012	November 16, 2022	C	1.07	186,916	96	28
				367,598		$53

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	Dates					
Issuance	Expiration	Series	Exercise Price	Warrants Outstanding at December 31, 2017	Initial Value	Fair Value at December 31, 2017
February 24, 2017	February 24, 2027	F	$1.37	29,197	$4	$13
August 7, 2015	August 7, 2025	E	2.62	29,580	33	8
June 27, 2014	June 27, 2024	E	2.62	76,334	85	21
August 5, 2013	August 5, 2023	C	1.07	74,768	39	33
November 16, 2012	November 16, 2022	C	1.07	186,916	96	82
				396,795		$157

end of user-specified TAGGED TABLE

The warrants issued on August 7, 2015 to purchase Series E preferred stock are subject to the conversion price of the underlying preferred stock. The warrants to purchase 29,580 shares of Series E preferred stock at $2.62 per share has been adjusted to purchase 56,569 shares of Series F preferred stock at $1.37 per share due to the dilutive issuance of the Series F preferred stock.

8. Stock Options

The Company adopted the 2007 Stock Incentive Plan (the Plan) in November 2007. The purpose of the Plan is to promote the interest of the Company and its stockholders by aiding the Company in attracting and retaining employees, officers, consultants, independent contractors, and directors capable of assuring the future success of the Company's business and to afford such persons an opportunity to acquire a proprietary interest in the Company. The Board may amend, alter, suspend, discontinue, or terminate the Plan at any time with the approval of the stockholders of the Company.

As of December 31, 2017, the number of shares reserved for issuance under the plan is 2,945,384 shares. The exercise price of stock options represent fair value of the common stock at the time of issuance and is determined by the Board of Directors. The options granted contain fixed exercise prices ranging from $0.94 to $6.65 per share with varying expiration and exercise dates. The stock options granted by the Company to employees during 2015, 2016 and 2017 have a weighted average exercise price of $2.07, $1.65 and $0.94, respectively. The stock options granted include a four year service period and 25% vest after the first year of service and then pro rata over the next 36 months of service. The stock options have a contractual life of ten years.

A summary of the Company's stock option activity and related information is as follows:

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	Options	Weighted Average Exercise Price
Outstanding at December 31, 2014	1,534,672	$1.77
Granted	49,235	2.07
Exercised	(21,545)	1.96
Forfeited	(21,199)	1.15
Outstanding at December 31, 2015	1,541,163	1.77
Granted	120,277	1.65
Exercised	(109,079)	1.74
Forfeited	(54,850)	1.87
Outstanding at December 31, 2016	1,497,511	1.76
Granted	721,763	0.94
Exercised	(127,122)	1.85
Forfeited	(20,536)	1.88
Outstanding at December 31, 2017	2,071,616	1.47
Exercisable at December 31, 2017	1,236,255	1.75

end of user-specified TAGGED TABLE

At December 31, 2015, the Company had 1,541,163 common stock options outstanding, with an average remaining contractual life of 6.6 years at a weighted average exercise price of $1.77 per share. At December 31, 2016, the Company had 1,497,511 common stock options outstanding, with an average remaining contractual life of 5.8 years at a weighted average exercise price of $1.76 per share. At December 31, 2017, the Company had 2,071,616 common stock options outstanding, with an average remaining contractual life of 5.9 years at a weighted average exercise price of $1.47 per share.

8. Stock Options (Continued)

Total stock compensation recognized, before taxes, during the years ended December 31, 2015, 2016 and 2017, is as follows:

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	Year Ended December 31		
	2015	2016	2017
General and administrative	$147	$108	$116
Sales and marketing	99	90	84
Research and development	59	50	43
	$305	$248	$243

end of user-specified TAGGED TABLE

As of December 31, 2017, the amount of unearned stock compensation currently estimated to be expensed from now through the year 2021 related to unvested employee and non-employee director share-based awards is $318 and the weighted average period over which the unearned stock compensation is expected to be recognized is 3 years. If there are any modifications or cancellations of the underlying unvested securities, the Company may be required to accelerate, increase, or cancel any remaining unearned stock compensation expense. Future stock compensation expense and unearned stock compensation will increase to the extent that the Company grants additional share-based awards.

The Company estimates the fair value of share-based awards on the date of grant using the Black-Scholes option pricing model using the fair market value of the Company's common stock on the date of grant and a number of other complex and subjective assumptions. These assumptions include, but are not limited to, estimates regarding the expected term of the Company's outstanding awards, estimates of the stock volatility over a duration that approximates the expected life of the Company's outstanding awards, estimates of the risk-free rate, and estimates of expected dividend rates.

Due to the Company's limited amount of historical exercise, forfeiture, and expiration activity, the Company has 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. The Company will continue to analyze its expected term assumption as more historical data becomes available. Due to the Company's limited operating history and a lack of company specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which it has based its expected stock price volatility, the Company generally selected companies with comparable characteristics to it, including enterprise value, stages of clinical development, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares over historical periods that approximate calculated expected term of the Company's share-based awards. The Company will continue to analyze the historical stock price volatility assumption as more historical data for the Company's common stock becomes available.

The risk-free rate assumption is based on the U.S. Treasury instruments with maturities similar to the expected term of the Company's stock options.

8. Stock Options (Continued)

The expected dividend assumption is based on the Company's history of not paying dividends and its expectation that it will not declare dividends for the foreseeable future.

The amount of stock compensation expense recognized is based on awards ultimately expected to vest. Due to the Company's limited forfeiture activity and its vesting terms, the amount of expense recognized by the Company has been reduced by actual forfeitures as they occur. The Company will continue to analyze its historical forfeitures as more historical data becomes available.

The fair value of options granted to employees or non-employee directors during the years ended December 31, 2015, 2016 and 2017 was estimated as of the grant date using the Black-Scholes option pricing model, assuming the weighted average assumptions listed in the following table:

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	Year Ended December 31		
	2015	2016	2017
Expected life (years)	6.2	6.2	6.2
Expected volatility	38.6%	40.6%	39.1%
Risk-free interest rate	1.65 - 2.14%	1.27 - 2.25%	1.88 - 2.32%
Dividend yield	0.0%	0.0%	0.0%
Weighted average fair value	$0.86	$0.47	$0.40

end of user-specified TAGGED TABLE

9. Related-Party Transactions

Board of Directors' Appointment

The Company has entered into various agreements and contracts with Medtronic, one of the Company's stockholders. Under these various agreements and contracts, Medtronic is allowed to name one person to be a member of the Company's Board of Directors. In connection with the Series F Preferred Stock purchase agreement in 2016, Medtronic agreed to move from one voting member of the Company's Board of Directors to two non-voting members.

Supply Agreement

The Company contracts with Medtronic to supply all of the Company's commercial and clinical requirements of certain components used to manufacture the Inspire system. The current Supply Agreement expired on June 5, 2017, but was extended to allow Medtronic to complete a final build of the pressure sensor used in the Company's original pressure sensing lead, which is expected to be completed in early 2018. Upon a change of control event whereby the Company is owned or controlled by a competitor of Medtronic, Medtronic would have the right to terminate the Supply Agreement, provided that, upon any such termination the Company would be entitled to exercise a one-time buy right of inventory using current product pricing and upon terms to be agreed upon in the definitive agreements.

Development Agreement

As part of the Development Agreement, Medtronic provided support to the Company for product development and was reimbursed on an hourly basis. The Medtronic services included project management, engineering, manufacturing, product quality, and testing of products. The Company

9. Related-Party Transactions (Continued)

continued to be responsible for all marketing, clinical, and regulatory efforts related to product development activities. The Development Agreement expired in 2015.

The Company has transactions at arms-length with Medtronic, a related party. These transactions are summarized for the years ended December 31, 2015, 2016 and 2017 as follows:

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	2015	2016	2017
Inventory purchases	$834	$848	$1,120
Research and development expenses	98	—	—
	$932	$848	$1,120

end of user-specified TAGGED TABLE

Right-of-First-Offer of the Company

Under a Right-of-First-Offer with Medtronic that expired on May 16, 2017, had the Company decided to initiate a possible sale of the Company prior to the expiration date, it would have been required to negotiate exclusively with Medtronic for such transaction for a period of 90 days prior to negotiating with a third party.

10. Income Taxes

During the years ended December 31, 2015, 2016 and 2017, the Company did not record an income tax benefit related to its loss before income taxes in the statement of operations and comprehensive loss because a valuation allowance has been required to be established for all deferred tax assets due to its cumulative net loss position.

The components of the Company's provision for income taxes are as follows:

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	Year Ended December 31		
	2015	2016	2017
Tax at federal statutory rate	35.0%	35.0%	35.0%
State, net of federal benefit	2.4	2.8	3.0
Permanent items	(0.8)	(0.5)	(1.1)
Research and development (R&D) tax credit	1.4	1.3	1.2
Federal tax rate change	—	—	(92.6)
Other	4.5	7.1	1.1
Change in valuation allowance	(42.5)	(45.7)	53.4
Total	—	—	—

end of user-specified TAGGED TABLE
On December 22, 2017, the Tax Cuts and Jobs Act of 2017 (the Act) was signed into law making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a corporate tax rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a territorial system, and a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings as of December 31, 2017. We have accounted for our best provisional estimate of the impact of the Act in

our 2017 income tax provision, the period in which the legislation was enacted, in accordance with our understanding of the Act and guidance available as of the date of this filing. The provisional amount recorded related to the remeasurement of our deferred tax assets and liabilities, based on the lower tax rates at which they are expected to reverse in the future, was $16.2 million of expense. This tax expense was entirely offset by an income tax benefit related to the reduction of our deferred tax asset valuation allowance of the same amount, resulting in no net impact to tax expense or benefit. The Company also provisionally estimates that it does not have any foreign earnings and therefore is not subject to any one-time transition tax on the mandatory deemed repatriation of foreign earnings.

Significant components of net deferred tax assets are as follows:

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	December 31		
	2015	**2016**	**2017**
Deferred tax assets:			
Net operating losses	$28,385	$36,626	$27,827
R&D tax credits	956	1,093	1,368
R&D expenditures, capitalized for tax	2,515	2,682	2,146
Accruals and other	1,165	1,065	753
	33,020	41,466	32,094
Deferred tax liabilities:			
Depreciation and amortization	(28)	(4)	4
Net deferred tax assets	32,992	41,462	32,098
Valuation allowance	(32,992)	(41,462)	(32,098)
	$–	$–	$–

end of user-specified TAGGED TABLE
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, 2017, the Company's gross federal net operating loss carryforwards of $110.9 million will expire at various dates beginning in 2028. In addition, net operating loss carryforwards for state income tax purposes of $65.9 million that include net operating losses that will begin to expire in 2028. The Company also has R&D credit carryforwards of $1.4 million as of December 31, 2017 of which will expire at various dates beginning in 2032.

Utilization of the net operating loss carryforwards may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of the net operating loss before utilization.

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, management believes it is more likely than not that the deferred tax assets are not recognizable and will not be recognizable until the Company has sufficient taxable income.

10. Income Taxes (Continued)

Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $9.1 million and $8.5 million during the years ended December 31, 2015 and 2016, respectively, and decreased by $9.4 million during the year ended December 31, 2017.

The Company had no unrecognized tax benefits as of December 31, 2016 and 2017. The Company files income tax returns in the U.S. federal and various state jurisdictions. The 2014 to 2017 tax years remain open to examination by the major taxing authorities to which the Company is subject. The Company does not expect a significant change to its unrecognized tax benefits over the next 12 months.

The Company's policy is to record interest related to uncertain tax positions as interest expense and any penalties as other expense in its statements of operations and comprehensive loss. There was no interest or penalties accrued at December 31, 2016 and 2017.

11. Segment Reporting and Significant Customers

Operating segments are defined as components 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. The Company globally manages the business within one reporting segment. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance.

Revenue by geographic region are as follows:

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	Year Ended December 31		
	2015	2016	2017
United States	$6,132	$13,789	$24,293
Europe	1,880	2,638	4,274
Total revenue	$8,012	$16,427	$28,567

end of user-specified TAGGED TABLE

All the Company's long-lived assets are located in the United States.

12. Loss Per Share

Under the two-class method, for periods with net income, basic net income per common share is computed by dividing the net income attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Net income attributable to common stockholders is computed by subtracting from net income the portion of current year earnings that participating securities would have been entitled to receive pursuant to their dividend rights had all of the year's earnings been distributed. No such adjustment to earnings is made during periods with a net loss as the holders of the participating securities have no obligation to fund losses. Diluted net loss per common share is computed under the two-class method by using the weighted average number of shares of common stock outstanding plus, for periods with net income attributable to common stockholders, the potential dilutive effects of stock options and warrants. In addition, the Company analyzes the potential dilutive effect of the outstanding participating securities under the if-converted

12. Loss Per Share (Continued)

method when calculating diluted earnings per share in which it is assumed that the outstanding participating securities convert into common stock at the beginning of the period. The Company reports the more dilutive of the approaches (two-class or if-converted) as its diluted net income per share during the period. Due to the existence of net losses for the years ended December 31, 2015, 2016, and 2017, basic and diluted loss per share were the same, as the effect of potentially dilutive securities would have been anti-dilutive.

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted average shares outstanding because such securities have an antidilutive impact due to losses reported:

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	Years Ended December 31,		
	2015	**2016**	**2017**
Convertible preferred stock outstanding	7,995,592	9,367,628	12,111,706
Convertible preferred stock warrants	367,598	394,587	423,784
Common stock options outstanding	1,541,163	1,497,511	2,071,616
	9,904,353	11,259,726	14,607,106

end of user-specified TAGGED TABLE

13. Subsequent Events

The Company has evaluated events or transactions that may have occurred since December 31, 2017, that would merit recognition or disclosure in the financial statements. This evaluation was completed through February 14, 2018, the date the financial statements were available to be issued.

On February 7, 2018, the Company borrowed an additional $8.0 million under the term B loan facility portion of its credit facility (see Note 4). After receipt of the $8.0 million, Company had a total of $24.5 million outstanding under the credit facility, which bears interest at a floating interest rate equal to the greater of 7.95% or LIBOR plus 6.9% per annum. All amounts borrowed under the credit facility are interest-only through March 1, 2019, after which the Company will make monthly payments of principal and interest through March 1, 2022; provided that the interest-only period will be extended will be

extended to March 1, 2020 if the Company has revenue, measured on a trailing 12-month basis as of December 31, 2018, of at least $25.0 million. The Company issued 233,577 ten-year warrants to purchase Series F preferred shares of stock at an exercise price of $1.37 per share.

In connection with the initial public offering of the Company's common stock (the "IPO"), the Company's board of directors and stockholders approved a 1-for-6.650 reverse stock split of the Company's common stock. The reverse stock split became effective on April 20, 2018. The par value of the common stock was not adjusted as a result of the reverse stock split. Adjustments corresponding to the reverse stock split were made to the ratio at which the convertible preferred stock will convert into common stock immediately prior to the closing of the IPO. Accordingly, all share and per-share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse stock split and adjustment of the conversion ratio of the convertible preferred stock.

THIS IS THE END OF A COMPOSITION COMPONENT

Condensed Balance Sheets

INSPIRE MEDICAL SYSTEMS, INC.

Condensed Balance Sheets

(in thousands, except share and per share amounts)

COMMAND=ADD_TABLEWIDTH,"100%" User-specified TAGGED TABLE

	September 30, 2018	December 31, 2017
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$26,312	$8,955
Short-term investments	94,114	7,188
Accounts receivable, net of allowances of $47	5,410	3,858
Inventories	3,075	3,670
Prepaid expenses and other assets	1,044	426
Total current assets	129,955	24,097
Property and equipment, cost	1,553	1,804
Less: accumulated depreciation	(788)	(810)
Property and equipment, net	765	994
Total assets	$130,720	$25,091

Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$2,449	$2,998
Accrued expenses	4,962	4,032
Accrued interest	184	117
Total current liabilities	7,595	7,147
Notes payable	24,814	16,460
Preferred stock warrants	—	157
Total long-term liabilities	24,814	16,617
Stockholders' equity		
Preferred Stock, $0.001 par value, 10,000,000 shares and 76,894,620 shares authorized at September 30, 2018 and December 31, 2017, respectively; none and 76,235,050 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	—	119,106
Common Stock, $0.001 par value per share; 200,000,000 shares and 110,000,000 shares authorized at September 30, 2018 and December 31, 2017, respectively; 21,391,590 and 1,272,360 issued and outstanding at September 30, 2018 and December 31, 2017, respectively	21	1
Additional paid-in capital	240,451	7,305
Accumulated other comprehensive loss	(26)	—
Accumulated deficit	(142,135)	(125,085)
Total stockholders' equity	98,311	1,327
Total liabilities and stockholders' equity	$130,720	$25,091

end of user-specified TAGGED TABLE

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

THIS IS THE END OF A COMPOSITION COMPONENT

Condensed Statements of Operations and Comprehensive Loss

INSPIRE MEDICAL SYSTEMS, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (Unaudited)

(in thousands, except share and per share amounts)

COMMAND=ADD_TABLEWIDTH,"100%" User-specified TAGGED TABLE

	Nine Months Ended September 30,	
	2018	**2017**
Revenue	$34,034	$18,610

Cost of goods sold	6,863	4,137
Gross profit	27,171	14,473
Operating expenses:		
Selling and marketing	31,913	19,566
Research and development	5,236	4,512
General and administrative	5,503	2,552
Total operating expenses	42,652	26,630
Operating loss	(15,481)	(12,157)
Other expense (income):		
Interest income	(1,049)	(119)
Interest expense	2,615	1,224
Other expense (income), net	3	(2)
Total other expense	1,569	1,103
Loss before income taxes	(17,050)	(13,260)
Income taxes	—	—
Net loss	(17,050)	(13,260)
Other comprehensive loss:		
Unrealized loss on short-term investments	(26)	—
Total comprehensive loss	$(17,076)	$(13,260)
Net loss per share, basic and diluted	$(1.40)	$(11.45)
Weighted average common shares used to compute net loss per share, basic and diluted	12,137,512	1,158,548

end of user-specified TAGGED TABLE

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

THIS IS THE END OF A COMPOSITION COMPONENT

Condensed Statements of Cash Flows

INSPIRE MEDICAL SYSTEMS, INC.

CONDENSED STATEMENTS OF CASH FLOWS (Unaudited)

(in thousands)

COMMAND=ADD_TABLEWIDTH,"100%" User-specified TAGGED TABLE

	Nine Months Ended September 30,	
	2018	2017
Operating activities		
Net loss	$(17,050)	$(13,260)
Adjustments to reconcile net loss:		
Depreciation and amortization	288	174
Accretion of debt discount	456	231
Stock-based compensation expense	696	189
Non-cash stock issuance for services rendered	37	—
Change in the fair value of preferred stock warrants	595	—
Changes in operating assets and liabilities:		
Accounts receivable	(1,552)	(1,105)
Inventories	595	312
Prepaid expenses and other assets	(618)	(93)
Accounts payable	(549)	445
Accrued expenses	997	593
Net cash used in operating activities	(16,105)	(12,514)
Investing activities		
Purchases of property and equipment	(59)	(350)
Purchases of short-term investments	(98,936)	(4,802)
Proceeds from sales or maturities of short-term investments	11,984	—
Net cash used in investing activities	(87,011)	(5,152)
Financing activities		
Proceeds from issuance of notes payable	8,000	458
Proceeds from the exercise of stock options and warrants	431	95
Proceeds from sale of common stock	112,042	—
Proceeds from sale of preferred stock	—	24,968
Net cash provided by financing activities	120,473	25,521
Increase in cash and cash equivalents	17,357	7,855
Cash and cash equivalents at beginning of period	8,955	6,685

Cash and cash equivalents at end of period	$26,312	$14,540
Supplemental cash flow information		
Cash paid for interest	$1,453	$984
Issuance of preferred stock warrants	103	4

end of user-specified TAGGED TABLE
The accompanying notes are an integral part of these unaudited condensed financial statements.

THIS IS THE END OF A COMPOSITION COMPONENT

Notes to Condensed Financial Statements

INSPIRE MEDICAL SYSTEMS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited)

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

1. Organization

Description of Business

Inspire Medical Systems, Inc. is a medical technology company focused on the development and commercialization of innovative and 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 obstructive sleep apnea. 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 received premarket approval ("PMA") from the U.S. Food and Drug Administration ("FDA") in April 2014 and has been commercially available in certain European markets since November 2011. In June 2018, Japan's Ministry of Health, Labour and Welfare approved Inspire therapy to treat moderate to severe OSA, and we will now seek reimbursement coverage in Japan.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed financial statements have been prepared without audit, pursuant to the rules and regulations of the SEC. The condensed financial statements may not include all disclosures required by U.S. GAAP; however, we believe that the disclosures are adequate to make the information presented not misleading. These unaudited condensed financial statements should be read in conjunction with the audited financial statements and the notes thereto for the fiscal year ended December 31, 2017 included in our audited consolidated financial statements for the year ended December 31, 2017 and the notes thereto for the year ended December 31, 2017 included in our final prospectus that forms a part of our Registration Statement on Form S-1 (File No. 333-224176), filed with the Securities and Exchange Commission ("SEC") pursuant to Rule 424(b)(4) on May 4, 2018 (the "Prospectus"). The condensed balance sheet at December 31, 2017 was derived from the audited financial statements.

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 for the interim periods, have been made. The results of operations for the interim periods are not necessarily indicative of the operating results for the full fiscal year or any future periods.

Reverse Stock Split

In connection with our initial public offering of common stock ("IPO"), our board of directors and stockholders approved a 1-for-6.650 reverse stock split of our common stock. The reverse stock split became effective on April 20, 2018. The par value of the common stock was not adjusted as a result of the reverse stock split. Adjustments corresponding to the reverse stock split were made to the ratio at which the convertible preferred stock will convert into common stock immediately prior to the closing of the IPO. Accordingly, all share and per-share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse stock split and adjustment of the conversion ratio of the convertible preferred stock.

2. Summary of Significant Accounting Policies (Continued)

Initial Public Offering

On May 7, 2018, we completed our IPO by issuing 7,762,500 shares of common stock, at an offering price of $16.00 per share, for net proceeds of approximately $112.0 million after deducting underwriting discounts and commissions and offering expenses payable by us. In connection with the IPO, our outstanding shares of convertible preferred stock were automatically converted into an aggregate of 12,111,706 shares of common stock, and our outstanding warrants to purchase shares of convertible preferred stock were automatically converted into warrants to purchase up to an aggregate of 100,558 shares of common stock, resulting in the reclassification of the related redeemable convertible preferred stock warrant liability of $0.9 million to additional paid-in capital ("APIC").

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 financial statements. We use significant judgment when making estimates related to the allowance for doubtful accounts, inventory reserves and the valuations of our common stock, share-based awards, and certain of our previously outstanding preferred stock warrants. 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.

JOBS Act Accounting Election

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We have elected to take advantage of the extended transition period for adopting new or revised accounting standards that have different effective dates for public and private companies until such time as those standards apply to private companies.

Cash and Cash Equivalents

We consider all highly liquid securities, readily convertible to cash, that mature within 90 days or less from the date of purchase to be cash equivalents. The carrying amount reported in the balance sheets for cash is cost, which approximates fair value.

Short-Term Investments

At September 30, 2018 and December 31, 2017, our short-term investments consisted of commercial paper, corporate bonds, and U.S. government securities which are classified as available-for-sale and had maturities less than one year. Short-term investments are reported at their estimated fair market value which approximates cost. Any unrealized gains and losses are

reported in accumulated other comprehensive loss. We had less than $0.1 million and $0 accumulated other comprehensive loss balance at September 30, 2018 or December 31, 2017, respectively. Any realized

gains and losses are reported net in interest income or interest expense. For the nine months ended September 30, 2018, we recognized $0.4 million of gains, net.

Fair Value of Financial Instruments

We measure certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents, short-term investments, and certain of our previously outstanding preferred stock warrants. 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—Other inputs that are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-based valuation techniques for which all significant inputs are observable in the market or can be derived from observable market data. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs, including interest rate curves, foreign exchange rates, and credit ratings.

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

We use the methods and assumptions described below in determining the fair value of our financial instruments.

Money market funds: Fair values of money market funds are based on quoted market prices in active markets.

Commercial paper: Short-term, highly liquid investments are included as a Level 2 measurement in the tables below.

Corporate bonds: Consists of notes, asset-backed securities and bonds with original maturities of less than one year and various yields. These are included as a Level 2 measurement in the tables below.

U.S. government securities: Consists of U.S. Government treasury bills with original maturities of less than one year. These are included as a Level 1 measurement in the table below.

The following tables sets forth by level within the fair value hierarchy our assets and liabilities that are reported at fair value as of September 30, 2018 and December 31, 2017. As required by Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 820, *Fair Value Measurement*, assets and liabilities are classified in their entirety based on the

lowest level of input that is significant to the fair value measurement. The following tables summarize certain information for assets and liabilities measured at fair value on a recurring basis:

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	Fair Value Measurements as of September 30, 2018			
	Estimated Fair Value	Level 1	Level 2	Level 3
Assets				
Cash equivalents:				
Money market funds	$14,250	$14,250	$—	$—
Commercial paper	10,382	—	10,382	—
Total cash equivalents	24,632	14,250	10,382	—
Short-term investments:				
Commercial paper	$47,631	$—	$47,631	$—
Corporate bonds	34,576	—	34,576	—
U.S. government securities	11,907	11,907	—	—
Total short-term investments	94,114	11,907	82,207	—
Total assets	$118,746	$26,157	$92,589	$—

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	Fair Value Measurements as of December 31, 2017			
	Estimated Fair Value	Level 1	Level 2	Level 3
Assets				
Cash equivalents:				
Money market funds	$6,446	$6,446	$—	$—
Commercial paper	1,099	—	1,099	—
Total cash equivalents	7,545	6,446	1,099	—
Short-term investments:				
Commercial paper	$5,384	$—	$5,384	$—
Corporate bonds	1,804	—	1,804	—
Total short-term investments	7,188	—	7,188	—
Total assets	$14,733	$6,446	$8,287	$—

Liabilities				
Preferred stock warrants	$157	$—	$—	$157

end of user-specified TAGGED TABLE

There were no transfers in and out of Level 1 and Level 2 fair value measurements during the periods ended September 30, 2018 and December 31, 2017.

The recurring Level 3 fair value measurements of our preferred stock warrant liabilities used the Black-Scholes option pricing model and value of the respective class of our convertible preferred

stock (see Note 8), which was unobservable. All other assumptions included in the model are observable Level 1 inputs.

The following table provides a reconciliation of the beginning and ending balances of our preferred stock warrant liabilities:

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	Nine Months Ended September 30,	
	2018	**2017**
Balance at beginning of period	$157	$53
Initial fair value of preferred stock warrants issued	103	4
Reclassified to equity	(855)	—
Change in fair value of preferred stock warrants	595	—
Balance at end of period	$—	$57

end of user-specified TAGGED TABLE

Changes in the fair value of the preferred stock warrant liability were recorded in other expenses on the condensed statements of operations and comprehensive loss. In connection with the closing of the IPO in May 2018, warrants to purchase shares of preferred stock automatically converted into warrants to purchase shares of common stock, resulting in the reclassification of the related convertible preferred stock warrant liability to APIC.

Concentration of Credit Risk

Financial instruments, which potentially subject us to concentrations of credit risk, consist principally of cash equivalents and accounts receivable. 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 been within management's expectations.

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 balance sheets. However, as of September 30, 2018 and December 31, 2017, we limited our credit risk associated with cash equivalents by placing investments with banks we believe are highly creditworthy.

Allowance for Doubtful Accounts

We record an allowance for doubtful accounts for accounts receivable deemed uncollectible. We evaluate the collectability of our accounts receivable based on known collection risks and historical experience. In circumstances where we are aware of a specific customer's inability to meet its financial obligations to us (e.g., bankruptcy filings, substantial downgrading of credit ratings), we record a specific allowance for bad debts against amounts due to reduce the carrying amount of accounts receivable to the amount we reasonably believe will be collected.

2. Summary of Significant Accounting Policies (Continued)

Inventories

Inventories are valued at the lower of cost or net realizable value, computed on a first-in, first out basis. 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. Our review of inventory for excess and obsolete quantities is based primarily on the estimated forecast of future product demand, product life cycles, including expiration of inventory prior to sale, and introduction of new products. The reserve for excess and obsolete inventory was $0.8 million and $0.5 million as of September 30, 2018 and December 31, 2017, respectively.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is determined using the straight-line method over the estimated useful lives of the respective assets, generally three to seven years. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the term of the lease.

Impairment of Long-lived Assets

Long-lived assets consist primarily of property and equipment and 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 during the nine months ended September 30, 2018 and 2017.

Revenue Recognition

We recognize revenue when persuasive evidence of an arrangement exists, product shipment has occurred, or there are no further obligations yet to be performed, pricing is fixed or determinable, and collection is reasonably assured. We make reasonable assumptions regarding the future collectability of amounts receivable from customers to determine whether the revenue recognition criteria have been met. Taxes assessed by a governmental authority that are directly imposed on revenue-producing transactions between a seller and a customer are not recorded as revenue. In general, our standard terms and conditions of sale do not allow for product returns. Sales returns have been limited to damaged product and have not been material. We expense shipping and handling costs as incurred and include them in the cost of goods sold. 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.

2. Summary of Significant Accounting Policies (Continued)

Cost of Goods Sold

Cost of goods sold consists primarily of manufacturing overhead costs, material costs, and direct labor. Overhead costs include the cost of material procurement, inventory control, facilities, equipment, and operations supervision and management. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as shipping costs.

Research and Development

Research and development expenses consist primarily of product development, clinical and regulatory affairs, consulting services, and other costs associated with products and technologies in development. These expenses include employee compensation, stock-based compensation, supplies, travel, and facility costs. Clinical expenses include clinical trial design, clinical site reimbursement, data management, travel expenses, and the cost of manufacturing products for clinical trials.

Common Stock Valuation and Stock-Based Compensation

We maintain an equity incentive plan to provide long-term incentives for employees, consultants, and members of the board of directors. The plan allows for the issuance of non-statutory and incentive stock options to employees and non-statutory stock options to consultants and non-employee directors.

We recognize equity-based compensation expense for awards of equity instruments to employees and non-employees based on the grant date fair value of those awards in accordance with FASB ASC Topic 718, *Stock Compensation* ("ASC 718"). ASC 718 requires all equity-based compensation awards to employees and nonemployee directors, including grants of restricted shares and stock options, to be recognized as expense in the statements of operations and comprehensive loss based on their grant date fair values. We estimate the fair value of stock options using the Black-Scholes option pricing model. We use the value of our common stock to determine the fair value of restricted shares.

We account for restricted stock and common stock options issued to nonemployees under FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees*. As such, the value of such options is periodically remeasured and income or expense is recognized over their vesting terms. Compensation cost related to awards with service-based vesting schedules is recognized using the straight-line method. We determine the fair value of the restricted stock and common stock granted to nonemployees as either the fair value of the consideration received or the fair value of the equity instruments issued. We have not granted any share-based awards to our consultants.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (i) the expected share price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) the expected dividend yield. Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The group of representative companies have characteristics similar to us, including stage of product development and focus on the life science industry. We use the simplified

2. Summary of Significant Accounting Policies (Continued)

method, which is the average of the final vesting tranche date and the contractual term, to calculate the expected term for options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to non-employees, we utilize the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. We use an assumed dividend yield of zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

We expense the fair value of our equity-based compensation awards granted to employees on a straight-line basis over the associated service period, which is generally the period in which the related services are received. We measure equity-based compensation awards granted to nonemployees at fair value as the awards vest and recognize the resulting value as compensation expense at each financial reporting period. We account for award forfeitures as they occur.

Advertising Expenses

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses were $5.8 million and $3.7 million during the nine months ended September 30, 2018 and 2017, respectively.

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. Our policy is to record interest and penalties expense related to uncertain tax positions as other expense in the statements of operations and comprehensive loss.

Comprehensive Loss

Comprehensive loss consists of net loss and changes in unrealized gains and losses on short-term investments classified as available-for-sale, if any. Accumulated other comprehensive loss is presented in the accompanying balance sheets as a component of stockholders' equity, if any.

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 for those periods as

NOTES TO CONDENSED FINANCIAL STATEMENTS (Unaudited) (Continued)

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

2. Summary of Significant Accounting Policies (Continued)

all potentially dilutive shares consisting of convertible preferred stock, stock options and warrants were antidilutive in those periods.

Recent Accounting Pronouncements

We are an "emerging growth company" as defined by the JOBS Act. The JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, (the "Securities Act"), for complying with new or revised accounting standards. Accordingly, an emerging growth company can selectively delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, as a result, our financial statements may not be comparable to the financial statements of issuers that are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable.

In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers*. The new section will replace Section 605, *Revenue Recognition*, and creates modifications to various other revenue accounting standards for specialized transactions and industries. The section is intended to conform revenue accounting principles with the concurrently issued International Financial Reporting Standards to reconcile previously differing treatment between U.S. practices and those of the rest of the world and to enhance disclosures related to disaggregated revenue information. The updated guidance is effective for interim and annual reporting periods beginning on or after December 15, 2018 for private companies and, therefore, us due to the JOBS Act exemption described above. We have commenced project planning for our implementation, which has included engaging an accounting firm to assist us. We have not yet made a determination on our transition method, nor have we determined whether this standard will have a material impact on our financial statements. We plan to complete our assessment of the impact of this standard during the fourth quarter of 2018.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* ("ASU 2015-17"). ASU 2015-17 is intended to reduce complexity surrounding the presentation of deferred taxes within the balance sheet. Specifically, ASU 2015-17 requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as non-current on the balance sheet, effectively eliminating the requirement to allocate deferred taxes between current and non-current amounts. The new guidance does not permit companies to offset deferred tax liabilities from one jurisdiction against deferred tax assets of another jurisdiction. This guidance was effective January 1, 2018 and did not significantly impact our financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-2, *Leases* (Topic 842), which supersedes the existing guidance for lease accounting, *Leases* (Topic 840). ASU 2016-02 requires lessees to recognize a lease liability and a right-of-use asset for all leases. Lessor accounting remains largely unchanged. The amendments in this ASU are effective for interim and annual periods beginning after December 15, 2019 for private companies; and, therefore, us due to the JOBS Act exemption described above. Early adoption is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial adoption, with an option to elect to use

certain transition relief. We plan to further evaluate the anticipated impact of the adoption of this ASU on our financial statements in future periods.

In March 2016, the FASB issued No. 2016-9, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-9"), which changes how companies will account for certain aspects of share-based payments to employees. As part of the new guidance, entities will be required to record the impact of income taxes arising from share-based compensation when awards vest or are settled within earnings as part of income tax expense rather than recorded as part of APIC and will eliminate the requirement that excess tax benefits be realized prior to recognition. Additionally, the guidance requires entities to present excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. Additionally, companies will be required to make an accounting policy election at the time of adoption of the new guidance to either account for forfeitures of share-based awards in a manner similar to today's requirements (i.e., estimating the number of awards expected to be forfeited at the grant date and adjusting the estimate when awards are actually forfeited), or recognizing forfeitures as they occur with no

estimate of forfeitures determined at the grant date. Companies will also be able to set a maximum statutory tax rate as it pertains to share-based awards it net settles on behalf of its employees. This will provide companies a greater ability to retain equity-award accounting treatment. Entities will apply the provisions of ASU 2016-9 using a modified retrospective transition approach, with a cumulative-effect adjustment booked to retained earnings as of the beginning of the period of adoption. This guidance was effective for us on January 1, 2018 and did not significantly impact our financial statements and related disclosures.

We have reviewed and considered all other recent accounting pronouncements and believe there are none that could potentially have a material impact on our business practices, financial condition, results of operations, or disclosures.

3. Composition of Certain Financial Statement Items

Inventories

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	September 30, 2018	December 31, 2017
Raw materials	$1,054	$1,323
Finished goods	2,021	2,347
Total inventories, net of reserves	$3,075	$3,670

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3. Composition of Certain Financial Statement Items (Continued)

Property and Equipment

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	September 30, 2018	December 31, 2017
Computer equipment and software	$333	$351
Furniture and office equipment	148	137
Manufacturing equipment	857	1,108
Research and development equipment	30	30
Leasehold improvements	185	178
Property and equipment, cost	1,553	1,804
Less: accumulated depreciation and amortization	(788)	(810)
Property and equipment, net	$765	$994

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Depreciation and amortization expense was $0.3 million and $0.2 million for the nine months ended September 30, 2018 and 2017, respectively.

Accrued Expenses

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	September 30, 2018	December 31, 2017
Payroll and commissions payable	$3,619	$2,871
Vacation	946	723
Other accrued expenses	397	438
Total accrued expenses	$4,962	$4,032

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4. Short-Term Investments

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

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	September 30, 2018			
		Unrealized		
	Cost	Gains	Losses	Fair Value
Commercial paper	$47,631	$—	$—	$47,631
Corporate bonds	34,598	—	22	34,576
U.S. government securities	11,911	—	4	11,907
Short-term investments	$94,140	$—	$26	$94,114

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4. Short-Term Investments (Continued)

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	December 31, 2017			
		Unrealized		
	Cost	Gains	Losses	Fair Value
Commercial paper	$5,384	$—	$—	$5,384
Corporate bonds	1,804	—	—	1,804

Short-term investments	$7,188	$—	$—	$7,188

end of user-specified TAGGED TABLE

As of September 30, 2018 and December 31, 2017, we had no investments with a contractual maturity of greater than one year. 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 at September 30, 2018.

5. Long-Term Debt

Credit Facility

In August 2015, we entered into a loan and security agreement, which provided for a term A loan facility in the amount of $15.5 million, the proceeds of which were used to refinance the $12.0 million of borrowings outstanding under our original credit facility, and a term B loan facility in an amount between $3.5 million and $10.0 million, subject to our achievement of certain revenue milestones. Amounts outstanding under the credit facility bore interest at a fixed rate of 7.95% per annum.

In February 2017, we amended the loan and security agreement. Under the loan and security agreement, as amended, and subject to the limitation noted below, amounts outstanding under the credit facility bear interest at a floating interest rate equal to the greater of 7.95% or LIBOR plus 6.9% per annum. Upon execution of the amendment, we borrowed an additional $1.0 million under the term A loan portion of the credit facility, receiving net proceeds of $0.5 million, net of expenses, for a total of $16.5 million outstanding under the credit facility and reduced borrowings available under the term B loan facility to $9.0 million. In connection with the execution of the amendment to the loan and security agreement, we issued 29,197 ten-year warrants to purchase Series F preferred shares of stock at an exercise price of $1.37 per share.

On February 7, 2018, we borrowed an additional $8.0 million under the term B loan facility portion of the credit facility. After receipt of the $8.0 million, we had a total of $24.5 million outstanding under the credit facility, which bears interest at a floating interest rate equal to the greater of 7.95% or LIBOR plus 6.9% per annum. All amounts borrowed under the credit facility are interest-only through March 1, 2019, after which monthly payments of principal and interest are due through March 1, 2022; provided that the interest-only period will be extended to March 1, 2020 if we have revenue, measured on a trailing 12-month basis as of December 31, 2018, of at least $25.0 million, which was met during the nine months ended September 30, 2018, and, therefore, the interest-only period is extended to March 1, 2020. In connection with this borrowing, we issued 233,577 ten-year warrants to purchase Series F preferred shares of stock at an exercise price of $1.37 per share.

5. Long-Term Debt (Continued)

In addition to the principal and interest payments, under the credit facility, we are required to pay a final payment fee of 5.0% on all amounts outstanding (or 5.5% if the interest-only period has been extended to March 1, 2020), which is being accreted using the effective interest rate method over the term of the loan and security agreement and shall be due at the earlier of maturity or prepayment. Because the interest-only period has been extended, the final payment fee will be 5.5%. If we repay all the amounts borrowed under the term A loan facility on or prior to maturity, we will also be required to pay a prepayment fee equal to 1.5% if such borrowings are prepaid after February 24, 2018 but prior to February 24, 2019, and 1.00% if such borrowings are prepaid on or after February 24, 2019. Borrowings under the term B loan facility are prepayable at our option in whole, but not in part, together with all accrued and unpaid interest thereon and, if not previously made, the Final Payment, subject to a prepayment fee of 2.5% if the such borrowings are prepaid prior to February 7, 2019, 1.5% if such borrowings are prepaid on or after February 7, 2019 but prior to February 7, 2020 and 1.00% if such borrowings are on or after February 7, 2020.

The credit facility includes affirmative and restrictive covenants and events of default, including the following events of default: payment defaults, breaches of covenants, judgment defaults, cross defaults to certain other contracts, certain events with respect to governmental approvals if such events could cause a material adverse change, a material impairment in the perfection or priority of the lender's security interest or in the value of the collateral, a material adverse change in the business, operations, or condition of us or any of our subsidiaries, and a material impairment of the prospect of repayment of the loans. Upon the occurrence of an event of default, a default increase in the interest rate of an additional 5.00% could be applied to the outstanding loan balance and the lender could declare all outstanding obligations immediately due and payable and take such other actions as set forth in the loan and security agreement.

Our obligations under the credit facility are secured by a first priority security interest in substantially all of our assets, other than our intellectual property. There are no financial covenants contained in the loan and security agreement. We were in compliance with the affirmative and restrictive covenants as of September 30, 2018.

We paid debt issuance costs of $0.1 million in connection with our entry into the loan and security agreement in August 2015. The costs are being amortized over the term of the loan using the effective interest rate method. We also issued preferred stock warrants in connection with our borrowings under our credit facilities (see Note 8).

Expected future principal payments for the credit facility are as follows:

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Year ending December 31:	
2018 (remaining)	$—
2019	—
2020	10,208
2021	12,250
2022	2,042
Total expected future principal payments	$24,500

end of user-specified TAGGED TABLE

6. Commitments

Operating Lease

We rent office space under an operating lease that expires on March 31, 2019. The lease allows us to terminate the lease any time after March 31, 2017 without a penalty.

In September 2018, we entered into a non-cancelable operating lease agreement to sublease approximately 44,000 square feet of office space for our corporate headquarters, which lease is scheduled to commence January 15, 2019 and expire November 30, 2020.

Future minimum annual operating lease payments are as follows:

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Year ending December 31:	
2018 (remaining)	$48
2019	1,043
2020	952
Total future operating lease payments	$2,043

end of user-specified TAGGED TABLE
Rent expense was $0.1 million for both the nine months ended September 30, 2018 and 2017.

Purchase Commitments

As of September 30, 2018 and December 31, 2017, we had commitments to suppliers for inventory purchases totaling $16.2 million and $9.0 million, respectively, of which less than $0.1 million and $0.4 million, respectively, was committed to Medtronic, a related party.

7. Employee Retirement Plan

We sponsor an 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. We may elect to make a voluntary contribution to the plan. We have not made contributions since inception.

8. Stockholders' Equity

Authorized Shares

As of December 31, 2017, we had authorized 186,894,620 shares of stock, of which 110,000,000 shares were designated as common stock and 76,894,620 shares were designated as Series A, B, C, D, E, and F preferred stock. All stock had a par value of $0.001 per share.

As of September 30, 2018, we had authorized 210,000,000 shares of stock, of which 200,000,000 shares are designated as common stock and 10,000,000 shares are designated as preferred stock. All stock has a par value of $0.001 per share.

8. Stockholders' Equity (Continued)

Preferred Stock

A summary of preferred stock and its terms as of December 31, 2017, is as follows:

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Series	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Preference per Share	8% Dividend per Share	Conversion Price per Share
A	5,375,507	5,375,507	$5,037	$1.00	$0.08	$6.65
B	8,706,909	8,706,909	15,913	1.84	0.15	9.91
	14,091,589	13,829,906	14,949	1.07	0.09	7.12
D	5,683,292	5,683,292	6,043	1.07	0.09	7.12

E	15,373,091	15,267,175	39,848	2.62	0.21	15.16
F	27,664,232	27,372,261	37,316	1.37	0.11	9.11
Total	76,894,620	76,235,050	$119,106			

end of user-specified TAGGED TABLE

In connection with the IPO in May 2018, the 76,235,050 shares of convertible preferred stock were converted into 12,111,706 shares of common stock, resulting in the reclassification of the related convertible preferred stock of $119.1 million to common stock and APIC. As of September 30, 2018, no preferred stock had been issued.

The dividend per share on the convertible preferred stock was only payable when and if declared by the Board of Directors.

Preferred Stock Warrants and Common Stock Warrants

As of December 31, 2017, we had warrants outstanding to purchase 396,795 shares of various series of our preferred stock. The warrants had been issued in connection with our various credit facilities and issuances of promissory notes. The original fair value of the warrants was determined using the Black-Scholes option pricing model.

In connection with the borrowing completed in February 2018 (see Note 5), we issued 233,577 ten-year warrants to purchase Series F preferred shares of stock at an exercise price of $1.37 per share. Based on the Black-Scholes option pricing model, the value of each warrant was determined to be $0.44, for a total value of $0.1 million at the date of issuance and was fully expensed during the three months ended March 31, 2018.

The preferred stock warrants issued in connection with the execution of the original credit facility and its subsequent amendments required re-measurement of the value of the preferred stock warrants each period, with changes in fair value recognized within other expenses on the statements of operations and comprehensive loss. The fair value of the preferred stock warrants was determined using the Black-Scholes option pricing model.

8. Stockholders' Equity (Continued)

As of May 7, 2018, the date of the closing of our IPO, the following preferred stock warrants issued under the original credit facility and subsequent amendments were outstanding and exercisable:

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Issuance	Expiration	Series	Exercise Price	Warrants Outstanding at May 7, 2018	Initial Value	Fair Value at May 7, 2018
February 8, 2018	February 8, 2028	F	$1.37	233,577	$103	$320
February 24, 2017	February 24, 2027	F	1.37	29,197	4	40
August 7, 2015	August 7, 2025	E	2.62	29,580	33	41
June 27, 2014	June 27, 2024	E	2.62	76,334	85	174
August 5, 2013	August 5, 2023	C	1.07	74,768	39	80
November 16, 2012	November 16, 2022	C	1.07	186,916	96	200
Total				630,372		$855

end of user-specified TAGGED TABLE

In connection with the closing of the IPO in May 2018, the warrants to purchase shares of preferred stock automatically converted into warrants to purchase shares of common stock, resulting in the reclassification of the related convertible preferred stock warrant liability of $0.9 million to APIC during the three months ended June 30, 2018. Upon the closing of the IPO, the warrants to purchase 630,372 shares of preferred stock at a weighted average exercise price of $1.46 per share became exercisable to purchase 100,558 shares of common stock at weighted average exercise price of $9.38 per share. Warrants for 19,674 shares were exercised through a cashless exercise on September 10, 2018, resulting in the issuance of a net 17,050 shares of our common stock.

As of December 31, 2017, the following preferred stock warrants issued under the original credit facility and subsequent amendments were outstanding and exercisable:

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Issuance	Expiration	Series	Exercise Price	Warrants Outstanding at December 31, 2017	Initial Value	Fair Value at December 31, 2017
February 24, 2017	February 24, 2027	F	$1.37	29,197	$4	$13
August 7, 2015	August 7, 2025	E	2.62	29,580	33	8
June 27, 2014	June 27, 2024	E	2.62	76,334	85	21
August 5, 2013	August 5, 2023	C	1.07	74,768	39	33
November 16, 2012	November 16, 2022	C	1.07	186,916	96	82
Total				396,795		$157

end of user-specified TAGGED TABLE

The warrants issued on August 7, 2015 to purchase Series E preferred stock were subject to the conversion price of the underlying preferred stock. The warrants to purchase 29,580 shares of Series E preferred stock at $2.62 per share has been adjusted to purchase 56,569 shares of Series F preferred stock at $1.37 per share due to the dilutive issuance of the Series F preferred stock.

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9. Stock Options

We adopted the 2007 Stock Incentive Plan (the "2007 Plan") in November 2007, which terminated in accordance with its terms on November 28, 2017; however, the outstanding stock options may continue to be exercised in accordance with their terms.

Immediately following the termination of the 2007 Plan, we adopted the 2017 Stock Incentive Plan (the "2017 Plan"), which contains substantially similar terms and conditions as the 2007 Plan. Upon the IPO, no further grants were made under the 2017 Plan and we adopted the 2018 Stock Incentive Plan (the "2018 Plan"). The purpose of the 2018 Plan is to promote the interest of our company and our stockholders by aiding in attracting and retaining employees, officers, consultants, independent contractors,

and directors capable of assuring the future success our business and to afford such persons an opportunity to acquire a proprietary interest our company. The Board may amend, alter, suspend, discontinue, or terminate the 2018 Plan at any time with the approval of our stockholders.

As of September 30, 2018, there were 1,386,809 shares reserved for issuance under the 2018 Plan, of which 1,036,392 shares were available for issuance. Prior to the IPO, the exercise price of stock options represented fair value of the common stock at the time of issuance and was determined by the Board of Directors. Post-IPO, options are granted at the exercise price, which is equal to the closing price of our stock on the date of grant. The options granted during the nine months ended September 30, 2018 contain fixed exercise prices ranging from $2.80 to $54.99 per share with varying expiration and exercise dates and have a weighted average exercise price of $15.04 per share. The stock options granted to employees include a four-year service period and 25% vest after the first year of service and with the remainder vesting pro rata over the next 36 months of service. The stock options granted to the Board of Directors include a one-year service period and all shares vest after the one year of service. The stock options have a contractual life of ten years.

A summary of stock option activity and related information is as follows:

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	Options	Weighted Average Exercise Price	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2017	2,071,616	$1.47	5.9	
Granted	385,056	$15.04		
Exercised	(227,114)	$1.90		
Forfeited	(31,428)	$1.05		
Outstanding at September 30, 2018	2,198,130	$3.80	6.8	$84,136
Exercisable at September 30, 2018	1,307,821	$1.58	5.4	$52,975

end of user-specified TAGGED TABLE

9. Stock Options (Continued)

Total stock-based compensation recognized, before taxes, during the nine months ended September 30, 2018 and 2017, is as follows:

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	Nine Months Ended September 30,	
	2018	2017
General and administrative	$592	$89

Sales and marketing	88	73
Research and development	16	27
Total stock-based compensation	$696	$189

end of user-specified TAGGED TABLE

As of September 30, 2018, the amount of unearned stock-based compensation currently estimated to be expensed from now through the year 2022 related to unvested employee and non-employee director share-based awards is $2.4 million and the weighted average period over which the unearned stock-based compensation is expected to be recognized is 2.6 years. 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 share-based awards.

We estimate the fair value of share-based awards on the date of grant using the Black-Scholes option pricing model using the fair market value of our common stock on the date of grant and a number of other complex and subjective assumptions. These assumptions include, but are not limited to, estimates regarding the expected term of our outstanding awards, estimates of the stock volatility over a duration that approximates the expected life of our outstanding awards, estimates of the risk-free rate, and estimates of expected dividend rates.

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. Due to our limited operating history and a lack of company specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. When selecting these public companies on which we have based our expected stock price volatility, we generally selected companies with comparable characteristics to it, including enterprise value, stages of clinical development, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. The historical volatility data was computed using the daily closing prices for the selected companies' shares over historical periods that approximate calculated expected term of our share-based awards. We will continue to analyze the historical stock price volatility assumption as more historical data for our common stock becomes available.

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

9. Stock Options (Continued)

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.

The amount of stock-based compensation expense recognized is based on awards ultimately expected to vest. The amount of expense recognized has been reduced by actual forfeitures as they occur.

The fair value of options granted to employees and non-employee directors during the nine months ended September 30, 2018 and 2017 was estimated as of the grant date using the Black-Scholes option pricing model using the following assumptions:

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	Nine Months Ended September 30,	
	2018	2017
Expected life (years)	5.50 - 6.25	5.75 - 6.25
Expected volatility	37.5 - 49.8%	39.9 - 41.5%
Risk-free interest rate	2.38 - 3.01%	1.88 - 2.32%
Dividend yield	0.0%	0.0%
Weighted average fair value	$7.43	$0.40

end of user-specified TAGGED TABLE

10. Related-Party Transactions

Board of Directors' Appointment

We are party to various agreements and contracts with Medtronic, one of our stockholders. Under these agreements and contracts, Medtronic was allowed to name one person to be a member of our Board of Directors. In connection with the Series F Preferred Stock purchase agreement in 2016, Medtronic agreed to move from one voting member of our Board of Directors to two non-voting members. This right terminated in connection with the completion of our IPO.

Supply Agreement

We contract with Medtronic to supply all of our commercial and clinical requirements of certain components used to manufacture the Inspire system. The current Supply Agreement expired on June 5, 2017 but was extended to allow Medtronic to complete a final build of the pressure sensor used in our original pressure sensing lead, which was completed in 2018. Upon a change of control event whereby we are owned or controlled by a competitor of Medtronic, Medtronic would have the right to terminate the Supply Agreement, provided that, upon any such termination we would be entitled to exercise a one-time buy right of inventory using current product pricing and upon terms to be agreed upon in the definitive agreements.

We purchased inventory at arms-length with Medtronic, a related party, of $0.3 million and $0.8 million for the nine months ended September 30, 2018 and 2017, respectively.

10. Related-Party Transactions (Continued)

Right-of-First-Offer of the Company

Under a Right-of-First-Offer with Medtronic that expired on May 16, 2017, had we decided to initiate a possible sale of our company prior to the expiration date, we would have been required to negotiate exclusively with Medtronic for such transaction for a period of 90 days prior to negotiating with a third party.

11. Income Taxes

During the nine months ended September 30, 2018 and 2017, we did not record an income tax benefit related to our loss before income taxes in the statement of operations and comprehensive loss because a valuation allowance has been required to be established for all deferred tax assets due to our cumulative net loss position.

As of December 31, 2017, our gross federal net operating loss carryforwards of $110.9 million will expire at various dates beginning in 2028. In addition, net operating loss carryforwards for state income tax purposes of $65.9 million that include net operating losses that will begin to expire in 2028. We also have R&D credit carryforwards of $1.4 million as of December 31, 2017 of which will expire at various dates beginning in 2032.

Utilization of the net operating loss carryforwards may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of the net operating loss before utilization.

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, management believes it is more likely than not that the deferred tax assets are not recognizable and will not be recognizable until we have sufficient taxable income. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance.

We had no unrecognized tax benefits as of September 30, 2018 and December 31, 2017. We file income tax returns in the U.S. federal and various state jurisdictions. The 2014 to 2017 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.

The Tax and Jobs Act (the "Act") was enacted on December 22, 2017. The Act reduces the U.S. federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign-sourced earnings.

We have applied the guidance in ASU 2018-5, Income Taxes (Topic 740): *Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*, when accounting for the enactment-date effects of the Act. At September 30, 2018, we have not completed our accounting for the tax effects of the Act, as we are in the process of analyzing certain aspects of the Act, obtaining information, and refining our calculations of the Act's impact. There have been no material measurement period adjustments made during the nine months ended September 30, 2018 related to the provisional

amounts recorded and disclosed in our Registration Statement Form S-1 and Prospectus dated May 2, 2018. We expect to complete the accounting for the tax effects of the Act during 2018.

12. Segment Reporting and Significant Customers

Operating segments are defined as components 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. We globally manage the business within one reporting segment. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance.

Revenue by geographic region is as follows:

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	Nine Months Ended September 30,	
	2018	**2017**
United States	$29,580	$15,922
Europe	4,454	2,688
Total revenue	$34,034	$18,610

end of user-specified TAGGED TABLE

All of our long-lived assets are located in the United States.

13. 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 for those periods as all potentially dilutive shares consisting of convertible preferred stock, convertible preferred stock warrants, convertible common stock warrants and common stock options were antidilutive in those periods.

The following potentially dilutive securities outstanding at the end of the periods presented have been excluded from the computations of diluted shares outstanding because such securities have an antidilutive impact due to losses reported:

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	September 30,	
	2018	2017
Convertible preferred stock outstanding	—	12,111,706
Convertible preferred stock warrants	—	65,434
Convertible common stock warrants	80,884	—
Common stock options outstanding	2,198,130	2,074,994
Total	2,279,014	14,252,134

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2,500,000 Shares

Inspire Medical Systems, Inc.

Common Stock

Prospectus

BofA Merrill Lynch

Leerink Partners

Wells Fargo Securities

Guggenheim Securities

Stifel

, 2018

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Part II INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee and the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee.

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	Amount
Securities and Exchange Commission registration fee	$16,688
FINRA filing fee	21,153
Accountants' fees and expenses	75,000
Legal fees and expenses	400,000
Transfer Agent's fees and expenses	6,200
Printing and engraving expenses	150,000
Miscellaneous	30,959
Total expenses	$700,000

end of user-specified TAGGED TABLE

Item 14. Indemnification of Directors and Officers.

The Registrant is governed by the Delaware General Corporation Law, or DGCL. Section 145 of the DGCL provides that a corporation may indemnify any person, including an officer or director, who was or is, or is threatened to be made, a party to any threatened, pending or completed legal action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was or is an officer, director, employee or agent of such corporation or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided such officer, director, employee or agent acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, the corporation's best interest and, for criminal proceedings, had no reasonable cause to believe that such person's conduct was unlawful. A Delaware corporation may indemnify any person, including an officer or director, who was or is, or is threatened to be made, a party to any threatened, pending or contemplated action or suit by or in the right of such corporation, under the same conditions, except that such indemnification is limited to expenses (including attorneys' fees) actually and reasonably incurred by such person, and except that no indemnification is permitted without judicial approval if such person is adjudged to be liable to such corporation. Where an officer or director of a corporation is successful, on the merits or otherwise, in the defense of any action, suit or proceeding referred to above, or any claim, issue or matter therein, the corporation must indemnify that person against the expenses (including attorneys' fees) which such officer or director actually and reasonably incurred in connection therewith.

The Registrant's amended and restated bylaws will authorize the indemnification of its officers and directors, consistent with Section 145 of the DGCL.

Reference is made to Section 102(b)(7) of the DGCL, which enables a corporation in its original certificate of incorporation or an amendment thereto to eliminate or limit the personal liability of a director for violations of the director's fiduciary duty, except (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the DGCL, which provides for liability of directors for unlawful payments of dividends of unlawful stock purchase or redemptions or (iv) for any transaction from which a director derived an improper personal benefit.

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act against certain liabilities.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding all unregistered securities sold by us since January 1, 2015. Also included is the consideration received by us for such shares and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

(a)

Issuance of Capital Stock, Convertible Notes and Warrants.

1. In August 2015, in connection with the amendment and restatement of our credit facility, we issued warrants to our lender to purchase 29,580 shares of our Series E convertible preferred stock at an exercise price of $2.62 per share. These warrants subsequently converted into warrants to purchase 56,569 shares of our Series F convertible preferred stock at an exercise price of $1.37 per share in accordance with the terms of the warrant agreements. Immediately prior to the closing of our IPO, these warrants became exercisable for up to 8,506 shares of our common stock, at an exercise price of $9.11 per share.
2. In July 2016 and August 2016, we issued a total of $4.0 million in aggregate principal amount of convertible promissory notes to investors. The convertible notes matured on December 31, 2016 and accrued interest at a rate of 10% per year. In October 2016, the convertible promissory notes and accrued interest thereon converted into 2,982,988 shares of our Series F convertible preferred stock.
3. In October 2016, we issued an aggregate of 9,124,084 shares of our Series F convertible preferred stock to investors at a price per share of $1.37, for aggregate consideration of approximately $12.5 million, $8.4 million of which consisted of cash and $4.1 million of which was funded through the conversion of the principal amount and accrued interest on convertible promissory notes issued in July and August 2016. These shares automatically converted into 1,372,036 shares of our common stock immediately prior to the closing of our IPO.
4. In November 2016, we issued 214,060 shares of our Series C convertible preferred stock to certain investors upon the exercise of warrants at an exercise price of

   $1.07 per share. These shares automatically converted into 32,188 shares of our common stock immediately prior to the closing of our IPO.
5. In December 2016, we issued 44,820 shares of our Series C convertible preferred stock to certain investors upon the exercise of warrants at an exercise price of $1.07 per share. These shares automatically converted into 6,739 shares of our common stock immediately prior to the closing of our IPO.
6. In February 2017, we issued an aggregate of 18,248,177 shares of our Series F convertible preferred stock to investors at a price per share of $1.37, for aggregate consideration of approximately $25.0 million. These shares automatically converted into 2,744,078 shares of our common stock immediately prior to the closing of our IPO.
7. In February 2017, in connection with the amendment of our credit facility, we issued warrants to our lender to purchase 29,197 shares of our Series F convertible preferred stock at an exercise price of $1.37 per share. Immediately prior to the closing of our IPO, these warrants became exercisable for up to 4,390 shares of our common stock, at an exercise price of $9.11 per share.
8.

In February 2018, in connection with additional borrowings under our credit facility, we issued warrants to our lender to purchase 233,577 shares of our Series F convertible preferred stock at an exercise price of $1.37 per share. Immediately prior to the closing of our IPO, these warrants became exercisable for up to 35,124 shares of our common stock, at an exercise price of $9.11 per share.

9. In September 2018, we issued an aggregate of 17,050 shares of our common stock upon the net exercise of warrants to purchase 19,674 shares of our common stock, each having an exercise price of $7.12 per share.

10. In November 2018, we issued an aggregate of 31,270 shares of our common stock upon the net exercise of warrants to purchase 39,165 shares of our common stock, which had exercise prices ranging from $7.12 to $15.16 per share.

(b) Equity Awards.

1. Since January 1, 2015, we have granted stock options to employees, directors and consultants, covering an aggregate of 1,276,331 shares of our common stock, having exercise prices ranging from $0.94 to $54.99 per share, in connection with services provided to us by such parties.

2. Since January 1, 2015, we have issued an aggregate of 477,496 shares of our common stock to employees, directors and consultants upon their exercise of stock options, for aggregate cash consideration of approximately $0.2 million.

Unless otherwise stated, the issuances of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. Individuals who purchased securities as described above represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the share certificates issued in such transactions None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

The following documents are filed as exhibits to this registration statement.

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Exhibit Number	Description of Exhibit
1.1	Form of Underwriting Agreement
3.3	Seventh Amended and Restated Certificate of Incorporation of Inspire Medical Systems, Inc., dated May 7, 2018 (incorporated by reference to Exhibit 3.1 of the registrant's Current Report on Form 8-K (File No. 001-38468) filed with the SEC on May 7, 2018)
3.4	Amended and Restated Bylaws of Inspire Medical Systems, Inc. (incorporated by reference to Exhibit 3.2 of the registrant's Current Report on Form 8-K (File No. 001-38468), filed with the SEC on May 7, 2018)
4.1	Form of Certificate of Common Stock (incorporated by reference to Exhibit 4.1 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 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 (incorporated by reference to Exhibit 4.2 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 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 (incorporated by reference to Exhibit 4.3 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 23, 2018)
4.4	Warrant to Purchase Series E Preferred Stock, dated June 27, 2014, issued by Inspire Medical Systems, Inc. to Silicon Valley Bank
4.5	Form of Warrant to Purchase Series F Preferred Stock, dated February 24, 2017 or February 7, 2018, issued by Inspire Medical Systems, Inc. to Oxford Finance LLC, together with a schedule of material differences
5.1	Opinion of Latham & Watkins LLP

10.1		Assignment and License Agreement, dated as of November 28, 2007, by and between Inspire Medical Systems, Inc. and Medtronic, Inc. (incorporated by reference to Exhibit 10.1 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 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. (incorporated by reference to Exhibit 10.2 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)
10.3		Loan and Security Agreement, dated as of August 7, 2015, by and between Inspire Medical Systems, Inc. and Oxford Finance LLC (incorporated by reference to Exhibit 10.3 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)

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Exhibit Number		Description of Exhibit
10.4		First Amendment to Loan and Security Agreement, dated as of February 24, 2017, by and between Inspire Medical Systems, Inc. and Oxford Finance LLC (incorporated by reference to Exhibit 10.4 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)
10.5		Bridge Note Purchase Agreement, dated July 7, 2016, by and among Inspire Medical Systems, Inc. and the Investors named therein (incorporated by reference to Exhibit 10.5 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)
10.6	#	2007 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.6 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)
10.7	#	Form of Incentive Stock Option Agreement pursuant to 2007 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)
10.8	#	2017 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.8 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)
10.9	#	Form of Incentive Stock Option Agreement pursuant to 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.9 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)
10.10	#	Form of Non-Statutory Stock Option Agreement pursuant to 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.10 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)
10.11	#	Inspire Medical Systems, Inc. 2018 Incentive Award Plan (incorporated by reference to Exhibit 10.11 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 23, 2018)
10.12	#	Form of Stock Option Award Agreement under Inspire Medical Systems, Inc. 2018 Incentive Award Plan (incorporated by reference to Exhibit 10.12 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 23, 2018)
10.13	#	Inspire Medical Systems, Inc. 2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.13 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 23, 2018)
10.14	#	Employment Agreement, dated November 16, 2007, by and between Inspire Medical Systems, Inc. and Timothy Herbert (incorporated by reference to Exhibit 10.14 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)
10.15	#	Amended and Restated Employment Agreement, by and between Inspire Medical Systems, Inc. and Timothy Herbert (incorporated by reference to Exhibit 10.15 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 23, 2018)

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Exhibit Number		Description of Exhibit
10.16	#	Employment Agreement, dated July 20, 2009, by and between Inspire Medical Systems, Inc. and Randy Ban (incorporated by reference to Exhibit 10.16 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)
10.17	#	Amended and Restated Employment Agreement, by and between Inspire Medical Systems, Inc. and Randy Ban (incorporated by reference to Exhibit 10.17 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 23, 2018)
10.18	#	Employment Agreement, dated June 1, 2014, by and between Inspire Medical Systems, Inc. and Richard Buchholz (incorporated by reference to Exhibit 10.18 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)
10.19	#	Amended and Restated Employment Agreement, by and between Inspire Medical Systems, Inc. and Richard Buchholz (incorporated by reference to Exhibit 10.19 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 23, 2018)
10.20	#	Employment Agreement, dated September 25, 2017, by and between Inspire Medical Systems, Inc. and Steven Jandrich (incorporated by reference to Exhibit 10.20 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)
10.21	#	Amended and Restated Employment Agreement, by and between Inspire Medical Systems, Inc. and Steven Jandrich (incorporated by reference to Exhibit 10.21 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 23, 2018)
10.22	#	Inspire Medical Systems, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.22 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)

10.23	Form of Indemnification Agreement between Inspire Medical Systems, Inc. and its directors and officers (incorporated by reference to Exhibit 10.23 of the registrant's Registration Statement on Form S-1 (File No. 333-224176), filed with the SEC on April 6, 2018)
21.1	Subsidiaries of Inspire Medical Systems, Inc.
23.1	Consent of Ernst & Young LLP
23.2	Consent of Latham & Watkins LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included on signature page)
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document

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Exhibit Number	Description of Exhibit
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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Indicates management contract or compensatory plan.

(b)

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

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

(1)

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

(2)

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

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Signatures

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Maple Grove, State of Minnesota, on this 4th day of December, 2018.

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INSPIRE MEDICAL SYSTEMS, INC.
By: /s/ TIMOTHY P. HERBERT Timothy P. Herbert *Chief Executive Officer and President*

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Power of Attorney (included on signature page)

SIGNATURES AND POWER OF ATTORNEY Each of the undersigned officers and directors of Inspire Medical Systems, Inc. hereby constitutes and appoints Timothy P. Herbert and Richard Buchholz, and each of them, either of whom may act without joinder of the other, the individual's true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for the person and in his or her name, place and stead, in any and all capacities, to sign this registration statement of Inspire Medical Systems, Inc. on Form S-1, and any other registration statement relating to the same offering (including any registration statement, or amendment thereto, that is to become effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended), and any and all amendments thereto (including post-effective amendments to the registration statement), and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

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Signature	Title	Date
/s/ TIMOTHY P. HERBERT Timothy P. Herbert	Chief Executive Officer (principal executive officer), President and Director	December 4, 2018
/s/ RICHARD BUCHHOLZ Richard Buchholz	Chief Financial Officer (principal financial and accounting officer)	December 4, 2018
/s/ MARILYN CARLSON NELSON Marilyn Carlson Nelson	Chair of the Board of Directors	December 4, 2018
/s/ JOYCE ERONY Joyce Erony	Director	December 4, 2018
/s/ JERRY GRIFFIN, M.D. Jerry Griffin, M.D.	Director	December 4, 2018
/s/ MUDIT K. JAIN Mudit K. Jain	Director	December 4, 2018
/s/ CHAU KHUONG Chau Khuong	Director	December 4, 2018

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Signature	Title	Date
/s/ DANA G. MEAD, JR. Dana G. Mead, Jr.	Director	December 4, 2018
/s/ SHAWN T MCCORMICK Shawn T McCormick	Director	December 4, 2018
/s/ CASEY TANSEY Casey Tansey	Director	December 4, 2018

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